ENHANCING PHARMACEUTICAL INNOVATION

THROUGH THE USE OF

KNOWLEDGE MANAGEMENT

by

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ABSTRACT

Pharmaceutical innovation is a complex task that is reliant upon the availability of relevant information and knowledge. To date, the aspects of how, when and where this information and knowledge is applied throughout the drug development processes, has been lightly researched. Furthermore, the science of Knowledge Management can potentially aid the drug development processes and allow an organisation to reduce the time and costs associated with innovative drug development. This thesis examines these issues in greater depth through a series of case studies conducted within the innovative pharmaceutical organisation AstraZeneca. The end result of this research is a Knowledge Management tool set which is capable of driving pharmaceutical innovation.

The thesis firstly explores the literature associated with innovation, pharmaceutical innovation, Knowledge Management and Intellectual Capital. The second aspect of the research used the literature review to develop a novel research framework with which to examine pharmaceutical innovation in greater detail. The third stage of the research utilised the results of the previous stages to develop a novel Innovation and Knowledge Management focused model. The fourth stage of this research utilised the research findings to develop a Knowledge Management tool set that can be used to drive innovation. This tool set is comprised of three distinct levels of functionality, namely: the social and collaborative level, the information assimilation and dissemination level and a level that encourages the capture of knowledge. The final stage of the research concludes with a discussion on evaluating Knowledge Management and its use in driving pharmaceutical innovation.

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The last and dearest thanks goes to Jo Gregory and my parents, who have supported me throughout this research and reminded me that one day, all that work and effort will be a distant and pleasant memory.

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CHAPTER 1

INTRODUCTION TO THE RESEARCH

1.0 INTRODUCTION

This thesis has developed from a three year collaborative research project with Loughborough University and the Clinical Department of AstraZeneca, R&D, UK. The research focuses upon the use of Knowledge Management tools and strategies to drive pharmaceutical innovation and evaluates the rise to prominence of Knowledge Management as a strategy to drive innovation.

This chapter places the research into context and introduces the concepts associated with pharmaceutical innovation and Knowledge Management. It continues to introduce the case study organisation of AstraZeneca and the rationale behind the research, before concluding with an outline of the thesis structure.

1.1 BACKGROUND TO THE RESEARCH

The pharmaceutical industry is a unique and challenging environment where the process of launching a new drug product takes between 10 and 14 years and incurs substantial expense (Davis, 2001). Faced with the challenges associated with this lengthy process and the spiralling upward costs of modern R&D, pharmaceutical companies are exploring ways to cut the time and resource required to release a new medical drug. Couple high R&D costs with fierce external competition from rivals and generic manufacturers, and it becomes clear that pharmaceutical companies are justified to worry about where their future profits are coming from (DiMasi et al. 1991). The days of large pharmaceutical companies dominating the R&D market are gone with the arrival of small agile competitors from the biotechnology field now supplying the majority of innovation within the pharmaceutical field (Schweizer, 2005). Pharmaceutical companies are being forced to take stock and address the very basis of innovation and look at how they can streamline the drug development processes.

Due to the complexities of drug development the requirements for knowledge and information are great. As Zack (1999) states, the trend of pharmaceutical companies merging and acquiring competitors and biotechnology companies is resulting in the wholesale distribution of the knowledge required to drive the development processes. Reining in, capturing and disseminating this knowledge thus becomes a major problem for pharmaceutical companies as the sheer scope and wealth of knowledge and information sources required to innovate are vast. However, in the stark competitive reality of pharmaceutical R&D, companies are being driven to address these issues and one such approach that has been suggested, is the use of the emergent science of Knowledge Management.

Knowledge Management is concerned with allowing employees to collaborate and innovate by providing them with the necessary knowledge to effectively fulfil their role (Havens & Knapp, 1999). Translating the benefits of Knowledge Management to the pharmaceutical industry, should equate, in theory, to the provision of a competitive advantage through retaining and building upon corporate knowledge (Wang, 2006). The progression of a chemical compound to a marketable drug that acts on a disease is a complex series of interacting processes, and when faced with challenges such as these it is not surprising that few drugs progress beyond the R&D lab:

"Pharmaceutical R&D is like juggling snakes--you must ensure that a drug can be readily formulated, remains stable when stored, resists destruction by stomach acids, gets into patients' bloodstreams, and doesn't break down into toxic compounds when metabolised. It's almost unheard-of for a randomly selected compound to meet all these requirements without major tinkering that takes months to years." (Stipp, 2005)

Thus it would seem that serendipity plays a small part in the initial development processes. At present, little is known on how these processes occur and how the pharmaceutical R&D employees locate the knowledge required to drive innovation and produce a workable and valuable drug over the 12 years of intense work (Dougherty, 2006).

Few studies have conclusively addressed these aspects and little academic literature can offer guidance to an organisation as it attempts to manage and apply its knowledge more effectively. This is largely due to the complex web of interrelated processes that support each other. Furthermore, each drug development process poses problems and beneath these problems will be a further set of problems that require further answers in order to progress (Bouthillier & Shearer, 2002). Research by du Plessis (2005) suggests that Knowledge Management would be the ideal vehicle to unravel and shed light upon these processes:

''Knowledge Management takes aim at evolving people's attitudes and work behaviours to effect new heights of collaboration—the international sharing of ideas, information, knowledge, and work itself—in support of a business need. It is about changing people's value paradigm from ''my information is power'' to ''sharing is power''. It's about large-scale cultural change, new incentive systems and performance metrics, and learning and education. It focuses on (re)shaping the attitudes and behaviours of people so they can ensure the ready availability and resolute application of both personal and institutional knowledge.'' (du Plessis, 2005)

The potential of Knowledge Management to deliver these benefits has not escaped the notice of the pharmaceutical companies. Research by Hung et al., (2006), Wang (2005), Davenport & Peitsch (2005) and Metaxiotis & Psarras (2005), amongst others, espouse the virtues of adopting pharmaceutical Knowledge Management, but conclude that Knowledge Management in practice is a rather subdued affair and rarely fulfils on its promise. Pharmaceutical studies by Hung et al. (2005) suggest that although Knowledge Management technology is in place within major companies, the cohesive integration of Knowledge Management practices falls behind and may even hinder knowledge exchange.

Critics of Knowledge Management are quick to point out that it is, in reality, a management fad representing little more than a revamped facet of information management (Wilson, 2002).

However, the sheer wealth of published Knowledge Management literature within other industries (e.g. Un & Cuervo-Cazurra, 2004) and the interest in Knowledge Management within the pharmaceutical industry organisations, such as AstraZeneca (Roth, 2003), suggests fad or not, Knowledge Management is at least worthy of attention. This is particularly emphasised by research from The Association of British Pharmaceutical Industry (2006) which indicates that British pharmaceutical manufacturers invested £3.2 billion in 2004 in R&D alone. With the average drug requiring £550 million of investment and with no guarantee of success, the appeal of cutting development times and using employee knowledge more efficiently is obvious. Yes, the advances in drug development technology (e.g. High Throughput Screening) and computing power are improving the capture and analysis of information and data (Donelly, 2003), but the impact of Knowledge Management on the knowledge required to utilise and act on this data and information within the drug development processes is rather less apparent.

The slow shift in the approach of Knowledge Management from the management of the tacit knowledge of the employee, to a holistic organisational 'capability' approach (Argote et al. 2003) would appear to hold promise. However, assigning metrics to measure and validate the performance of a Knowledge Management strategy still remains ambiguous and notoriously difficult (Marr & Starovic, 2003). As Knowledge Management is evolving, the means to measure knowledge is also evolving in tandem. The Intellectual Capital approach favoured by authors such as Kaplan & Norton (2001) and Edvinsson & Malone (1997) assigns measurable value to knowledge driven activities, yet to date, little work has been conducted that specifically targets pharmaceutical innovation and drug development.

The research project described in this thesis has been commissioned to address some of the issues raised above and pays particular attention to the relationship between pharmaceutical innovation and Knowledge Management.

The research seeks to clarify the importance of Knowledge Management through the use of metrics, and to shed light upon the knowledge and information needs of the employees.

1.2 INDUSTRIAL SPONSOR

AstraZeneca is one of the world's leading pharmaceutical companies with an operating profit of $6.5 billion and a total sales figure of $24 billion. The company portfolio operates over a variety of disease areas and top growth medications include: Arimidex (cancer), Crestor (cardiovascular), Nexium (gastrointestinal disease), Seroquel (schizophrenia) and Symbicort (asthma and chronic obstructive pulmonary disease). The company employs over 12,000 R&D personnel and invests a total of $14 million a day into the development of new medicines across the group. Within the UK its R&D functions are situated across eight sites with the research described in this thesis conducted primarily at the Charnwood R&D site in Leicestershire.

The Charnwood site concentrates upon the development of medicines that target asthma, chronic bronchitis, emphysema and rheumatoid arthritis and osteoarthritis. The case study is focused upon the Clinical function which acts as the centre of excellence for the company's clinical inflammation knowledge. The company prides itself on its creativity and its innovative approach to drug development, the mantra taken from the AstraZeneca website reads:

"At AstraZeneca, innovation is about more than just research. We aim to stimulate continued creativity throughout our organisation by maintaining a culture in which our people feel valued, energised and rewarded for their ideas and contribution to our success - ideas which can make a difference in all aspects of our business." (AstraZeneca, 2006).

Throughout the business, collaboration is regarded in high esteem and as such, during the research, the business underwent restructuring to encourage cross-project working and collaboration.

The results of this restructuring are discussed in later chapters, but were intended to produce a flatter organisational structure replacing the previous hierarchical structure that was deemed to inhibit effective drug development.

The company has responded to external competition and changes in the value of its portfolio, as a number of key products face patent expiry over the next decade, by nominating a number of new chemical entities into Phase III trials in 2005. Building upon and developing a long term drug development pipeline by maximising short term growth within the early stages of the internal R&D processes is a priority. The organisation is also increasing its focus upon the external acquisition of innovation through in-licensing and biotechnology buy outs, and is actively working upon expanding its current four therapy areas to five with the development of a New Opportunities group, specifically created to spearhead innovative work.

1.3 RESEARCH RATIONALE

AstraZeneca R&D Clinical at Charnwood is committed to producing high quality medicines and recognised that Knowledge Management may be able to offer a tangible benefit within the Clinical environment of the company. A number of Knowledge Management schemes have been running within the company and in recent years a long term Knowledge Management (KM) and Information Systems (IS) strategy is in the process of being implemented across the R&D function within the UK. The Knowledge Management strategy was developed from a variety of pilot schemes in operation that lacked focus and cohesion and hence IS management deemed it was necessary to take ownership of the various schemes and ensure they represented the interests of AstraZeneca. This research was commissioned to analyse the impact of Knowledge Management activities on innovation and knowledge sharing within the organisation. In light of this, a key component of the research is to analyse the IS/ KM strategy and suggest the means to improve, standardise and measure the value of Knowledge Management throughout the organisation. The following section outlines the structure of the thesis with regards to the areas of Knowledge Management and innovation within AstraZeneca.

1.4 STRUCTURE OF THE THESIS

The thesis chapters and scope are outlined in the following section with reference to the papers and reports on which the chapters are based.

1.4.1 CHAPTER 1: INTRODUCTION

This Chapter provides a brief introduction to the research scope, the rationale behind the research, the case study organisation and the structure of the thesis.

1.4.2 CHAPTER 2: RESEARCH AIM AND OBJECTIVES

Chapter 2 gives a synopsis of the research Aims and Objectives concerned with the main research theme of Knowledge Management and pharmaceutical innovation.

1.4.3 CHAPTER 3: LITERATURE REVIEW

This chapter provides an in-depth analysis of the problem scope through a review of the published academic and practitioner based work within the fields of Knowledge Management, innovation, pharmaceutical drug development and Intellectual Capital research. The chapter highlights areas for future research and reviews the initial aim and objectives, thus ensuring that the research is worthwhile and addresses the gaps in the current knowledge of the topic. The chapter is based in part, upon a paper submitted and presented at the IRMA Conference, San Diego 2005 (Parsons et al. 2005b).

1.4.4 CHAPTER 4: METHODOLOGY

Chapter 4 gives review of research methods and the rationale behind the choice of the interpretive case study as the research philosophy.

1.4.5 CHAPTER 5: A KNOWLEDGE AND INNOVATION FRAMEWORK

Chapter 5 details a pilot study of innovation and Knowledge Management within AstraZeneca. This chapter was based upon a paper presented at the EuroIMSA 2005 conference (Parsons et al. 2005a).

1.4.6 CHAPTER 6: THE KNOWLEDGE AND INNOVATION CRITERIA

Chapter 6 covers the generic innovation drivers that are not specific to AstraZeneca.

1.4.7 CHAPTER 7: ASTRAZENECA AND AN INNOVATION CULTURE

Chapter 7 covers the innovation drivers from an AstraZeneca-specific perspective and concentrates upon the culture of the organisation.

1.4.8 CHAPTER 8: KNOWLEDGE MANAGEMENT AND INNOVATION

Chapter 8 examines the use of Knowledge Management within AstraZeneca.

1.4.9 CHAPTER 9: AN INNOVATION CASE STUDY

Chapter 9 details a case study conducted within AstraZeneca with regard to innovation and Knowledge Management

1.4.10 CHAPTER 10: DEFINING A KM AND INNOVATION FRAMEWORK

Chapter 10 discusses the results of the research and develops an innovation and Knowledge Management based framework.

1.4.11 CHAPTER 11: DEVELOPMENT OF THE KM TOOL SET

Chapter 11 discusses the development of a Knowledge Management tool set and its potential use to drive innovation within AstraZeneca.

1.4.12 CHAPTER 12: EVALUATING KNOWLEDGE MANAGEMENT

Chapter 12 discusses the evaluation of Knowledge Management and suggests the means to assess the worth of Knowledge Management as a tool to drive innovation.

1.4.13 CHAPTER 13: CONCLUSION

Chapter 13 concludes with the main findings of the research, the implications and areas of further research.

1.5 CONCLUSION

The background and rationale to the research have been covered within this chapter. The following chapter details the research aims and objectives and indicates how the challenges associated with this research will be overcome.

CHAPTER 2

RESEARCH AIMS AND OBJECTIVES

2.0 INTRODUCTION

This chapter defines the aims and objectives on which the research described in this thesis is based. The objectives are broken down into a number of tasks which define individual actions and deliverables.

2.1 THE RESEARCH AIM

The aim of the research project is to contribute to the research and knowledge surrounding the use of Knowledge Management for pharmaceutical innovation. Therefore the main aim of the research is:

To create and evaluate a Knowledge Management tool set to enhance innovation within AstraZeneca.

The tool set is intended to be used across AstraZeneca global sites to provide greater access to the knowledge and information required by innovators who are responsible for producing innovative drugs. It is believed the tool set will also be applicable to other innovative organisations that are reliant upon knowledge and information to innovate.

2.2 OBJECTIVES

The aim of the study was clarified by using the following high level objectives. Each objective was assigned specific stages that combine to support the overall aim of the project:

Objective 1: Identify the general views associated with innovation and pharmaceutical innovation.

The first objective covers the initial investigation stages where the scope and area of the problem is defined. The objective is broken down into two stages that address individual areas of the objective:

- Conduct a review of the literature to identify and understand the general views on innovation and innovative processes within the literature. This stage will identify what constitutes innovation and what processes are thought to support innovation

- Conduct an exploratory case study on innovation within AstraZeneca to identify the departments and principle innovative employees across AstraZeneca R&D. This will take the form of a qualitative case study utilising semi-structured interviews

Objective 2: Identify the drivers, the criteria for innovation, the outputs of the innovation and the themes associated with innovation specifically within AstraZeneca.

The second objective aims to pinpoint what exactly drives pharmaceutical innovation within AstraZeneca and identify the knowledge and information required to support innovation. The objective is broken down into three stages that address individual areas of the objective:

- Conduct a series of detailed case studies to identify the knowledge and information needs of the innovative employees and departments within AstraZeneca. These will form a set of innovation and knowledge criteria, drivers, outputs and themes to be used to develop the Knowledge Management tool set

- Produce a model of pharmaceutical innovation that reflects what is occurring within AstraZeneca based upon: the identified themes, criteria, outputs and drivers of innovation

- Clarify and compare the innovative practices of these departments and innovators across AstraZeneca with the literature concerning pharmaceutical innovation

Objective 3: Examine and evaluate the Knowledge Management strategy and existing tools in use across AstraZeneca R&D.

The third objective will clarify the existing Knowledge Management tools and strategies in use across the organisation, with a view to identifying areas of success, weaknesses and gaps in the current tools and strategies employed within AstraZeneca:

- Conduct a review of the academic and practitioner's literature to identify Knowledge Management methods, tools and strategies

- Define how the value of knowledge and Knowledge Management is assessed within the literature

- Conduct a qualitative case study and consult with employees within AstraZeneca, to identify Knowledge Management tools that are being used to support innovation

- Examine how Knowledge Management is and could be evaluated within AstraZeneca

Objective 4: Examine potential Knowledge Management tools that could be used to support innovation in AstraZeneca and evaluate their potential use and impact to enhance innovation.

The fourth objective intends to analyse potential Knowledge Management and information based tools that may be employed to enhance pharmaceutical innovation:

- Produce a model of Knowledge Management that could be used to drive pharmaceutical innovation within AstraZeneca

- Develop a Knowledge Management tool set from the previous review of the literature and the existing Knowledge Management tools within AstraZeneca. This will identify the worth of the tool based upon the previously identified innovation and knowledge criteria within Objective 2

Objective 5: Test the validity of the Knowledge Management tool set and research by publishing the results within AstraZeneca and producing peer-reviewed conference proceedings:

- Evaluate the results of the research and the Knowledge Management recommendations by conducting a series of interviews to seek the opinions of the employees responsible for innovating within AstraZeneca

- Publish peer reviewed conference papers and present the results to promote discussion

The fifth objective seeks to validate the research with both AstraZeneca and academia.

Objective 6: Deliver the tool set to AstraZeneca R&D.

The final objective requires the implementation of the Knowledge Management toolset so that AstraZeneca may derive value from the research and the evaluation of the toolset as it is found to work in practice in the company environment:

- Facilitate the implementation of the Knowledge Management tool set

- Evaluate the Knowledge Management tool set through a series of systematic surveys and further case studies.

2.3 CONCLUSION

The research aim of enhancing pharmaceutical innovation through the use of Knowledge Management tools will be addressed by undertaking the objectives outlined in Section 2.2. Each objective is supported by a number of stages which emphasises the role knowledge and information plays within pharmaceutical innovation. Every effort will be made to fulfil the objectives described within this chapter and produce a working and beneficial Knowledge Management tool set that addresses the needs of the innovators within AstraZeneca.

The next chapter will discuss the wealth and breadth of academic literature that focuses upon Knowledge Management, innovation and intellectual capital across a broad range of environments.

CHAPTER 3

LITERATURE REVIEW

3.0 INTRODUCTION

The following chapter concentrates on providing the justification and background to the proposed research, by identifying the gaps in the literature on Knowledge Management, pharmaceutical innovation and Intellectual Capital.

The chapter begins with an analysis of published work on innovation, creativity and pharmaceutical innovation. The chapter then proceeds to review the literature on Knowledge Management and Knowledge Management tools. It is important to define the applicable areas of Knowledge Management at an early stage, so as to enlighten the reader as to how and why Knowledge Management may have a role in enhancing pharmaceutical innovation. Both pharmaceutical innovation and Knowledge Management are broad topics. Hence the aim of this chapter is to condense the available material, so as to note similarities and familiarise the reader with how the two research components of Knowledge Management and pharmaceutical innovation interrelate.

The final stage of the literature review addresses the models and strategies to evaluate Intellectual Capital. In order to develop the Knowledge Management tool kit suggested in Objective 4, it is important to address the Knowledge Management frameworks and strategies already in place within innovative industries and address their successes and failings. Innovation has experienced a rise in prominence of late. Whether the innovative process is concerned with new product development, incremental or process based innovation, knowledge plays a crucial role in the ability of an organisation to innovate. The growing practitioner and academic interest in finally tracking down what drives innovation, is reflected by the wealth of published strategies and theories available for review. The following critical review will cover these areas that are most applicable to the research question and address whether Knowledge Management can theoretically drive pharmaceutical innovation.

3.1 INNOVATION

3.1.1 INTRODUCTION

The subject of innovation and the associated processes of innovation management have attracted over 50 academic titles that specialise in the exploration of innovative processes within a broad range of fields. However, discrepancy lies in the research approaches and areas studied within such literature, and as such, a common standard of applied thought and consensus is lacking within the field. The following review aims to answer the questions suggested by Objectives 1, 2 and 3 and provide a comprehensive guide to innovation within the pharmaceutical business environment. Firstly the concepts involved within the terminology will be explored and a definition related to drug development and innovation within the firm proposed. Further sections of the review will discuss the importance of innovation within the business of pharmaceutical drug development, before continuing to examine the potential application of Knowledge Management techniques and strategies to enhance these processes, later within Section 3.6 of the chapter.

3.1.2 DEFINING INNOVATION

The innovation literature is awash with definitions and concepts which are distinct, yet inexorably linked through the use of key themes and are alike in many ways to the ambiguous definitions surrounding Knowledge Management. Innovation is perceived to be connected with areas such as competitive advantage, risk management, technological management, collaborative activity, creativity and Knowledge Management amongst other related fields (Tidd et al, 2001; Nieto, 2004; Dosi, 1998). It is therefore wise to attempt to define the principles of innovation by utilising key literature sources from these areas. Proceeding with a business based view; the work of Hausman & Fontenot (1999) suggests innovation produces a competitive advantage, via the adaptation of a firm's resource to satisfy customer demands within a rapidly changing commercial environment.

Undeniably the application of an organisation's resource allows the firm to attain a competitive advantage over rival companies (Sundgren & Styhre, 2004); however, the authors suggested view neglects to address the concept of what actually constitutes innovation. Innovation is commonly referred to as the creation of value through the use of assets, whether they are intangible or tangible assets, yet in many senses innovation relates to the creation of a tangible product (Nonaka & Takeuchi, 1995).

Although innovation may be described as the formation of a tangible product (Cooper, 2003), innovation may also be construed as a strategic concept, where the option to improve the organisation and therefore induce a competitive advantage through the use of innovative business practices (Montes, Moreno & Morales, 2005). Assigning innovation as a strategy and not as a tangible end product, suggests innovation has constituent parts that lead to an innovation. Tether's (2003) work questions the view (e.g. Hausman & Fontenot, 1999) that innovation must create a new product and provides a framework to assess how an innovation may be reached and how types of innovation may enhance the firm's competitiveness. The three concepts of innovation as proposed by Tether (2003) are:

1. Innovation as a technological achievement
2. Innovation as a consequence of technological achievement
3. Innovation as a result of a firm's dynamic capabilities

The view of innovation as a technological achievement, consists of the classical representation of innovation as a ground breaking invention, examples of this include the jet engine, the telephone and the semiconductor. These inventions possess the characteristics of a unique solution and possess a great impact upon their respective field, while their innovativeness is weighted upon the uniqueness of their market application (Lee & O'Connor, 2003). Essentially they have provided the 'significant leap forward' to overcome a technological block or readdress an existing problem or strategy and provide a solution.

The second stance views innovation as a natural progression of a technological achievement or inventions, it is the evolution of an initial concept or invention that attains greatness and the characteristics of an innovation over time (Tether, 2003). This process may occur through the adoption of a risk based strategy, on which a company gambles that a rough concept may be taken through to a competitive product and hence a commercial advantage (Rothwell, 1983) or through a continuous process of improvement and prototyping of an established invention. The final concept penned by Tether's (2003) views innovation as a process that is driven by an organisation's dynamic capabilities. Here innovation is not simply the achievement, invention or new product, it is instead the organisational practices and strategies which merge to form an original stand point or a differentiated product from that of their rivals (Holt, 1999).

Tether's (2003) third view of innovation is of most relevance to the research, but unfortunately the least clearly defined. The view implies that it is not the end product of a new drug that solely typifies pharmaceutical innovation. Instead the organisational processes within AstraZeneca which lead to a new medical product may also be regarded as innovations in their own right. However, collating the published innovation literature reveals a variety of theories regarding this view. For example an organisation may label an innovative process as a ground breaking technical achievement, while another firm may consider the same innovation to be the result of incremental steps and hence a consequence of a technological achievement (Hitt et al. 1998). Work by Garcia et al. (2002) suggests the literature interplays the terminology of 'innovation' and 'innovativeness'. This may explain the confused view where innovation is viewed as both a new product and a process. Evidently it is important to the research aim and objectives to define innovation. In light of the literature and the research direction, the definition offered by Damanpour (1991) appears fitting:

"Innovation is the adoption of an internally generated, system, policy, program, process, product or service that is new to the adopting organisation"

The definition is broad, yet the rudimentary basis suggests that an innovation occurs only when a company encompasses a new direction or process and hence foresees value from adopting a particular approach.

Freeman (1991) notes that process driven innovation may only be labelled as an innovation after the process has generated value. Likewise Garcia (2002) suggests a product that does not progress to market is merely an invention. This supports the aspiration that innovation is intrinsically linked to value and a marketable product. Garcia (2002) also suggests that the innovativeness of a company is also a valuable and hence marketable commodity.

Viewing innovation as a series of process based iterative steps recognises that a company possesses the ability to progress an invention to a marketable product and may be used as a measure of a company's innovativeness (Tether, 2003; Hitt et al. 1998). Nieto (2004) defines process based innovation as "technological innovation" whereby the set of activities which contribute to the overall new goods, services or new forms of production are considered to be the innovation. Pluskowski (2003) aligns innovation with the adoption of change within the organisation, the process of change having resulted from recognising the need to adapt and developing a solution or solutions to these needs, which is again a stance focused upon the process and the end result rather than the end product alone.

As the research area is primarily considering how to enhance drug development through applying Knowledge Management techniques and strategies, innovation will be viewed as a series of processes that yield a new medical drug, aligning most strongly with Nieto's (2003) and Tether's (2003) concept that innovation may be perceived as process and not a tangible end product.

3.1.3 INNOVATION, CREATIVITY AND KNOWLEDGE

The term innovation is certainly popular and is becoming progressively more widespread within the Knowledge Management literature, when illustrating a Knowledge Management system few authors neglect to emit innovation as a key benefit and output of using their system (e.g. Park & Kim, 2005). Indeed innovation has attained considerable importance, yet is important to firstly analyse where innovation stems from, so as to identify the drivers of innovation within AstraZenecas's processes of pharmaceutical innovation and satisfy Objectives 1 and 2.

The principle driver of innovation has long been regarded as creativity (Cothrel & Williams, 1999). Creativity is described by Mumford & Gustafon (1988) as the generation and emergence of new ideas and is akin to the generation of ideas through the "thinking out of the box" analogy. However, creativity may also be construed in a number of other ways. Tomas (1999) ascertains creativity stems from original thought, while Shalley & Perry Smith (2001) advocate true creativity is not only focused upon original thought, but also rests upon the processes of implementing the thoughts. It is evident that confusion reigns concerning the terminology of creativity and innovation. Shalley & Perry Smith's (2001) view, essentially ties in with Tether's (2003) view of innovation. Yet what may be grasped from the literature is that creativity is the production of the idea or concept that leads to an innovative process (Mumford & Gustafon, 1988; Handzic & Chaimungkalanont, 2004). Ford (2000) labels these processes as 'creative thinking' and is said to be a response to a complex or ill defined problem that has arisen within an organization. The development of creative solutions to these complex problems and issues may then be defined as innovations. In light of pharmaceutical innovation this would equate to the processes under study in Objectives 1, 2 and 3, so how are organisation's addressing problems?

Mumford et al. (2002) note that the initial definition of the organisational problem is driven by the appliance of a conceptual structure to the problem scenario. This structure serves to define the problem within the boundaries of the organisation. Handzic & Chaimungkalanont (2004) conclude that creativity then stems from the organisation's employees once the problem has an organisational context. This implies that the employee is directly responsible for the appliance of their knowledge and information to defining and solving a problem (Reiter-Palmon & Illies, 2004). Perez-Bustamante (1999) suggests that the initial driver of innovation is information, where the information defining a problem is first outlined, before the employees are then able to apply their knowledge to tackle the problem through creative thinking.

Above all, it is clear that innovation is reliant upon the knowledge and expertise of the employees. Yet as Mumford et al (2002) note, the complexities of a typical organisation demand multiple expertise areas.

It is largely agreed that employees no longer have the skills, expertise or resource to address complex problem scenarios on their own (Scott, 2000), particularly with regards to the processes of drug development. Terziovski & Morgan (2004) describe the biomedical innovation processes as:

"A process of creating and developing new products or services through collaborative team processes and mechanisms that utilise and empower the skills and knowledge of the people".

Here we witness the use of teams of employees to overcome creative problems that arise within the organisation, reinforcing the idea that creativity and hence innovation, stems from the ability of the employees to combine or create problem solving ideas in a unique form (Reiter-Palmon & Illies, 2004). Ford (2000) advocates the need to provide a creative culture within the organisation, one where innovation progresses from creative inception, to application and then dissemination. The idea that an innovative culture is indicative of a desire to share knowledge is widespread within the Knowledge Management literature (e.g. Mahesh and Suresh, 2004; Gunnlaugsdottir, 2003). An organisational culture rich in knowledge is a powerful resource, while possessing knowledge allows employees to learn, to understand, to solve problems, preserve traditions, create competency and allow innovation (Liao, 2003). Innovation can be seen as the bridging of the gap between the current platform of knowledge and the target knowledge required to develop the new product (Hall & Andriani, 2002). However, in practice a company often does not know what is required or may be required to achieve innovation. This implies that complex problems often demand complex solutions that span an organisation. As Adler (2002) notes, cross organisational innovation requires diversity across the employees involved within innovative work, where the process of development and R&D commences with the creativity of the employees and is reliant upon the quirks and acquired knowledge of the employees and the cultural confines the organisation operates within. Within this complex environment, innovative knowledge is said to exist on a modular basis, scattered over the organisation as a whole, requiring innovators to collaborate and form networks in order to acquire the knowledge (Baldwin & Clark, 2000).

However, predicting and mapping the knowledge requirements of staff across such a network and providing an elaborate Knowledge Management system to provide this is daunting (Laudon & Laudon, 2002).

The proviso of such an environment that allows and encourages innovation has attracted a great deal of research and interest from the academic community, yet remains an elusive goal. What is clear is that organisational innovation is driven by collaborative practices and the formation of collaborative networks (Bougrain & Haudeville, 2002). The stereotypical vision of the innovative maverick is though to be far removed from the practice found within a R&D led organisation. The focal point of creativity no longer rests with the individual but with the employees across the organisation (Gatignon et al. 2002). Throughout the innovation literature, knowledge is viewed as an essential aspect of innovation and it would seem that the research aim of encouraging pharmaceutical innovation through Knowledge Management is plausible. However, Schultz & Leidner (2002) acknowledge that too much knowledge causes staid business practices, while too little knowledge leads to inefficiency. Evidently a balance is required that drives creativity through to innovation and as Brown & Eisenhardt (1995) note, this process of product and competency development is essential for the very survival of the organisation.

The review will now discuss pharmaceutical innovation in line with published literature on innovation, drug development and organisational knowledge and detail the growing role and awareness of knowledge within the innovative processes.

3.1.4 PHARMACEUTICAL INNOVATION

The following section provides the context to the thesis, detailing the steps of innovation within the pharmaceutical industry and outlining the areas that may benefit from Knowledge Management. The review will concentrate upon the drug development process within AstraZeneca so as to provide a basis for understanding the research within Chapter 5 of the thesis. Figure 3.1 demonstrates that the processes and stages required to develop a drug from a chemical to a marketable drug product, are wide and varied:

Figure 3.1: AstraZeneca Drug Development Processes

To try and gain a clearer picture, the complexity of the drug development process within AstraZeneca is conceptually outlined in the following paragraphs using internal AstraZeneca data and published research literature (Davis, 2001; Sundgren & Styhre, 2004).

The drug development process begins within the Discovery wing of the company, where knowledge is applied to identify worthwhile biological targets for the company to develop a New Chemical Entity (NCE) to act upon. The NCE is a chemical compound designed to have a pharmacologically active effect on a disease, the scientists responsible for developing a NCE aim to relieve symptoms of a disease, such as lowering blood pressure, or attack the root of the disease and provide a cure. A useful analogy to explain the action of an NCE on a biological target is a lock and key.

The target acts as the lock and the NCE provides the key, the key allows a change in the behaviour of the biological target and this in turn produces a 'knock on effect' and allows regulation of the disease or its symptoms.

Central to the development of an NCE, is the knowledge of the scientists within the Discovery wing of the company. The scientists are required to develop NCEs that are both pharmacologically active against the target and are unique in their chemical structure. Suitable NCEs are then forwarded within the organisation to the Clinical wing as a Candidate Drug (CD). The safety credentials of the compound are verified with regards to their performance within biological models, before finally being forwarded to a marketable position as a New Medical Entity (NME) or new drug.

The process of testing and transferring a NCE to a CD is equivalent to the validation of an invention. From a theoretical perspective the NCE lives up to the defined chemical expectations of Discovery and is a potential marketable drug. The Discovery organisation may pass on many 10s of NCEs to the Clinical wing, all of which have the potential to be marketable drugs, however the Clinical wing is then responsible for confirming that these compounds are safe and effective within a biological system. Within these stages of Clinical validation, almost all of the CDs will fail to meet the stringent criteria defined by the organisation and external regulatory bodies. This process is labelled as attrition and effectively equates to a maximum of four CDs a year, being forwarded by the relevant Clinical areas of AstraZeneca by the Discovery wing. The complex series of tollgates and milestones associated with developing a compound, which is pharmacologically active against a biological target, to a marketable drug takes up to 14 years. It is not uncommon for the identification of a CD to take up to 5 years and the time to market release of the drug taking a further 6 years. Hence the long time scales from innovation to product release. This is at odds with the majority of other R&D taking place within businesses such as the semi-conductor industry (Davis, 2001). The slow evolution of products means failure at any point is financially dire. Hence a pharmaceutical company must invest a considerable amount of resource in its R&D activities in order to provide the company with future products up to a decade from their original inception.

Cutting the rate of attrition and ensuring that an initial NCE stands a higher chance of progressing from a CD to a marketable drug, is the principle underlying aim of the research.

3.1.5 THE DRIVERS OF PHARMACEUTICAL INNOVATION

Zeller (2002) acknowledges that intensified global competition and the strong oligopolies of Western pharmaceutical companies has forced companies to increase innovative output. As a result, financial pressures and not medical need is driving drug research. Innovative products enable a pharmaceutical company to create wealth. Within the development pathways to making the end product, there are innumerable innovative processes, all of which link together and all of which requires innovative behaviour that is backed by accurate knowledge. Tether (2003) concludes that very few ground breaking pharmaceutical drugs are released. The majority are a gradual redefinition of an existing family of chemical compounds in order to produce a new marketable drug. Therefore, viewing pharmaceutical innovation as outright technical achievement is less relevant to the research. A more conducive stance would be to focus upon the processes of innovation, creativity and strategy which coexist to support the release of a drug. This stance would then clarify and build upon the existing published literature that takes this viewpoint (e.g. Handzic & Chaimungkalanont, 2004)

In order to provide further context to the research and ascertain the drivers of pharmaceutical innovation, it is important to outline the financial and commercial environment AstraZeneca operates within. As is similar to other high technology industries, the pharmaceutical industry is reliant upon protecting its innovations and financial resource through patenting (Pearce, 2005). A patent confers to its owner the sole rights of manufacture and the offering for sale of the patented product (Levin, 1986). From a financial perspective, the patent is critical to maintaining a market position and allows the company to recoup the initial R&D investment required to develop and release a drug. To put the importance of patents into context, the average revenue of a market leading drug, such as Prilosec or Claritin equates to $2.6 million per day.

Hence protecting the intellectual property of a drug and retaining sole manufacturing rights, not only sustains a company in the short term and recoups the initial R&D investment, but also provides the basis for further R&D expenditure (Pearce, 2005).

However, competition is fierce within the industry and rival manufacturers produce drugs that act upon the same disease areas. Competition also stems from the generic pharmaceutical industry, which specialises in manufacturing drug products that have expired patents. Due to the lack of initial R&D costs, generic manufacturers are able to offer these drugs at significantly lower costs than the initial developer and the company who initially invented the drug will quickly lose market revenue. Thus an R&D focused pharmaceutical company that fails to develop new patentable products and finds itself having to rely upon its existing product portfolio, will rapidly founder (Chataway et al. 2003). Historically pharmaceutical innovation has focused upon in-house R&D where organisational innovation stems from the research ability of the employees (Rosenberg & Birdzell, 1990). Yet, in recent years a study by Bottazzi et al. (2001) across 150 pharmaceutical firms has drawn the conclusion that the differentiation between the tiers of R&D focused companies is widening. The syndicate of top R&D organisations, such as AstraZeneca, are strategically positioning themselves to develop new and 'first to market drugs' across similar therapeutic areas. The secondary R&D organisations are increasingly focusing upon expired patent drugs and drugs that are manufactured under licence (Bottazzi et al. 2001). Unfortunately these strategies are generating a deficit in innovative practice as a new drug must be truly remarkable to be granted a patent. Additionally when it is released it must show considerable medical benefit over its rivals to gain a market share (Heller & Eisenberg, 1998).

To further complicate the problem, Terziovski & Morgan (2004) note the innovative R&D work is moving from the in-house R&D pharmaceutical departments, such as the Discovery wing at AstraZeneca, to external biotechnology companies and smaller research establishments. However, the extent of this shift is unclear within the literature. Branca (2002) suggests large pharmaceutical companies will come to rely upon sequestering the products of the smaller firms as their own in house innovative capabilities become diminished.

Large pharmaceutical companies (e.g. Pfizer) are also acquiring larger marketing forces in an attempt to quickly assert market dominance.

This is leading to an inevitable down turn in innovative activity, as resource is diverted away from R&D to marketing (Branca, 2002). There is an increasing awareness of this within the literature (e.g. Terziovski & Morgan, 2004; Coombs & Metcalfe, 2002) yet little notion of how such an environment may be countered and innovative work may be increased in this environment. Yet what is clear is that this trend is set to escalate. Work by Cardinal & Hatfield (2000) observes the paradigm shift from in-house R&D to a collaborative outsourced model is occurring rapidly. An unwelcome consequence of this, is that pharmaceutical organisations are increasingly realising that the knowledge involved in 'buying in' innovation is difficult to elucidate and capture. However, is essential in order to understand how the purchased innovation may be eventually be realised as a marketable drug (Dixon, 2000). Factors such as financial resource, trust, intellectual property rights, patent rights and access to technology, equates to many quantifiable hurdles that must be addressed in order to successfully acquire an innovative product that may be marketed (Zeller, 2002).

The pharmaceutical industry has long held the view that innovation is a linear scientific process begun in house, one where R&D develops products which are eventually passed to marketing (Trott, 2002). The realisation that the initial innovative R&D may be external is slowly being realised. The previous acknowledgement that Pfizer are purchasing marketing forces over investing in their in-house R&D capabilities, lends weight to this observation. Taking this one step further, Koberstein et al. (2002) suggests that feedback from the Marketing department which is derived from client contact, may be used to influence and drive the R&D and innovative processes. In effect R&D responds to market characteristics rather than scientific criteria alone (Becker & Lillemark, 2006). Although this concept is plausible, supporting research within this field is scant and the linear model of drug innovation, as advocated in Figure 3.1 is still widely exercised within pharmaceutical innovation (Becker & Lillemark, 2006). A clearer strategy revolves around the use of networked collaboration to drive R&D and innovation. This process involves the collaboration of a number of organisations with the resulting innovation or product being progressed by research driven collaboration Gemser et al. (1996).

This changing model of pharmaceutical innovation rather undermines the assumption that a pharmaceutical organisations in-house R&D, is a measure of an organisations financial value (Achilladelis & Antonakis, 2001). The developing trend towards the 'buy-in' of innovation also effectively negates valuation of the company by the filing of patents (Sakakibara & Branstetter, 2001). As many drug patents are now filed outside the organisation in smaller biotechnology or universities. Yet as Garcia & Calantone (2002) notes, a company's valuation is rarely measured upon its ability to innovate. In the case of the pharmaceutical industry, the measure of value is increasingly being aligned with the ability of the organisation to manage the innovative processes that occur after the nomination of a CD and not the initial R&D behind discovering an NCE (Hara, 2003).

3.1.6 SUMMARY

The proposition that value is linked to the management of innovative processes inevitably returns to the application of the organisation's knowledge (Penrose, 1959; Ford, 2000). Undeniably AstraZeneca is a world leader in a number of therapeutic areas, yet the company's leading drugs have been developed over a decade previously. In order to maintain market position, the company is adapting to the external commercial pressures and attempting to redefine its existing working practices through the embrace of Knowledge Management practices (Zeller, 2002; Roth, 2003). As knowledge is at the crux of the pharmaceutical development process and the knowledge required to innovate is a main asset of an organisation (Nahapiet & Ghoshal, 1998; Kandampully, 2002), AstraZeneca is keen to harness the competitive advantage Knowledge Management may offer. Whether innovation is acquired externally, through collaboration or developed in-house, the knowledge within these processes is creating value for the organisation.

Knowledge Management would to all intents and purposes, appear to be an ideal vehicle with which to reduce the amount of resource involved with the laborious process of developing a new drug and capture the knowledge internally and externally. Knowledge Management is intended to curtail the resource costs involved with developing a new product (Snowden, 2002; Lemon & Sahota, 2004) and should ultimately allow a process or organisation to operate more effectively.

However, the physical process of managing the knowledge and providing a viable return is still shrouded in ambiguity (Stacey, 2001). Davenport & Marchand (1999) suggest Knowledge Management may help to create new knowledge through active management of the knowledge use of the staff within the business environment. Authors such as Jennex & Weiss (2002) and Hendrike (1999) recognise that Knowledge Management will aid a research-based organisation. However, to date, little academic research targets the practical applicability of Knowledge Management tools and strategies specifically within pharmaceutical innovation. One of the main aims of the research is to address this issue. To achieve this, the review will now move on to discuss Knowledge Management, Knowledge Management strategies and the tools which are available to help promote innovation and knowledge sharing across their organisation.

3.2 KNOWLEDGE MANAGEMENT

3.2.1 INTRODUCTION

Knowledge Management has emerged as a popular and important area of academic and practitioner research. The principle reason behind the rise in popularity is that authors such as Drucker (1993) have assigned a value to the knowledge within an organisation. Due to this, organisations are becoming increasingly aware of the need to actively manage the knowledge of their employees. Largely in response as their operating strategies of utilising modern cross functional and cross team working practices (Argote et al. 2003). Large multinational organisations have long valued the use of technology to facilitate organisational learning and knowledge behaviour. Yet the smaller organisations are also recognising the value Knowledge Management may impart to their operating models (Baum & Greve, 2001). The growth of awareness in recognising knowledge as a valuable asset and the need for organisational learning has been coupled with the rapid growth of information technology. Together these areas have merged into the science of Knowledge Management.

The following review of the Knowledge Management literature relates to Objectives 3 and 4.

These objectives require the analysis of the Knowledge Management strategies and tools that are currently in use within AstraZeneca and the suggestion of potential new Knowledge Management approaches.

3.2.2 KNOWLEDGE MANAGEMENT AS A CONCEPT

Defining KM is itself a detailed problem and one, that the researches believes, may never be truly answered as perspectives and opinions on what Knowledge Management denotes are wide and varied. What is clear is that Knowledge Management may be viewed from a multitude of perspectives. Either as a high level strategy, a practical IT based approach or one that attempts to view knowledge from an employee's perspective. Ultimately each perspective supports the research aim, and seeks to enhance the use, creation and the exploitation of knowledge within the workplace. Newman & Conrad (1999) define Knowledge Management as:

"A discipline that seeks to improve the performance of individuals and organizations by maintaining and leveraging the present and future value of knowledge assets".

Newman & Conrad (1999) acknowledge that Knowledge Management is not a new approach, but an integration of many disciplines that are linked by the guiding principle of deriving value from managing organisational knowledge. The advent of Knowledge Management has introduced a wide range of strategies and methodologies, all of which proclaim to be the definitive answer to knowledge sharing and creation within the business environment. Academic literature widely acknowledges that Knowledge Management creates value from the exploitation of the organisations knowledge and intangible assets (Alavi, 2000). Although how an organisation may achieve this and what constitutes an intangible or tangible asset, is often far from clear. It is also fair to say that Knowledge Management is in a state of continuous flux. As it has undergone a transition from the management of technology to the management of the social aspects of the organisation, where the focus upon what employees do with their knowledge has taken precedent over the provision of tools to capture the employee's knowledge (Darroch, 2005).

Knowledge Management literature is quick to point out that the processes of inter and intra organisational knowledge exchange is the driving factors behind the success of R&D strategies and the innovative performance of the organisation (Faems et al. 2005). However, what is less clear, is the relationship between adopting a certain Knowledge Management strategy and the potential benefits on driving innovation. A factor that is largely due to the obscure nature of organisational knowledge.

Lerner & Merges (1997) describes how the unpatented intellectual property or unpatented core technology of the organisation can be described as 'know how', which when captured and applied, allows the development of innovation. It is evident that the bundled 'know how' does lie within all organisations, but it is only through tackling the problems and inertia that revolve around the processes and application of this knowledge can the benefits by realised. In this way Knowledge Management creates value not through the management of the knowledge itself, but through the management and creation of a culture that is favourable to knowledge sharing and knowledge interactions (Walczak, 2005).

The examination and improvement of the processes within a business have long been a source of academic research, continuous improvement, benchmarking and reengineering may be regarded as the fore runners of Knowledge Management (Hammer & Champy, 1993). Yet largely due to the promise of a tangible financial gain, Knowledge Management has leapt to the forefront and is now proclaimed as an essential facet of a successful business strategy (Drew, 1999).

Since the meteoric rise to fame of Knowledge Management in the late 1990's, the process based reengineering methodologies have been relegated. This is due in part, to the emergence of the concept of an organisation's capability (Dosi, 1988). An organisation's capabilities directly relates to the ability of an organisation to manage its own internal resources or content to create innovation (Argote et al. 2003). In this case, the content or resources invariably translates to organisational knowledge and the 'know how' of the employees. Drucker (1993) was amongst the first to ascertain that the knowledge content within an organisation's many processes can be measured as a tangible resource.

The intangible value of the organisation's 'know how' equates to a tangible financial value which may be measured and evaluated. This shifts the focus from the organisation as a whole, to a dissection of the processes that generate knowledge. Techniques such as Business Process Reengineering required the entire organisational structure and operating models to be realigned and largely failed due to the prohibitive costs (Hall et al. 1994). Knowledge Management is said to offer a more direct approach by identifying specific areas that require consideration. Drucker's (1993) work stated the possession of relevant knowledge and expertise infers value to an organisation. Yet scant regard has been paid to establishing a rigid terminology within Knowledge Management and little deliberation has been given to the study of where and how Knowledge Management can impart a positive influence upon an organisation. In an attempt to address this, the following literature review intends to shed light upon the terminology and concepts surrounding Knowledge Management. In addition to clarifying the environments in which Knowledge Management may be harnessed, in order to bring value to AstraZeneca and fulfil the research aim and objectives.

3.2.3 A THEORETICAL PERSPECTIVE ON KNOWLEDGE AND KM

Knowledge Management aspires to address and exploit the knowledge within an organisation, yet there is considerable ambiguity over the definitions surrounding knowledge. The present state of confusion persists through the poor definition of knowledge. In accordance with Polanyi (1967) and Davenport & Prusak (1998) knowledge is said to be construed of both tacit and explicit knowledge. These terms are a cornerstone of Knowledge Management and in simplistic terms: tacit knowledge refers to the expertise, insights and intuition of the organisations workforce. Explicit knowledge is construed to be the organisation's knowledge that is committed to storage, such as documents, words and archives.

These two hierarchical types exhibit a degree of interchange ability and the knowledge of an organisation is interpreted as a combination of the two types (Davenport & Prusak, 1998). Due to this complexity, the majority of Knowledge Management literature fails to categorically outline the knowledge interactions that are being studied, preferring in the main to offer ambiguity, in the form of a generic framework or knowledge black box (e.g. Leonard-Barton, 1995).

In light of the lack of clarity within the field, it is prudent to clarify the research aim and objectives in relation to the largely ill-defined field of Knowledge Management. A fitting point to start would be the definition of knowledge. Knowledge is a commonly referenced term within the literature sources, yet what does the term 'knowledge' imply and how does this differ from the overlapping areas of information?

An attempt to answer such a question from a philosophical pitch is beyond the scope of the review, and would raise untold arguments and counter arguments, many of which date from discussions surrounding the work of the Greek philosophers Plato. However, the research aim squarely focuses upon the use of knowledge within an organisational context and hence falls in line with the majority of published Knowledge Management literature. As Alavi & Leidner (2001) note, Knowledge Management lacks a true accepted definition of knowledge. Instead the academics and practitioners rely upon the premise that knowledge is an entity, over which a degree of control may be exerted (Lamberts & Shanks, 1997). From an organisational Knowledge Management perspective, Saberhal & Saberhal (2005) view knowledge as:

"The set of justified beliefs that enhance a firm's capability for effective action."

Unfortunately the term 'belief' implies that Knowledge Management seeks to manage an unknown and indefinable entity or essence. Together these beliefs provide the drivers behind an organisation's performance. Inevitably confusion reigns within the classification of these drivers and consequently information may at times, be construed as a driver (Fukuhara, 2003). The definition of knowledge and information are a stumbling block of Knowledge Management and authors such as Wilson (2002) suspect Knowledge Management is simply Information Management under a different guise. Wilson's (2002) research demonstrates how confusion reigns concerning the terms information and knowledge. In particular noting that the practitioner's view of knowledge differs greatly from the academic perspective, yet all fall under the notion of Knowledge Management. An academic definition offered by Gunnlaugsdottir (2003) looks upon the knowledge within the organisation as *"information with a contextual element."*

Importantly the definition applies to all knowledge within the organisation, regardless of whether the knowledge consists of tacit or explicit knowledge. Gunnlaugsdottir (2003) states that the contextual element of knowledge is important, as it will provide the facility for critical understanding. This allows the information to be placed within a logical and intelligible sense within the organisation.

Gunnlaugsdottir's (2003) definition of knowledge evolves from the capture of information with the accompanying and relevant contextual data. Gunnlaugsdottir (2003) identifies that the information within the knowledge, is itself composed of data, which has been organised, analysed and interpreted to become usable information. The lower level of the three tiers consists of data, which remains at the factual level where the role and context are ambiguous. Essentially, the meaning of data is entirely subjective until processing or an interpretation is applied to form a meaningful construct and render information (Gunnlaugsdottir, 2003).

The three tiers of knowledge, information and data demonstrate how knowledge holds great importance to the commercial organisation and is viewed as the basis of an organisation's commercial ability (Davenport, 1998). Although knowledge creation, manipulation and reuse are the drivers behind an organisation's innovative ability, knowledge alone must be supplemented and derived from information and data within the organisation in order to drive innovation (Goh, 2005). It is rare to read a Knowledge Management paper that does not advocate that the application of knowledge, information and data will ultimately leads to innovation (e.g. Stewart, 1997). Yet if knowledge itself is widely recognised to be intangible (Hall, 1992), how may an organisation apply its knowledge?

It is easy to accept that information and data are captured in tangible stores such as IT software, databases and documents and their application is relatively straightforward, yet knowledge is a more elusive entity. Stewart's (1997) work suggests the very nature of knowledge is an intangible asset or resource that lies within the employee. This consists of the employee's knowledge, experience and experience within the organisational culture in which they act.

Presenting the opportunity for an employee to act and apply their knowledge appears to be at the crux of obtaining value from a Knowledge Management approach. However, this process is rarely straightforward.

Gopal & Gagnon (1995) acknowledge that the knowledge within the employee is inherently difficult to capture and store. Over a decade has passed since their work and no satisfactory Knowledge Management frameworks or strategies are widely in place as yet. In an attempt to answer this, the Knowledge Management literature has adopted an interesting juxtaposition with regard to managing knowledge and there are two distinct arenas of thought. Firstly, knowledge may be viewed as an intangible asset held within the minds and actions of the organisation's employees (Nonaka & Takeuchi, 1995). Secondly, knowledge may also take the form of a tangible asset that may be manipulated through technology (Nonaka & Takeuchi, 1995). These views return to Polanyi's (1967) notion of explicit and tacit knowledge, yet little research successfully addresses the balance and relationship between the utilisation of the two forms within an organisation (Tiwana, 2000), let alone with regard to pharmaceutical innovation. What is clear is that these areas are intertwined, as the effective management of the employee directly influences the success of the socio-cognitive technological strategies (Ahonen, 2000).

An alternative view of Knowledge Management, offered by Montano et al. (2001), focuses upon allowing the organisation to target the constituent knowledge within the organisation's business processes through the use of technology. The social aspect of knowledge is addressed by modelling an organisational environment that is conducive to the application of knowledge. Hence although Knowledge Management purports to manage knowledge, the existence of knowledge, information and data within a typical business process illustrates that Knowledge Management is not only addressing the notions of knowledge, but is also encompassing the information and data within these processes. The confusion surrounding Knowledge Management frameworks (e.g. Rubenstein-Montano et al. 2001) is concerning and would negate a large body of Knowledge Management work that confuses knowledge with information.

However, Gunnlaugsdottir's (2003) definition of knowledge as information with a context implies that information management tools will also fall under the umbrella of Knowledge Management tools, providing that can capture the additional contextual elements successfully. This argument is far from conducive, Allee (1997) states that knowledge may not be designed or processed or managed from an Information Management perspective. Instead knowledge requires a different approach. Although Allee (1997) does not successfully explain how to achieve this approach, it is implied that Knowledge Management seeks to organise, analyse and interpret organisational knowledge in order to provide usable knowledge that may be used to encourage creativity and innovation. Therefore Knowledge Management is addressing the practical aspects of the application of knowledge within the organisation (Kirchner, 1997). Svieby (1997) suggests that this returns to the exploitation of the knowledge that is held within the mind of the individual. A notion that implies that knowledge can only be released through social interaction. Due to the social aspect, Nomura (2002) suggests organisational Knowledge Management may be viewed simply as knowledge based management, rather than the management of physical knowledge.

As can be seen Knowledge Management research is rarely clear. An uneasy balance exists within the Knowledge Management literature as to the relative importance of the social cognitive aspects and the technological focus of knowledge. Bresnen et al.'s (2003) research notes that even though explicit and tacit knowledge may be articulated and captured. The exploitation of this knowledge may then be hindered by the lack of suitable shared resources. This suggests that Knowledge Management must address both social and technical aspects in order to be valuable. Evidently this balance remains a contentious issue and further research within this thesis will shed light upon this area with regard to pharmaceutical innovation. However, the message is that technology should supply a means by which knowledge's context and understanding may be disseminated (Davenport & Prusak, 1998).

Unfortunately the complexities of social and technical Knowledge Management pale when compared to the fundamental stumbling block of understanding the role tacit knowledge holds within the company. Tacit knowledge underpins the majority of business transactions and while considerable efforts have been made to visualise and store tacit knowledge, there remains a substantial amount of knowledge that will stay within the heads of the business's employees (Nonaka et al. 2001). The management trend of "downsizing" illustrated the importance of tacit knowledge within the organisation. Knowledge accumulated by the time served employees was lost and the information that remained within the organisational databases was of little use, without the experience of these 'downsized' staff to interpret and apply it (Martensson, 2000). As organisations realised this, Knowledge Management emerged as a tool to reverse and prevent this loss of knowledge from reoccurring. In a maelstrom of hype, large scale Knowledge Management schemes were specifically created to tackle these issues of tacit knowledge loss. Anderson Consulting chose the "Knowledge Manager" system and Price Waterhouse used "Knowledge View". However, Davenport & Prusak (1998) found that both schemes suffered from scant forward planning and the systems resulted in the wholesale storage of data and not applicable knowledge. Davenport & Prusak (1998) concluded that these schemes failed because the knowledge and business processes they were designed to capture rapidly became redundant as the key actors within the processes left the organisation. Hence with little or no contextual element, the knowledge lacked the authority, trust and verifiability which an employee, unfamiliar with a process, needed to make a reasoned decision and hence the existing business processes were quickly superseded.

This example demonstrates that information management tools are unlikely to offer the correct means to store knowledge. This is because they do not take in to account the tacit knowledge transactions that occur when the experienced employee utilises the information or data (Nonaka & Takeuchi, 1995; Ruggles, 1997; Silver, 2000; Gunnlaugsdottir, 2003). Nonaka et al. (2001) suggest tacit knowledge is personal, it may have meaning to a group, department or individual, and attempting to communicate the essence of the knowledge captured is essential to the success of a Knowledge Management system.

Even though Knowledge Management has evolved, the concept of organisational knowledge taking one of the dual classifications of tacit and explicit knowledge has remained predominant. It is rare to read a Knowledge Management paper that neglects to mention tacit or explicit knowledge management. However, Collins (1993) & latterly Blackler (1995), suggests that instead, knowledge possesses five facets. Knowledge may be embodied, encultured, embrained, embedded and encoded. Knowledge within the organisation is represented by the following definitions in Table 3.1:

Table 3.1: The Components of Knowledge

Knowledge Types	Description
Embrained Knowledge	The inherent knowledge of the individual where the employee is the focus of the organisations knowledge.
Embodied Knowledge	A representation of the know-how derived from an employee's experience and the action based processes of the organisation.
Encultured Knowledge	The knowledge that is shared throughout the social structure of the organisation.
Embedded Knowledge	The knowledge held within the Knowledge Management systems and documented processes of the organisation.
Encoded Knowledge	Embedded knowledge that is accessible only to those who are familiar with the codification strategy of the knowledge.

Of the five areas, three relate to the knowledge within the individual and may be generally construed under the banner of tacit knowledge. Dougherty (1999) and Allee (1997) offer further insight and proclaim that embrained and embodied knowledge describes the rich subjective knowledge of the organisation.

However, to pigeonhole knowledge within categories alludes to an acceptance that knowledge can be specifically identified as holding characteristics of type X or Y. Yet within an organisation, knowledge resources may lie within and across these hypothetical boundaries (Allee, 1997). Scant empirical research is available to enlighten how the operational aspects of the five types of knowledge interact.

Let alone divulging how a Knowledge Manager may apply the various types of knowledge once they are recognised. Although the five distinctions are fuzzy, they provide a higher level of detail over the duality of tacit and explicit knowledge. An encouraging point to note for this research is that little, if any, study has been carried out on the types of knowledge necessary for pharmaceutical innovation and as yet no studies have linked these knowledge types to Knowledge Management tools.

3.2.4 SUMMARY

Even at the early stages of Knowledge Management work Reich (1992) noted that research on the operational side of applying and capturing the types of knowledge was progressing slowly. Petty & Guthrie (2003) suggest that capturing organisational knowledge requires strong hierarchical control and guidance by management. Alternatively, authors such as Ndlela & Toit (2001) suggest Knowledge Management is dependent upon undertaking a series of reiterations, from the focus upon technology to a focus upon the assessment of the human factors within the organisation. Work by Balafas et al. (2003) and Heisig (2001) suggests Knowledge Management should address the business processes of an organisation. However, there is little doubt that Knowledge Management has undergone a shift in emphasis from the technology based Knowledge Management to an analysis of the knowledge within the business processes of the organisation.

It is feasible that knowledge which falls within the categories defined by Collins (1993), Blackler (1995) and Dougherty (1999) when identified, may be supported through the application of Knowledge Management systems and tools (Jashapara, 2004).

The following sections of the literature review will now turn to address the tools and practical approaches advocated by Knowledge Management academics and practitioner. Seeking to highlight Knowledge Management tools that may be used to enhance knowledge sharing and support the research aims and objectives.

3.3 KNOWLEDGE MANAGEMENT TOOLS & STRATEGIES

Knowledge Management is proclaimed by many authors to offer the key to a successful business and appears to offer an organisation the 'magic bullet' of increased productivity, efficiency and profitability (Choo & Bontis, 2002). Unfortunately, achieving these results is a somewhat grey area; the early rush of interest in Knowledge Management meant that many systems were enthusiastically introduced in many organisations and fell flatly out of use (Gartner Group, 2003). This is largely due to the scope of the field, Knowledge Management may be viewed from both an academic and a practitioner based view. A practitioner aims to create an environment conducive to knowledge sharing and is largely reliant upon the implementation of technology to support such knowledge interaction (Richardson, 2001). On the other hand, the academic arena approaches Knowledge Management from a conceptual angle, seeking to analyse the underlying basis of knowledge and create an environment conducive to knowledge sharing without the emphasis upon technology (Sullivan, 2000; Nomura, 2002).

The two fields do agree that the basis of a successful Knowledge Management schema is an appreciation of the cultural and people centred aspects of the organisation (Rubenstein-Montano et al. 2001). Knowledge Management literature exhibits a fascinating degree of variability with regards to the acceptance of technology as a basis for a Knowledge Management strategy. Authors such as Alavi & Leidner (2001) advise the practitioner to view knowledge as a manageable entity and refrain from philosophical discussion. Work by Zack (1999) focuses upon knowledge as a codifiable and hence manageable entity. However, few authors will describe how these processes can be carried out and implemented. In the case of Yu et al. (2003), a set of step-by-step guides relating Knowledge Management to the creation, collection, codification, personalisation and dissemination of knowledge are suggested.

Yet when analysed further, the steps fail to provide further information with regards to practical application.

However, Knowledge Management is a forward looking discipline and seeks to build upon the foundation of Information Management and establish its credibility. As previously mentioned, Wilson's (2002) argument that Knowledge Management is little more than Information Management appears to hold true on occasion. Indeed, as far as Knowledge Management tools are concerned it appears exceptionally well founded. Wang & Ariguzo's (2004) study indicates that the majority of Knowledge Management tools or Knowledge Management Systems (KMS) are in fact based upon the framework of an Information Management tool. A survey and review of these tools indicates there are four defined categories of Knowledge Management systems and tools (Ruggles, 1997). Jashapara (2004) & Benbya et al. (2004) suggests the four categories comprise of the following types of tools:

1. Content management tools allow the codification, classify and capture of knowledge
2. Knowledge sharing tools support the sharing of knowledge
3. Knowledge search and retrieval systems allow the discovery of knowledge
4. General Knowledge Management systems that attempt to answer a firm's knowledge needs in one package.

The four definitions cover the majority of KMS within use, but substituting 'knowledge' for 'information' still conveys meaning. It is odd to include type one, as the majority of content management tools are primarily based upon the management of documents and information (Jashapara, 2004). Accepting that a Knowledge Management System may in reality be an Information Management system unfortunately appears to be necessary. The confusion may be answered by the work of Pohs et al. (2001) emphasises that companies seek to introduce a Knowledge Management system that encompasses all of the four categories. While few organisation's view Knowledge Management tools as distinct subsets (Rubenstein-Montano et al. 2001).

Hence a KMS may have many components including an information based tool, indeed Benbya et al. (2004) final recommendation is an amalgamation of the aforementioned concepts under the guise of a Knowledge Management System. Duffy (2001) states that a KMS is said to possess the capability to create knowledge and guide the use of these knowledge sources. Yet there remains a tenuous argument in the definition of a Knowledge Management and Information Management tools. Alavi & Leidner (2001), Gunnlaugsdottir (2003), Wilson (2002) and Scarborough et al. (2005) propose that the archetypal Knowledge Management System is an Information System. With the tag of KMS, being attributed to the concept of external guidance and management surrounding the information based systems. Holsapple & Joshi's (2002) study within the Delphi organisation places considerable emphasis on the dynamics of the knowledge activities within the organisation. Such knowledge related activities occur through the social interaction of individuals, the communities and the organisation, and to all intent a KMS should serve as a framework upon which these activities progress (Choo & Bontis, 2002).

Evidently the knowledge aspect of the KMS stems from the aim of imposing a structure upon the knowledge led organisation, and in doing so provides clarification of the role and boundaries relating to the use and introduction of a KMS. However, deploying a KMS framework that produces value is rarely an easy task. Work by Rubenstein-Montano et al. (2001) notes that no single unifying Knowledge Management framework has been developed. Instead the authors define two co-existing frameworks, namely the prescriptive and the descriptive. The prescriptive framework is widely deployed and suggests that one should undertake defined actions in order to acquire, disseminate and amass knowledge. The prescriptive framework suggests a defined methodology with supporting KMS tools and is widely found throughout the literature (e.g. Alavi, 2000, Tiwana, 2002; Jashapara, 2004). Although case study evidence suggests the likelihood of failure of prescriptive frameworks within an organisation is of concern (Malhotra, 2004).

A descriptive framework contrasts the rigidity of a set Knowledge Management methodology, by focusing on providing components of a Knowledge Management strategy. Although descriptive frameworks act as a hypothetical guide by highlighting areas to be addressed before implementing a Knowledge Management strategy, the physical implementation of tools and associated strategy aspect is lacking (Malhotra, 2004). There also appears to be little consensus concerning the standardisation of the traits associated with the prescriptive and descriptive frameworks (Earl, 2001). Furthermore, as collaboration takes place within the physical and technological realm of the organisation, it is implied that the practitioner will include both prescriptive and descriptive elements within a Knowledge Management strategy that are derived from multiple frameworks (Rubenstein-Montano et al., 2001).

The issue of identifying what KMS framework to deploy certainly lacks a clear focus. Authors rarely adopt a homogenous tool set and this confusion represents a clear avenue for further research, particularly within the pharmaceutical environment. To illustrate this Nonaka et al. (2001) and Lindvall et al. (2003) signify that a KMS is a means to capture, codify and generate knowledge and is reliant upon information based principles. In contrast Holsapple & Joshi's (2002) and Wenger & Snyder (2000) work targets the adoption of a KMS to promote collaboration. This begs the reader to question how and what is meant by a KMS?

Certainly there is a technological aspect, but what is meant by this? Hansen et al. (1999) rapidly concluded Knowledge Management requires the provision of information technology (IT) as a means to store knowledge through codification or as a means to provide the user with a personalised view of knowledge. Yet in this respect, little additional work has clarified this viewpoint. The Knowledge Management literature remains obstinately divided as to whether Knowledge Management should (or can) be deployed through tools and systems or whether it is an organisational dilemma alone (Horwitch & Armacost, 2002). Such a notion returns to the idea that of whether the individual is the sole provider of knowledge (Tsoukas & Vladimirou, 2001), or whether technology has its place to act as the facilitator of knowledge between individuals (Hansen & Haas, 2001).

Additionally there appears to be a delicate balance between the culture and Knowledge Management tools. Earlier Knowledge Management research often assigns greater importance to the creation of a culture that is pervasive to knowledge exchange and interaction, over the introduction of tools to facilitate such interaction (DeLong & Fahey, 2000). In spite of this, the majority of Knowledge Management literature is based upon the notion of tangible prescriptive frameworks and it would be foolish to dismiss technologies role as an enabler of knowledge creation (Rubenstein-Montano et al., 2001).

Knowledge Management literature can regard information technology as a separate entity and strategy. With an often dismissive attitude, prevalent within the Knowledge Management academic circle and literature, when IT driven Knowledge Management strategies are proposed (Un & Cuervo-Cazurra, 2004). Such views may stem from early research by authors such as Earl (1996) who championed the introduction of IT systems to support knowledge activities, yet disregarded the cultural aspects associated with the organisation.

A more rounded approach details Knowledge Management and IT in tandem with the culture and strategy of the organisation. Rubenstein-Montano et al. (2001) noted this lack of an appreciation of the strategic element associated with IT hampers the introduction of Knowledge Management Systems. The cautionary tale of KMS failure provided by Odom & Starns (2003), dispels the myth that a prescriptive IT led KMS framework will always provide tangible value. Instead Rubenstein-Montano et al. (2001) conclude Knowledge Management frameworks should be approached from a systems thinking concept. This links the people, their knowledge, the organisational culture, the organisational strategy and the technological infrastructure as a whole integrated system, while seeking to provide mechanisms for double loop learning.

Double loop learning implies the organisation actively challenges assumptions and processes rather that simply reacting to a challenge, as describes single loop learning (Agyris & Schon, 1978; Rubenstein-Montano et al., 2001). While Rubenstein-Montano et al.'s (2001) work was conducted five years previously, little further work has focused upon addressing all the components of Rubenstein-Montano et al.'s (2001) framework.

The concepts of strategically aligning IT with Knowledge Management, is gaining acceptance as organisations realise information technology may facilitate Knowledge Management success (Kankanhalli et al. 2003).

The shift from the IT led perspective to a knowledge led perspective has continued to fuel debate concerning IT and culture. As mentioned previously, the generations of Knowledge Management noted by Malhotra (2005) are in reality turning full cycle, returning to IT as a basis for Knowledge Management and collaborative activities. The re-emergence of technology as a key facet to address knowledge activities within R&D and innovation is being promoted by a new wave of innovation driven KMS systems that takes account of the knowledge required by innovators (e.g. Park & Kim, 2005). Hoadley & Kilner (2005) describes this as an 'information to knowledge' cascade. Whereby knowledge is constructed, shared and reconstructed by individuals from varying knowledge sources. Where the primary role of the KMS is to provide the knowledge sources on which an employee may act (Brown & Duguid, 2001).

3.3.1 STRATEGIES FOR KM & INNOVATION

As the review has witnessed, the Knowledge Management literature can portray the use of Information Technology as a necessary evil, although as Malhotra (2005) notes, IT plays an important role when deployed in conjunction with the business processes and strategy of the organisation. In this light, strategy, innovation and Knowledge Management are closely linked concepts (Un & Cuervo-Cazurra, 2004). The concept of strategy and innovation or 'strategic innovation' is defined by Drejer (2006) as the ability to create and revitalise the business ideas and concepts of the company. This is achieved by addressing the market, the competencies and business systems of the company in such a way as to develop these areas across the entire organisation. However, the concept is also very similar to the ideals that Knowledge Management strives to achieve, as suggested by Scarborough (2002). Although strategic innovation is said to focus upon developing a differentiation strategy that allows innovative behaviour and hence may be of use to the overall research aim, it is still unclear what exactly the focus should be upon.

Drejer (2006) suggests that the current strategic literature is overly concerned with the operational aspects of the organisation, yet to an extent a strategy must address the operational aspects of the organisation in order to be successful (Un & Cuervo-Cazurra, 2004).

Strategy or not, the very basis of an organisation's competence and ability stems from managing the employees and their knowledge and ensuring the organisational strategy reflects these aims (Benbya et al. 2004). Nonaka & Takeuchi (1995) suggest that the primary means of achieving a successful strategy is through social interactions, which may, as we have previously witnessed, be encouraged through KMS technology. Returning to the topic of technology, an empirical study by Mustonen-Ollila & Lyytinen (2003) concerning the adoption of information systems, suggests it is prudent to identify the correct technologies to support the application areas. Interestingly their study assigned little importance to the cultural and social factors, such as strong management support, visibility of product champions and cost effectiveness. When the overall success of a strategy is considered these are areas that are key to the implementation of a successful strategy (Drejer, 2006). An earlier study by Thomas et al. (2001) concluded it is the social factors which hold the true weight of success. Ascertaining that Knowledge Management is concerned with the human aspects of the organisation and it is simply a matter of getting the right knowledge, to the right person, at the right time.

In order to shed light upon these points and provide examples of KMS tools, the review will now look at the physical implementation of the Information Systems tools within Knowledge Management and outline how they may be used within an organisation.

3.3.2 KNOWLEDGE MANAGEMENT TOOLS

In compiling this review, the researcher realised there is such a wide variety of Knowledge Management based software tools available that to review each one is beyond the scope of the review. There is however, an arbitrary classification of the tools relative to the four classifications suggested by Jashapara (2004) and Benbya et al. (2004), cited earlier within Section 3.3.

These categories are broad in dimension, but Saito et al. (2006) have compiled a more accurate overview that is based upon the tools associated with Knowledge Management and provides examples at the component level. This differs from the four categories previously discussed, in that software systems form the basis of each category.

Table 3.2, 3.3 and 3.4 illustrates the current software system components available, drawing examples primarily from Saito et al. (2006) but also Liao (2003), Gunnlaugsdottir (2003) and Wiig et al. (1997).

Table 3.2: Content Management Tools

Content Management Tools	Allow the codification, classify and capture of knowledge
Storage	Databases, repositories, file-servers, data warehouses & data marts
Authoring	Office suites, desktop publishing, graphic suites & multimedia

Table 3.3: Knowledge Sharing Tools

Knowledge Sharing Tools	Support the sharing of Knowledge & Information
Distribution	Web, intranets, extranets, enterprise portals, personalisation, syndication & audio/video streaming
Connectivity	Internet, security, authentication, wireless networking, mobile computing & peer-to-peer
E-learning	Interactive multimedia, computer-based training, web seminars, simulations & learning objects
Collaboration	Calendaring, file sharing, meeting support, application sharing, groupware & decision support technology
Community	Community management, Web Logs (Blogs), Wikis & social network analysis
Creativity	Cognitive mapping & idea generation

Table 3.4: Knowledge Search & Retrieval Systems

Knowledge Search & Retrieval Systems	Allow the discovery of knowledge & information
Search	Search engines, search agents, indexing, glossaries, thesauri, taxonomies, ontologies, collaborative filtering & the Semantic Web
Analytics	Querying, reporting, multi-dimensional analysis & on-line analytical processing
Workflow	Process modelling & process engines
Data mining	Statistical techniques, multi-dimensional analysis & neural networks
Text mining	Semantic analysis, Bayesian inference & natural language processing
Web mining	Collaborative profiling & intelligent agents
Visualisation	2D and 3D navigation & geographic mapping,
Organisation	Ontology development, ontology acquisition, taxonomies, glossaries & thesauri
Reasoning	Rule-based expert systems, case-based reasoning, knowledge-bases, machine learning & fuzzy logic.

Table 3.2, 3.3 and 3.4 illustrate the complexity and breadth of Knowledge Management component technologies available. When viewed from the previously mentioned categories of Jashapara (2004) and Benbya et al. (2004), it is evident that category four encompasses many of the available components. Citing the widely used Knowledge Management portal as a typical example, we witness that this contains an element of content management, knowledge sharing and search and retrieval components (Benbya et al. 2004). Many of the Knowledge Management technologies listed by Saito et al. (2006) may be fundamentally described as information systems. Yet it is only upon application of the information within these systems that knowledge is created (Liao, 2003). Thus the inclusion of information based software under the Knowledge Management umbrella certainly lends credibility to the protagonists of Knowledge Management, such as Wilson (2002). Knowledge Management based systems were originally said to stem from the field of Artificial Intelligence, whereby researchers attempted to capture and display human knowledge (Wiig, 1997).

It is evident however that this label has been extended to include a variety of further systems. However, true knowledge representation is apparent within the use of reasoning and semantic systems although the majority of Knowledge Management tools simply offer an information or data store (Berners-Lee et al. 2001). The following section covers the semantic web that has been described as the future of pharmaceutical Knowledge Management (Davenport & Peitsch, 2005), and provides an overview of the application and scope of the technology with relation to Knowledge Management systems and activities.

3.3.3 THE SEMANTIC WEB AND KNOWLEDGE MANAGEMENT

The semantic web is an emerging concept that creates a framework around information and knowledge stores. It is rapidly gaining acceptance as a credible knowledge and information retrieval approach (McGuiness, 2003). The semantic web is reliant upon the creation of domain ontologies to represent, map and search the information and knowledge within the organisation (Ding et al. 2002). Domain ontologies are a formal, explicit specification of a shared conceptual model (Gruber, 1993; Ding et al. 2002). The ontology models phenomena within a domain and explicitly defines the concepts and relationships within the model and hence the domain as a whole, may be understood, mapped and searched. The formality of Gruber's (1993) definition is associated with the machine readability aspect of the model, which is largely written within XML or an RDF/ XML framework (Anagnostakis et al. 2005). The concept of a shared and machine readable model of an organisational domain has not escaped the interest of the pharmaceutical industry. Gardner (2005) notes the semantic web offers pharmaceutical R&D industries the means to:

1. Generate information that may be harnessed
2. Distribute the generated information in a structured manner in order to generate knowledge
3. Provide the ability to search across information sources
4. Integrate the diverse ranges of information sources across an R&D organisation.

The semantic concept effectively tags encoded information with descriptors which describe the relation of the encoded information to other encoded information within the domain (Chiang et al. 2001). However, as Chiang et al. (2001) note, the semantic web suffers from a need to create and then actively manage the domain ontologies which are required for its success.

Ontologies within a rapidly changing domain, such as drug R&D, must reflect current knowledge and thinking to provide the valuable relationships between terminologies and project work (Goble et al. 2005). Public domain ontologies such as WordNet consist of 100,000 concepts and require considerable management (Fensel et al. 2000). The management aspect makes it clear that the pharmaceutical domain ontologies are also expected to pose similar problems (Goble et al. 2005). Due to this, Gardner (2005) concludes that the semantic web is reliant upon accurately mapping the nomenclature and terminology found within the organisation and domain. As such this requires considerable investment over traditional free text search structures and information management systems. Early pioneers of the semantic web note the semantic structure may offer considerable benefit in the codification and retrieval of knowledge and information within the life sciences. In particular Goble et al. (2005) notes the semantic web addresses the issues of information search and retrieval across multiple life science domains, which is a commonly cited failing of Knowledge Management technology (Nonaka et al. 2001).

3.3.4 REFLECTIONS ON KNOWLEDGE, INFORMATION AND SYSTEMS

The intrinsic principles of the semantic web are linked with those of Knowledge Management. This link may provide an important tool with which to manage and locate an organisation's knowledge across multiple domains. Although the semantic concept is in its infancy, it would appear to offer considerable advantages through the linking of information and knowledge as a series of interrelated concepts. Information without searchable context is ambiguous in meaning and draws a parallel with unanalysed data (Gunnlaugsdottir, 2003), yet the semantic web may be used to provide the all important contextual element.

In reality though, too few KMSs or Knowledge Management papers address this issue and hence lack the contextual support, often simply rehashing an information tool under the guise of Knowledge Management (Chua, 2004). The reasoning behind this stems from a lack of specificity, few authors will tailor Knowledge Management tools to a specific environment, preferring instead to provide a multi-environment prescriptive framework that is based upon commercially available tools that will function in a variety of industries (Tiwana, 2002). Hence tools are rarely built to exploit the knowledge of a particular environment and become 'generalist'. This is odd, as the basis of Knowledge Management is to extract and use the knowledge that is within the organisation (Stewart, 1997) which implies that specificity is preferable. The research aim will address this within the R&D pharmaceutical environment, but this trend maybe attributed to the acknowledgeable gap between the knowledge held within a Knowledge Management System and the application of knowledge by a human expert (Skyrme, 1999; Cooper, 2003). Such a gap often appears insurmountable and authors such as Havens & Knapp (1999) believe that rather than attempting to capture the knowledge of the employee's within a system, Knowledge Management should instead encourage collaboration and provoke discussion across knowledge sources, although Roberts' (2000) concedes that such a system may never manage to emulate a face to face environment.

Theoretical research carried out by Chua (2004), reviewed established KM methodologies that purport to bridge the gap between the elusive organisational tacit knowledge and the existing Knowledge Management technology. From these models Chua (2004) outlined a KMS architecture, which drew upon three distinct service areas. Namely:

- The infrastructure services such as knowledge storage and communication
- The knowledge services that deal with the creation, sharing and reuse of knowledge
- The area of presentation, where the visualisation and personalisation of the knowledge occurs.

Altogether these aspects combine to form a theoretical basis to address the balance of technology in relation to organisational knowledge processes. However, it is apparent that the proposed system fails at grasping the importance of intangible knowledge and represents a clear example of the confusion between the terminology of knowledge and information. When describing the contents of the knowledge storage service Chua (2004) proposes that 'a knowledge repository could either be populated with data or documents', hence in effect the grounds of the 'Knowledge Management' system is firmly based within the realms of document and information management. This trend is apparent throughout the Knowledge Management literature and little explanation is offered as to the how the feat of intangible knowledge capture may be carried out. In reading papers such as these, it becomes apparent that although Knowledge Management research is established and varied, few people have attempted to apply their theoretical work within industry (Mouritsen & Thorsgaard-Larsen, 2005).

A survey carried out by the Knowledge Management Consortium International (KMCI, 2003) in late 2003, questioned 110 KM professionals. From these discussions it emerged that KM practitioners are looking for and failing to find insight into how companies can physically implement KM within the workplace. The studies sample population revealed few studies provided practical instruction, while the associated standard means of operating a Knowledge Management schema were also shown to be lacking. Many Knowledge Management practitioners are in reality baffled by the scope and application of Knowledge Management within an organisation. As an example, Dilnutt (2002) has authored one of the few academic studies of Knowledge Management in practice. He describes three case study scenarios where Knowledge Management has aided a problem domain. The first is within a large bank call centre, where the introduced Knowledge Management system provided staff with a taxonomy that provided details of the knowledge required to carry out procedures, its location and the form of the knowledge. The second and third Knowledge Management schemas took place in a fund management company and a government office, and both also revolved around the same principles of providing access to the required knowledge, its location and its format.

Although this example provides a valuable illustration of knowledge and information manipulation, it denotes Knowledge Management at its most basic level and may readily be construed as information management. The implemented Knowledge Management systems revolved around a Lotus Notes system employed to classify and record information based best practice documents and guidelines as knowledge, in a similar respect to Chua's (2004) system.

The Knowledge Management aspect of Dilnutt's (2002) research derived from the mapping of the employee's knowledge requirements and the gap analysis required to develop a taxonomy to map an organisation's information. The tangible benefits of the scheme did not stem from providing the employees with greater access to information, such as best practices and use case scenario, but from educating the organisation and employees to recognise and nurture the knowledge within themselves and the operating procedures of the organisation (Dilnutt, 2002). A side effect of this action, was an elucidation of the knowledge structures within the organisation, which when identified was assigned ownership within an individual's job description (Dilnutt, 2002). Indeed authors such as Blair (2002), suggest mapping of an organisation's knowledge may help an organisation's best practice and decision support systems, but it does not replace an employee's tacit knowledge. It is the concept of knowing within an employee, which only begins with understanding and often reflects upon experience that differs from the capability of knowledge captured within a machine (Ghandi, 2004).

3.3.5 SUMMARY

Darroch & McNaughton (2002) propose Knowledge Management seeks to create or locate local knowledge. Therefore from a theoretical perspective a logical framework to capture knowledge within a machine may appear effective at recording the organisation's knowledge (Mayo, 1998). Yet the subsequent reuse is often limited by the lack of a contextual element (Gunnlaugsdottir, 2003). From this, the key to an effective Knowledge Management system appears to be providing the employee with an understanding of the captured knowledge from which to form reasoned judgements (Cooper, 2003).

Knowledge Management literature largely focuses upon the capture of an organisation's tacit knowledge into an explicit form in a KMS (Ghandi, 2004). This action detracts from the fact that an organisation's innovative knowledge can take a variety of forms.

Albino et al. (2001) conclude knowledge is created through employee interactions and the tumultuous mix of knowledge and information that occurs within a business process. They also warn that ill formed attempts to compartmentalise such knowledge may hamper this reaction. From a pharmaceutical perspective, authors such as Roth (2003) advocate the use of multi skilled teams within pharmaceutical R&D and a Knowledge Management system in tandem. Authors such as Hoadley & Enyedy (1999) conclude that although information systems promote knowledge creation, the primary means of knowledge creation is through employee dialog that is centred upon and supported through information sources.

The mention of dialog turns to the concept of the Community of Practice as a Knowledge Management tool. Watson (1999) notes the capture of knowledge within an organisation is not the only crucial aspect, it is the subsequent application of the knowledge within an organisational community that yields value. Deciding upon how to address how to encourage communities where knowledge is exchanged is where the challenge for Knowledge Management lies, and has so far yielded few methodologies or strategies. Of the few methodologies reviewed, the Community of Practice model occupies a prominent position within the Knowledge Management literature as a strategy to capture and disseminate the tacit and explicit knowledge of the organisation (Nahapiet & Ghoshal, 1998; Hoadley & Kilner, 2005). The review will now discuss the Community of Practice and its applicability to Knowledge Management and innovation within an organisation.

3.4 TIIE COMMUNITY OF PRACTICE

3.4.1 INTRODUCTION

As the review has previously noted, the advent of the knowledge based economy has caused great interest to be taken in the phyśical and psychological aspects of knowledge sharing and creation (Drucker, 1993). A large amount of academic and practical based research has focused upon how the knowledge within an organisation is shared and this has led to the evolution of the term a Community of Practice (CoP) (Wenger & Snyder, 2000). The following section discusses the nature and deployment of the CoP and aims to clarify the accuracy and extent to which a community may be used within the innovative arena. The study aims to throw light upon the ambiguity present within current research, which sees co-operative groups falling under many different names and guises. All of which can seemingly be construed to be under the larger banner of a Community of Practice. Firstly the review will examine the theoretical basis of the CoP, before continuing to analyse their application and their impact on decision making, knowledge sharing and knowledge generation within an innovative business environment.

3.4.2 DEFINING THE COMMUNITY OF PRACTICE

The literature is extensive in scope and depth upon the subject of Communities of Practice, yet there are believed to be a number of factors which form to constitute the definition of a valid CoP. The key factor appears to be a shared or common interest centred upon a particular subject area (Davenport & Hall, 2001). Research by authors such as Lave and Wenger (1991) has elucidated that the knowledge sharing processes involved within the organisation are dependent upon the formation of communities. In this light Lave & Wenger (1991) define the CoP as:

"An activity or system that includes individuals who are united in action and meaning, to provide reason for the larger collective or community."

Similarly the definitions offered by Wick (2000) and Cortada & Woods (2000) share a common knowledge creation theme, in that they encourage active participation and a fostered team work ethic, which is intended to complement and mirror the standard working practices of the organisation.

Such communities are often centred upon specific projects and focus on answering a specific project related task or a business process that is often the crux point of an innovative process, with the end results realising a step towards new product development or innovation (Collier & Esteban, 1999). Hence the CoP appears to be focused upon specific business processes and these include innovative and project related work.

When looking to further define a CoP it is wise to look at the meaning attributed to the community aspect of the term. Drawing upon the view point of Heller (1989), we begin to see a focus upon interaction and participation where a community is characterised by the relational interactions or social ties which bind people together. This view ties in well with the definition of a CoP as penned by Lave & Wenger (1991). Although, Rothaermel & Sugiyamas (2001) believe a CoP allows people to come together to share knowledge and collaborate only when centred upon a technological framework or a Knowledge Management system. Earlier literature by Gusfeld (1975) focuses upon the existence of two different types of community - both a geographical and a relational community. Here the sense of close spatial proximity is inherent within the definition of the community, countering many of the definitions of a distributed community that is commonly associated with a CoP within a Knowledge Management system. However, to a large extent, the CoP associated with the technical realm is deemed non-geographical and independent of time (Markus et al., 2000) and hence not bound by the traditional restraints associated with a physical community more in keeping with Gusfeld's (1975) traditional definition.

At this stage it must be noted that the CoP may exist both within the realm of the traditional physical work place and the virtual realm of technology backed interaction. The distinction defines a Community of Practice to involve physical interaction, while the virtual Community of Practice allows faceless interaction over a communicative medium (Rheingold, 1994; Palloff & Pratt, 1999). As both virtual and physical communities occur within the pharmaceutical innovative domains the research will cover both types, although the Knowledge Management literature is on the whole more concerned with the application of the virtual CoP.

The online or virtual CoP may be regarded as a predetermined situated learning or collaborative environment, where the instigators and practitioners are physically free from constraints such as their geographic location and provided they can gain access to the service, remain tentatively linked through their online relationships to form a working community (Nonaka & Takeuchi, 1995). The work of Davenport & Hall (2001) proclaims that a CoP will display three traits. These traits are based upon the organisation and virtual interaction of participants, rather than the spatial awareness and proximity of the participants:

1. Firstly a group is said to display situated actions based upon a specific problem

2. Secondly there is situated learning where both novices and experts learn and exchange knowledge when located within the same virtual space and context

3. The third and final trait is distributed cognition where the phenomenon of learning as a collective is deemed to be greater than that possible by the individual.

As the community evolves, the structure and rules associated with the accumulation of knowledge and the traits are said to be adapted and developed by the group, creating an environment that is specifically adapted to solving specific process driven requirements within the organisation (von Krogh & Kleine, 1998).

Johnson's (2001) review of CoP literature provides further clarification into the definition and scope of the CoP, where the author notes that these characteristic traits and definitions merge to support the view of a the CoP working on a shared goal or consensus. Johnson (2001) also implies that CoPs are based upon the principles of constructivism. Where the term constructivism denotes that we learn from our own experience, hence meaning and understanding of an issue are inferred by applying a community's current knowledge to a problem and then constructing their own meaning to suit each problem area.

Viewing the CoP in such a way allows us to comprehend their value within a business environment. By allowing and promoting the interactions of individuals who apply their knowledge and experience to a problem area, in the hope of ultimately devolving a meaning and solution to their quandary.

The main points raised by Johnson's (2001) literature review on the means and application of a CoP to promote organisational learning and knowledge creation are:

- A CoP will evolve and challenge ill-structured problems which have defied traditional attempts to solve, such as commercial problems which are complex and ill-suited to be solved by generalised concepts found within a traditional rigid working pattern.

- Teams are paramount to the CoP and the emphasis is on attacking a problem with multiples of knowledge and experience in the hope of divulging a rationale outcome.

- The ultimate goals and answers are shared and all participants are working towards the effective resolution of a scenario. CoPs demand negotiation and discussion, which further promote a sense of ownership and interest amongst the participants.

- CoPs often utilise a facilitator or advisor to guide rather than instruct the participants to a novel solution.

Perhaps the most important feature raised by Johnson (2001) is the use of a CoP to organise and categorise knowledge through the use of a communities within the organisation. Although communities may naturally categorise knowledge across an organisation, little explanation is provided concerning the technology required to achieve and manage this knowledge. Rather it is implied that the process of learning how to create relationships across the organisation will foster knowledge and interaction across the organisation (Newell, et al., 2002). Here the value of the knowledge surrounding the formation and instigation of ties between employees may outweigh the knowledge contained within the community itself (Crampton, 2001).

This point acknowledges that the formation of community is a valid approach to problem solving, as a group discussion or consensus formulates the knowledge within the community. Yet Huysman (2004) believes that organisations may be unaware of the CoPs that operate within its boundaries and even less aware of the learning and knowledge that occurs within them. Further to this, is the interaction of like minded communities that interact to form Communities of Interest that span multiple CoPs and multiple domains across an organisation (Fischer, 2002), further clouding the decision and knowledge processes of the organisation.

Thus a Community of Interest differs from the process or practice based CoP and provides a wider group that has the capability to address a broader range of topics (Liedka, 1999). Fischer (2002) also argues that due to this a Community of Interest displays a potentially increased return due to the increased levels of interaction. If a CoP centred upon a process lacks the required number of participants to function effectively, the conglomerate of CoPs within a Community of Interest may offer a greater return. The literature suggests that the tight knit CoPs within an organisation may be used to form a larger framework of Communities of Interest throughout an organisation (Johnson, 2001).

Unfortunately the specific Knowledge Management strategies and tools to achieve a viable Community of Interest are unclear. What is also unclear is the precise definition of a Community of Interest. A Community of Interest is described as a large CoP by many authors, yet each type of community appears important to the organisation and should be considered to meet the research aim. The problem of ill definition can affect how an organisation reacts and manages such communities. Kankanhalli et al. (2003) describes how companies such as Shell extract value through the deployment of discussion and collaboration tools to encourage communication across the organisation. This in effect, describe a Community of Interest, yet the reader may only assume that the base CoPs providing the basis for interaction, stem from similar groupware tools.

Hence the deployment, management and framework of communities within an organisation is a key Knowledge Management strategy.

Although they are driven to produce a similar tangible result, CoPs differ from the classical notion of an organisational team which has assignable and measurable deliverables (O'Donnell et al., 2003). Teams are formally identified and explicitly supported by an organisation's structure and software tools (Cabrera & Cabrera, 2002). CoPs on the other hand, are often outside of the organisation's structure and lack allocated resources. Rather than this being a disadvantage, authors such as O'Donell et al. (2003) proclaim that organisational teams are too rigid and solely driven by management goals, and instead it is the CoP that offers:

"The opportunities to learn, to share and to critically evaluate what the participant's discover and what may unexpectedly emerge".

It is interesting to note that author's (e.g Kirkman et al., 2001) focus upon the organisational team as the ideal medium in which to achieve this, identifying that the label of the CoP is a relatively recent term. Indeed Johnson (2001) notes a CoP may itself consist of teams, although the precise definition of these teams and whether their origins were within the established organisational structures or resulted as a result of the formation of a CoP is unclear. Zárraga-Oberty & De Saá-Pérez (2006) attempt to clarify this anomaly by differentiating the CoP from the work team, they conclude:

"Communities of practice are not a new type of organizational unit, but rather a different "section" of the structure of the organization that emphasizes the joint learning of the individuals, rather than the unit to which they are accountable".

The CoP would appear to form in response to a defined need that cannot be addressed via the traditional organisational team. Such formation links the basis of a CoP to the Knowledge Management principles of innovation, intellectual capital creation, trust, common understandings and a mutual climate of knowledge sharing and trust (O'Donell et al., 2003; Zárraga-Oberty & De Saá-Pérez, 2006). Although Vangen & Huxham (2005) note the creation of such a collaborative environment requires substantial management and strategy. The Community of Interest would also appear to possess these facets of Knowledge Management.

Essentially, by extending the domain of the traditional CoP both internally and externally, across the organisation by creating 'communities of communities' (Brown & Duguid, 1991). Murray's (2002) research supports such a notion that 'communities of communities' are common in organisations and those centred upon biotechnology companies are supporting innovation within this field.

Overall the literature is unclear as to the strategic similarities and software components that may support the CoP, Community of Interest and the work team respectively. In addition the introduction of technology to encourage the collaborative activity between actors is less defined, with few case studies addressing the necessary components to facilitate such interactions. Murray (2002) suggests that the majority of collaboration is still via face to face meetings and hence spatial proximity plays an important role in initially establishing a CoP.

As the review has discussed, the scope of the CoP is rather broad and it would appear that transient teams and occasional mass participation of employees can be included within the ambiguous realm of the CoP. The research aim and objectives are all concerned with enhancing knowledge sharing and pharmaceutical innovation. Hence the use of the CoP would appear to be a useful model to include within the tool set of Objective 4, particularly with regards to improving decision making and encouraging collaboration.

3.4.3 IMPLEMENTING A COMMUNITY OF PRACTICE

The work of Wenger (1998) and Johnson (2001) describes the virtual CoP as the designed community, where the community evolves as the result of users interacting with the technology. In order to believe this view, the practitioner inevitably questions what constitutes the underlying framework of a virtual community and how may a practitioner encourage the formation of a CoP?

The commonest form of virtual community springs from a web or intranet medium with a text based interface. From a Human Computer Interface perspective, Kollock (1998) argues we should aim to recreate traditional community values within the virtual community. Through avoiding the use of flashy graphics and instead focusing upon persistence of identity, coherence and ritual within the community space in order to identify users with the community.

The basis of CoP software is also discussed by Whitaker & Parker (2000) and Godwin (1994) and they include ensuring that the software chosen, suits the needs of the users by using a customisable knowledge sharing environment. However, specific frameworks detailing the requirements necessary for implementing a CoP are lacking within established literature (Stacey, 2001).

Preece et al. (2003) have conducted a review of community software. The earliest identified community technology focused upon Listservers that contain a simple list of topics that are commonly truncated into an emailed digest, which is then emailed to users. Technology was then used to map physical bulletin boards to the virtual realm, allowing users to post and respond to information and questions in defined hierarchies and categories. The aforementioned technologies are asynchronous in nature, allowing users to post a query or information that may not elicit an immediate response. Yet the post remains as a permanent record that users may view and contribute to as they wish (Hammond, 2000). Synchronous communication mediums that may be used to form a CoP, include live chat systems, video conferencing, whiteboards and instant messaging technology that require respondents to be online (Preece et al. 2003; Park & Kim, 2005).

The inclusion of an instant messaging system within accepted CoP tools, suggests that the definition of a community may be somewhat stretched. Research by Cameron & Webster (2005) suggests a critical mass of instant messaging participants is required to form a valid CoP. On the whole, users prefer to use the technology on a personal one-to-one basis to quickly reach colleagues, instead of on a community level. However, what may be implied from Cameron & Webster's (2005) research is that although communication largely occurs between two actors, the participants do form a viable Community of Practice via personal social networks. Furthermore the information of this network may be captured within an instant messaging system (Segerstad & Ljungstrand, 2002). Interestingly instant messaging technology allows users to immediately access a colleague above other communication mediums such as email and the telephone. Unfortunately, instant messaging also appears to invoke an appreciable sense of disruption to an employee's productivity (Cameron & Webster, 2005).

A finding that is akin to Jackson et al.'s (2003) research concerning the negative impact of email interruptions on employee productivity.

A common finding throughout the study of instant communicative media is the lack of richness of context and meaning associated with the face to face meeting (Cameron & Webster, 2005). This collaborative aspect is regarded by Park & Kim (2005) to form an important component of a Knowledge Management system that is intended to enhance R&D functionality and innovation. Instant messaging has been envisaged by some to supplement email and face to face meetings (e.g. Segerstad & Ljungstrand, 2002). Although research by Smith & Fiore (2001) suggests that visualisation tools such as graphical timelines and content trees are also to replace face-to-face communication.

3.4.4 CREATING A SUCCESSFUL COMMUNITY OF PRACTICE

The Knowledge Management literature is awash with how a CoP can enhance human interaction and the virtual CoP aims to promote human interaction through the use of computer mediated technology (e.g. Cortada & Woods, 2000; Liedtka, 1999) The ultimate aim is the proliferation and dispersion of knowledge and there is widespread belief that adopting such a practice will automatically confer these benefits to the participants (Wenger & Snyder, 2000). However knowledge sharing within a community is a delicate balance of participation and coercion (Adichvill et al. 2003). Werry (1999) is a noted author on CoPs and believes the value of a community is linked to the number of participants, thus the greater the number of participants the richer the tapestry of knowledge created.

However, Werry (1999) does little to mention *which* parties and people should be involved within the community, in order to gain the correct balance and return on knowledge creation. This is an important point which is largely passed over by literature which, on the whole, expects a community model to be successful regardless of the environment it is deployed within.

Therefore in order to solve an innovative problem, knowledge must flow from the participants and it stands to reason that unless a CoP is deployed and managed so as to reach key contributors then the return will be low (Cox et al. 2003).

Hayes & Walsham (2000) take this premise further by implying that the technology supporting the capture of explicit knowledge may never truly impart the true nature of the knowledge. This factor suggests that the discussions occurring within a virtual CoP must then be followed by face-to-face communication, to successfully convert the explicit knowledge within the community to useable tacit knowledge. This supports Cook & Brown's (1999) observation that creating worthwhile knowledge, from which an organisation may learn, relies upon both the interaction of physical (e.g. explicit) and social (e.g. tacit) knowledge.

Work by William & Cothrel (2000) propose three management strategies for introducing and maintaining a successful CoP. Members must be encouraged and developed, the community must be actively managed as an asset and the organiser must strive to build and foster community relationships. Methodologies and strategies for achieving these three strategies, theorised by Ardichvilli et al. (2003) and Hayes & Walsham (2000), focus upon promoting interaction between the users, managers and strategists within the organisation, and engaging participants in live chats, Q&A sessions and providing feedback on postings.

The answer to successful knowledge creation and innovation via CoPs is elusive and is certainly dependent upon the aim of the community and the individual participants taking part. Additional research by Wenger (1998), Werry (1999) and Ardichvilli et al. (2003) notes that a 'champion' or leader is required to promote a CoPs use and focus the aim. In addition to a 'champion figure' a strong supporting organisational culture must exist to allow the community participants and champions to exert a bearing influence on the proceedings (Ardichvilli et al. 2003).

An interesting conceptual idea by Koh & Kim (2004), recommends participants subscribe to a CoP to attain the status and behaviour of citizens and within this concept a crucial percentage of users contribute without a formal reward. The notion of reward generates heated debate throughout the literature. Kankanhalli's (2003) study of organisational practice noted both Buckman Laboratories and Ernst & Young offer a monetary reward for contributing to a discussion forum based CoP.

On the contrary, academic literature focuses upon the intangible benefits an employee will encounter by regularly contributing knowledge to a community environment (Kwok & Gao, 2004). Kollock's (1998) cites that the factors driving users to participate are: the expectation of helpful research in return, contributing will increase the user's personal reputation and greater contributions will increase the sense of belonging within the community. Flower (1999) on the other hand recommends monetary reward as the only sure means to ensure users contributed knowledge to community software, which focused upon capturing innovative practices.

3.4.5 SUMMARY

The CoP literature review has been useful in outlining the role a CoP plays within a business environment. Conceptual literature is wide spread there are many case studies that support the viability and role of a CoP. However, there is a lack of applied research towards the commercial tangible evaluation of the CoP. Johnson (2001) notes that a business based CoP, promotes knowledge across a broad range of groups. Effectively creating value by allowing a "knowledge network" to form and promote the conversion of the explicit knowledge, held within the community software, to tacit knowledge through employee interactions. However, there is little evidence that this occurs as a matter of course or what strategies should be employed to achieve this, particularly with regards to enhancing innovation and drug development.

A key role of the CoP appears to be as a facilitator to remove the barriers that impede the formation of relationships across work groups, companies and cross company teams. In this respect the CoP seemingly is an ideal Knowledge management tool. Yet the reality is convoluted, in that a KM professional must actively promote, manage and guide the CoP to success which requires resource. Hence there must be a tangible benefit which outweighs the time and efforts required to instil and maintain such a successful community. The excessive hype surrounding the appeal and application of a CoP which dominated the literature previously (e.g. Wenger & Snyder, 2000), is now being replaced by tentative steps to evaluate the active management and problems associated with their use Martin (2004).

However, there remains scope for extensive study into how informal learning and knowledge interaction spawns knowledge generation within a CoP, particularly regarding how the Knowledge Management professional can encourage and enhances these processes.

Wick (2000) surmises that *"the effective management of the employee's knowledge becomes the value creating element within the company"*. This lends weight to the use of the CoP as an important component of a Knowledge Management strategy. Although perhaps the most important feature raised by Johnson (2001), is the use of a CoP to organise and categorise knowledge through the use of communities across the organisation. Although communities may naturally categorise knowledge, little explanation is provided concerning the technology required to achieve and manage this knowledge. In addition there is little information regarding their use in driving pharmaceutical research. Hence research leading to the development of a Knowledge Management framework or tool set that includes CoPs within an organisation would undoubtedly be useful research. The principles of Knowledge Management require knowledge and information reuse and while the CoP and community model may encourage such behaviours, there remains many unclear areas.

The review now turns to focus upon measuring and evaluating the knowledge and the myriad of Knowledge Management technologies that are available. Seeking to clarify the extent and success of the techniques employed to measure the intangible nature of organisational knowledge.

3.5 INTELLECTUAL CAPITAL

3.5.1 INTRODUCTION

Supporting the deployment of a Knowledge Management system and strategy is an intricate balancing act of tangible costs weighed up with the intangibility of perceived benefits. Establishing a measurable return on a Knowledge Management investment has had, or can have, on a business area, is often essential to sway the opinions of staff that the scheme is having a positive benefit and is worth persevering with (Milis & Mercken, 2004; Wilcocks & Lester, 1996).

Knowledge Management within an organisation undergoes a slow process of evolution. From the basic building blocks of system appraisal and the analysis of the problem scope, to the introduction of a proposed strategy and the associated technology, the process occurs over a lengthy period of time. Mouritsen & Thorsgaard Larsen (2005) propose Knowledge Management has evolved from the first wave that viewed the employee as the central source of knowledge within the organisation. To a second wave that addresses the knowledge resources of the organisation in terms of both the employees and the organisation as a whole. The results of introducing Knowledge Management to target multiple stakeholders and knowledge across an organisation will be immediately visible in terms of access to explicit knowledge. Yet the indoctrination of the system within the organisational culture of the organisation will be less evident and leads many organisations to question the true worth of a Knowledge Management strategy (Mahesh & Suresh, 2004).

The field of intellectual capital and intangible metrics essentially aims to assign a value to the use of knowledge within an organisation. Furthermore, it is increasingly linked to the area of Knowledge Management activities (Bukh et al. 2001). On first glance, measuring knowledge and Knowledge Management activity would appear a difficult process and the multitude of available methodologies to achieve this confirms this prognosis (e.g. Kuczmarski, 2000; Marr et al. 2004).

After all how can one assign a value to the intangible processes of knowledge generation and the subsequent processes of utilisation, storage and retrieval?

A wealth of literature assures the reader that companies who embrace newer technology will gain a distinct and measurable financial advantage over their competitors (Barney, 1991). Measuring the means and objectives behind a successful strategy should be considered within the first stages of a KM schema (Marr & Starovic, 2003). Only once this aspect has been addressed, can an organisation truly value the benefits a Knowledge Management schema has bought to the working practices of the company (Havens & Knapp, 1999).

The following sections aim to provide a detailed analysis of the concept of intellectual capital in relation to innovative activities within the modern knowledge creating organisation. The section concludes with recommendations that apply to evaluating the knowledge requirements within the area of pharmaceutical innovation.

3.5.2 QUANTIFIABLE KNOWLEDGE

The traditional view of knowledge creation championed by authors such as Nonaka (1991) typifies a chain of events, when linked together allows the continuous interaction of tacit and explicit knowledge within the company. The key actors within this process are the employees who are deemed to carry out this process on a daily basis and this in turn generates organisational and innovative knowledge. Further work by Nonaka & Takaeuchi (1995) discusses these interactions in greater detail. Firstly tacit to tacit knowledge, which occurs on the social level is often observed within the corridors or rest areas of a company. The second type of interaction covers the explicit to explicit level of knowledge interchange, which allows the combination and reappraisal of knowledge confined within the operating and technological layers of the company. The third type of interaction is tacit to explicit knowledge conversion or externalisation, where knowledge is captured from employees and by such processes may then be deemed to be accessible to the company on a whole.

The final type suggested by Nonaka (1991) is a reverse of the third process and results in explicit to tacit knowledge being internalised within the company. These processes of knowledge externalisation and internalisation are deemed by Albino et al. (2001) to be the crux of knowledge creation as they necessitate a change in the nature of knowledge. From this an inference is made, which argues knowledge will be retained by the workforce when processed in this way and knowledge interactions revolve around the employee. However, as previously mentioned, Mouritsen & Thorsgaard Larsen (2005) propose that the employee is not the sole source of valuable knowledge. Instead knowledge may be derived from the organisation itself from a series of knowledge resources. This in itself presents an interesting angle of introducing metrics to measure knowledge exchange and knowledge retention across multiple and non-homologous sources. The knowledge resources described by Mouritsen & Thorsgaard Larsen (2005) are believed to constitute:

"A series of heterogonous knowledge resources such as employees, processes, customers and technologies, each of which is a possible object for decision-making".

Unfortunately this view is generic in character and does little to accurately map and identify the knowledge within these resources. Sullivan (1998) on the other hand, calls for the codification and commercialisation of these knowledge sources, believing that this process allows the valuation of the intangibles that constitute organisational knowledge. Desouza (2003) contributes to the notion of quantifiable knowledge by identifying two further perspectives, he believes knowledge can either be classified as an object, which exists independently of humans and can be exchanged as a commodity. While the second perspective views knowledge as being entrenched within the human resource, where workers are motivated to seek and share their abilities with co-workers and thus expertise is transferred. Edvinsson (2000) proclaims that such interaction generates value for the organisation, a company rich in such interaction is said to hold a higher financial value.

The pharmaceutical industry is typical of such an area. Companies that invest in R&D generate substantially more revenue in the long term that is disproportionately above the value of the investment (Lev & Sougiannis, 1999). The discrepancy in apparent and realised value lies in the knowledge contained within the company. Knowledge which allows the organisation to lever a competitive advantage, fuel innovation and create a 'supernormal' economic return (Zucker et al. 1998). Alavi & Leidner (2001) believe that only individuals with a certain requisite of knowledge can exchange the knowledge that creates such value though. Establishing a means to measure the extent of this knowledge transfer is the precise realm that the field of intellectual capital and intangibles addresses. A role which equates to the measurement of the extent, and role, contextual metadata plays in the conveyance of understanding to the process of knowledge exchange (Lev 2001).

Nonaka et al. (2001) suggest that for individuals to transfer knowledge from tacit to tacit requires substantial cognitive and implicit reasoning. The transfer of knowledge from tacit to explicit such as during a meeting, requires a similar process. The assignment of measurable variables to the phases associated within this transference would allow a tentative value to be eluted and forms the basis of the measurement of knowledge within the innovative processes (Mascitelli, 2000).

Yet in order to achieve this, the metrics chosen would have to align with the drug development process of Figure 3.1, as how can we measure a process we don't understand?

The processes, problem scenario and knowledge activities must firstly be defined and only then may the organisation define the metrics to measure the proposed knowledge system (Robertson, 2003). Unfortunately as many attempts at measurement fail to realise quantifiable or empirical data, this apparently simple statement is often complex. Metrics and the constituent parts of knowledge interaction comprise many facets and may also include additional financial constraints (Andriessen, 2004). The traditional Knowledge Management strategy of the introduction of a groupware system, implies that knowledge may be transferred within the collaborative medium of the system and also outside the system through contacts made within the system.

Wenger & Snyder (2000) note the individuals utilising the system may possess similar knowledge, but in order to teach and learn from each other the knowledge must be unknown to at least one party. Therefore capturing the information surrounding these processes, would in theory allows the management and quantification of the knowledge. As Mouritsen & Thorsgaard Larsen (2005) note, these are the principles that facilitate the translation of the 'three-dimensional' complex processes of knowledge interaction to be captured as 'two-dimensional inscriptions', which are akin to metrics.

The review will now examine the components of intellectual capital and the methodologies that contribute to the evaluation of knowledge within the innovative processes of an organisation.

3.5.3 INTELLECTUAL CAPITAL

Firstly, it is advisable to cover the terminology surrounding intellectual capital and outline the common ground the Knowledge Management literature and the intellectual capital literature occupy. Stewart (1997) defines intellectual capital as the properties that allow an organisation to innovate, such as:

"Knowledge, information, intellectual property, and experience that can be put to use to make wealth"

The definition takes account of the many grey areas that may not be recognised by traditional fields of financial reporting using Capital Investment Appraisal Techniques, which tend to focus upon tangible assets (Augier & Teece 2005). Rather than the traditional tangible assets of financial reserves, stock and machinery, knowledge is placed at the forefront of the evaluation and it is this that allows a company with little visible assets to report a high turnover through the application of its intellectual capital (Aston, 2002). On this premise, it is important to note that intellectual capital is based upon knowledge and hence this knowledge is measurable and can be tracked and exploited within the company. Intellectual capital is not simply a measurement of the potential of the knowledge within a company it also reflects the actual use of the knowledge (Luthy 1998).

Thus there appears to be an irrevocable link between the areas of improving the use and exploitation of knowledge within the company, and the acknowledgement of intellectual capital as an important step in proving the worth of Knowledge Management. As Bukh et al. (2001) surmise:

"Intellectual capital allows the reporting of the activities that management initiate and support in the name of knowledge management".

However, it is evident that definitions surrounding intellectual capital are interchangeable and can be misconstrued. Bontis (2001) found companies and consultancies often define intellectual capital according to their specialist area. Yet most will include a reference to knowledge, organisational competence, their valued customer relations and the employees' professional skills. Edvinsson & Malone (1997) recommend that intellectual capital can be further defined within the three categories of human, customer and structural capital. These are defined as:

1. Human capital is classified as the knowledge, skills, problem solving abilities and experience that can be lost when employees depart the company. Often this knowledge is generic, but depending on the role, a large extent of employee knowledge may be specialist. The loss of this may directly affect innovation, creativity and the fluidity of the company and has particularly consequences for R&D driven organisations. Losing a pivotal employee, knowledge champion or team within the new product development arena, can adversely affect the company's performance as staff adapt and fill the void in knowledge left by the individual or team.

2. Customer or Relational capital refers to the links and resources that are external to the organisation - notably the customers, suppliers, or R&D partners. This area directly relates to the company's public image, customer satisfaction and the perceived value of the organisation by the customers and suppliers.

3. Structural capital provides the necessary supportive structures to define, to capture and retain knowledge within the company. The buildings, hardware, software, standard operating procedures, routines, business processes, knowledge stores and databases may all be classified as structural capital under the higher mantle of intellectual capital. This capital can be said to provide the supportive framework around which employees are able to generate knowledge within an organisation.

Edvinsson & Malone (1997) further refine structural capital by including three further subsets in Table 3.5:

Table 3.5: Structural Capital

Type of Structural Capital	Description
Organisational Capital	Organisation's philosophy and systems for leveraging the firm's knowledge capability.
Process Capital	The techniques, procedures and programs that allow the goods and services involved within knowledge creation to be delivered.
Innovation Capital	Intellectual property and intangible assets, which allows company growth and new product development.

Marr & Starovic (2003) note there is often confusion as to the nomenclature to be used when discussing the types of capital, assets, intangibles and intellectual capital, as they are frequently classified as the same meaning. Marr & Starovic (2003) indicate that the assets of intellectual property should be identified as resources that can be legitimately recognised by an accountant and appear on the balance sheet of the company. Hence they do not fall under the remit of intellectual capital. Conversely, Edvinsson & Malone (1997) and Luthy (1998) classify these assets as a form of structural capital, particularly when they support innovation.

Mo & Zhou (2003) state that an intangible asset is a conglomerate of sources and confuse the terminology by including defined processes, intellectual property and tacit and explicit knowledge sources under the intangible asset boundary and not under the accepted definition of Human Capital as assigned by Edvinsson & Malone (1997).

Work by Brooking (1996) and Luthy (1998) adds further confusion to the definition of intellectual capital by describing four areas that overlap and differ from the definitions supplied by Edvinsson & Malone (1997). When describing innovation capital, Brooking (1996) and Luthy's (1998) define four areas:

- Market assets: these are the product brands, customers, distribution processes and business collaborations.
- Intellectual property assets: include the patents, copyrights, hidden innovations and the expertise to innovate in an area.
- Human centred assets: include the education, skills and knowledge capacity of the employees.
- Infrastructure assets: look at the information system framework, the IT and financial systems in place and importantly the culture, management philosophy and management processes surrounding the knowledge.

What is clear from reviewing the literature is that the term intellectual capital and the term "intangible" relates to a wide variety of the fuzzy knowledge components within an organisation and hence an accurate definition is rarely observed. Peppard (2005) is one of the few authors who attempts to look beyond the association of knowledge and information management activities with structural and organisational capital, by describing the processes that create value within the organisation. Edvinsson & Malone (1997) and Luthy's (1998) definitions cover similar ground yet use different categories and terminology.

Peppard (2005) notes the terminology confusion and argues that the tacit knowledge of the employee falls within the boundaries of human capital. However, they also assert that structural capital can be an important component in supporting the human aspects of value creation. However, the overlap between the definitions offered by Edvinsson & Malone (1997), Brooking (1996) and Luthy (1998) are evident and on the whole, offer complementary views that are useful to an organisation seeking to define intangibles and discuss Knowledge Management processes.

Peppard (2005) states that intellectual capital may be represented as the management of the infrastructure that supports information and knowledge exchange. This then implies that intellectual capital may be used to measure the success and innovative behaviour of not only the IS/ Knowledge Management implementation, but also the subsequent generation of knowledge and information by the users. Although intellectual capital is based upon measurement and metrics, few authors commit these metrics to print. Brooking (1996) is one of the few to offer metrics to measure each stage of a process to provide an auditable outcome. However, the main proponents of intellectual capital, such as Edvinsson and Malone (1997), prefer to offer a generic view of intellectual capital which may be used to draw the attention of senior management to the organisation's intangibles.

The aim of the generic metrics is to identify relevant subsets within the organisation, which relate to the definition of intellectual capital and relate to the structural capital, the cultural aspects, the management of the organisation and the knowledge potential of the employees (Edvinsson and Malone, 1997; Marr & Starovic, 2003; Peppard, 2005). Choo & Bontis (2002) describe intellectual capital as an organisational resource and note that no academic models provide sufficient rigour to explore these organisational resources accurately. They do however, list relational, human capital and structural capital as components and hence in keeping with the majority of published literature. This research will concentrate upon these aspects and the associated methodologies which may be used to assess these areas.

Assigning a metric to these areas of intellectual capital suffers from similar confusion, as the definition of an intangible may be a component of a business process that is unique to that process. The potential interactions this sole process may have within the realms of human, relational and structural capitals are many. Hence an analysis of the environment and the interactions of the studied process are required, in order to assign a tangible value to an individual processes (Marr & Starovic, 2003). As the high level drug development diagram in Figure 3.1 illustrates, this process is extremely complex and as yet little published work exists on these processes.

Although a new technique labelled 'Strategic Performance Management' by Marr (2006) shows promise in this field and will be addressed as a potential methodology in Chapter 4. One reason for the lack of published metrics, is that each metric found within an assessment of the process is unique to that process. A concrete example of an intangible metric is Moerman & Der Laan's (article in press) research into drug costs. Here they regard pharmaceutical intangibles as the investment in information and knowledge that are required to determine a drug's safety characteristics and effectiveness. These intangibles then determine the costs of the R&D work that will eventually lead to the generation of a patent and justify the steep costs associated with drug development.

The review will now analyse the strategies and methodologies which are commonly implemented to measure intellectual capital and assess the value of a Knowledge Management strategy within an organisation.

3.5.4 REPORTING INTELLECTUAL CAPITAL

The following section aims to provide an overview of the methodologies that are commonly employed to measure organisational knowledge and attempts to provide justification for the use of intellectual capital assessment within drug development. It is important to note that the review serves to highlight methodologies that may be used within Objective 3, seeking to outline points that should be considered, rather than attempt to advance the field of intellectual capital research. To date little published work has been conducted on intangibles and intellectual capital within pharmaceutical R&D. Therefore the results of the research are expected to provide valuable insight into assessing innovative knowledge and Knowledge Management strategies within this area.

Many in-depth studies on the development and measurement of intellectual capital are available (e.g. Andriessen, 2004; Marr, 2006; Bontis, 2001; Wilkins et al. 1997) and each offer insight into measuring intangibles. However, what is apparent is that the popular models of assessing tangible capital such as the Payback Period, the Return on Investment (ROI) and the Net Present Value as suggested by Milis & Mercken (2004) and Fairchild (2002) are far from suitable for measuring Knowledge Management activities.

The Payback Period defines the time required for a business project to generate a return on the initial investment. Milis & Mercken (2004) suggest that this is the least suitable for measuring the return on Knowledge Management as such schemes are generally long term projects. In the case of Knowledge Management, there is often no quick win or rapid strategy to generate a measurable return. As was witnessed in the earlier stages of the review, Knowledge Management success is often dependent on cultural change or at the very least progressive adoption (Darroch & McNaughton, 2002). This inevitably requires a larger time scale. Companies who adopt the Payback Period as their evaluation model may find they needlessly plump for short projects in order to show a tangible return. At worst, they may fail to acknowledge the benefits from the implementation (Milis & Mercken, 2004). The Payback Period also fails to take account of the risk from a failed or rehashed project. Within industry, KM implementations are notorious for continual reworks once operational (Hung et al. 2005), with little excess budget to accommodate reworking, schemes will almost certainly fail in accordance with a Payback Period evaluation. The Return On Investment is considered to be a worthier technique, as there is the facility to evaluate the total lifecycle of the project. Thus the calculated return represents a more accurate picture of the schemes true financial value and can be used to track the long term performance of a project (Milis & Mercken, 2004).

Although each financial assessment model provides valuable short-term feedback to senior management on their investments (Waterhouse & Svendsen, 1998), what they lack is recognition of the long-term human and social capital that may be generated from the inception of a Knowledge Management system or strategy (Scarbrough & Carter, 2001). The financial assessment models lack the concept of "*intellectual agility*" that are derived from social and human capital and are said to be the drivers of innovation (Roos et al. 1998). These include the invention, reuse, adaptation and exploitation of knowledge and as such are vital to innovative processes. The following section will now address measurement methodologies that address this shortfall and cover their usefulness to the research aim.

3.5.5 USING METRICS TO MEASURE KM

Although there are many theoretical and practical techniques available for use when determining Knowledge Management strategies, most are regarded as flawed and inaccurate (Andriessen, 2004; Bontis, 2001). When viewed from the perspective of biotechnology and pharmaceutical innovation, each strategy should aim to assess the intellectual capital required to create intellectual property and reach the end result of a marketable patents (Augier & Teece, 2005). The number of filed patents may not be used as a measure on its own however. Augier & Teece (2005) note that although patents are a measurable and visible means of assessing intellectual capital, it is only when a patent has proven market application that it possesses a tangible value. The majority of patents within the Pharma industry are filed at very early stages of drug development. Often as a means to prevent competitors exploiting a particular compound family or drug group, hence the valuation of pharmaceutical innovation cannot solely be judged upon the production of patents (Hine & Kapeleris, 2006). A patent offers a 25 year protection period on a new drug and a typical drug may take up to 15 years to reach the market. Hence the pharmaceutical companies have a short time to recoup their investment and the financial measurement of a marketable patent is easily visible through drug sales results (Hine & Kapeleris, 2006). What is less apparent though is the cumulative intellectual capital that has contributed to the successful marketable patent and the market release of a drug. SubbaNarasimh et al. (2003) conclude that a firm capable of not only retaining and owning a diverse technological knowledge base, but also knowing how to effectively apply this knowledge to achieve a marketable patent, ultimately allows a company to perform significantly better than its rivals.

Yet how is intellectual capital measured? Luthy (1998) believes intellectual capital may be measured on a component-by-component basis which is supplemented by the measurement of intellectual assets (e.g. patents) and is akin to a resource based view of the firm (Barney, 1991). Directly associating the measurement of intellectual assets with the financial aspects of the company, allow the company's intellectual capital to be related to the share price.

This is believed to reflect the effectiveness of the company in managing and utilising its assets and intellectual capital to create further value from a given situation (Luthy, 1998). At present, many component-by-component models exist, which attempt to assess the use of knowledge within intellectual capital. Of these the standard is the Balanced Scorecard or BSC, penned by Kaplan, & Norton (2001) which accounts for the majority of KM related metric surveys and as such will be covered in detail within this review.

The component-by-component models share the common processes of assessing and assigning a metric to each component of the knowledge processes located within the area to be studied. As will be seen in later sections, they rely upon compartmentalising intellectual capital within constituent blocks that may be analysed in turn. However, a common failing suggested by Leitner & Warden (2004), is that the methods divulge little information regarding the relationships between the intellectual capital entities. Instead Leitner & Warden (2004) suggest a methodology that analyses the interactions within intellectual capital that contribute to the value chain and will ultimately reveal which processes drives innovation. However, their methodology falls short of visualising these links and instead provides indicators on how to assess the knowledge within these relationships within an R&D process. As in the intellectual assets model, the associated metrics may be quantitative and reflect higher level organisational traits. These traits may be the financial results or detailed unit metrics, such as the number of scientific researchers required (i.e. Full Time Employees), when quantifying units of work at a process level. A key characteristic of the technique is the assignment of accurate units of measurement to each component level and its inputs and outputs. It is thought that failure to do this may result in a poor evaluation of the target scenario (Leitner & Warden, 2004).

It became evident while covering the literature, that the component-by component models are consistently popular, although many other methods are available. Svieby (2004) and Andriessen (2004) provide an excellent overview of assessment techniques and currently list twenty six methods between them. Although many are applicable to the research, to review all would be beyond the scope of this report.

Instead the review concentrates upon the models which may be used to identify the drivers of Knowledge Management that are termed by Du Plessis (2005) as the *"catalysts that allow an organisation to achieve a competitive advantage"*. The following section will outline the various intellectual capital assessment models and provide details on their strengths and weaknesses, before concluding with a section analysing the use of these models.

3.5.5.1 COMPONENT-BY-COMPONENT EVALUATION

3.5.5.1.1 THE BALANCED SCORECARD

When discussing metrics to ascertain the worth of a Knowledge Management schema and intellectual capital it is rare that the work of Kaplan & Norton (1996) is not mentioned. They penned the use of the Balanced Scorecard (BSC) which was initially used to provide a measure of a company's intellectual capital, the potential future return and analyse how these factors stand in regards to the financial measure of the business. The scorecard has evolved however, to provide indicators that explain an organisations strategy with regard to intellectual capital (Kaplan &Norton, 2001).

The balanced scorecard may be used to define metrics, indicators and Key Success Factors (KSF) for individual projects and overall goals and is widely used within Knowledge Management (Robertson, 2003). Marr et al. (2003) suggest the balanced scorecard may be used to assess the learning and growth potential of the organisation, through the elucidation of 'leading' and 'lagging' indicators that indicate areas of potential or concern respectively. The balanced scorecard framework uses a framework of four groups to offer a perspective of four measurable items, which individually equate to four scorecards. These are explained by Milis & Mercken (2004) and Spender & Marr (2005) as:

1. Financial Perspective

A financial scorecard that contains the traditional financial performance measures such as Return on Investment or Payback Period. Sets of financial targets are assigned to projects and then assessed against management criteria.

2. Customer Perspective

The customer scorecard is provided in order to obtain an objective view of how customers, whether internal or external, respond to, and rate the company or business department under scrutiny.

3. Internal Processes

An internal business scorecard provides goals, measures and indicators to be used in measuring the internal value chain of the company.

4. Learning and growth

The final scorecard addresses innovation and the organisational learning ability of the company, analysing how knowledge and value can be created and improved alongside the growth of the company.

The model determines a cause-and-effect relationship, where the evaluation of the results then leads to the formulation of a future strategy, rather than a tool with which to provide a definitive analysis of intangible assets (Marr & Starovic, 2003). Bontis et al. (1999) suggests the technique offers managers a method of visualising the cause and effect relationships that occur within a given strategy. This is in addition to relating any financial failures to relationships that occur within the chain. Bontis et al. (1999) outline how the tool may be used by an organisation's management within Table 3.6:

Table 3.6: Uses of the Balanced Scorecard

Area	Outputs
Communication and linking	Achieving a strategic alignment of the objectives of the whole organisation.
Business planning	Managing targets, co-ordinating initiatives and planning the budget.
Translating the company's vision	Clarifying the mission and long-term company strategy to all constituencies inside the organisation.
Feedback and learning	Update plans, strategies and the BSC.

It is clear from the outputs in Table 3.6, that the adoption of non-financial measurements provides strategic benefit to the model and the reasons behind this lie with the engagement of top-level management to decree the measurement criteria (Kaplan & Norton, 2001). As Bukh et al. (2001) note traditional accounting techniques rely upon financial experts, while the involvement of management in deciding the areas to be assessed, allows the BSC to supplement the traditional accounting approach with additional strategic value. Milis & Mercken (2004) argue that due to this, the balanced scorecard may be used to force company management to take on a broader view of a Knowledge Management strategy. Fairchild (2002) supports this view, though stresses that in parallel to the evolution of a Knowledge Management strategy there must be supporting realignments of business practice and the organisation to reflect these facets. Kaplan & Norton (2001) suggest the BSC tool may be used to create strategy maps that visualise a cause and effect relationship or value chain. These maps start from the Learning and Growth Perspective, to the Internal Perspective, to the Customer Perspective and then on to the Financial Perspective. The four cards of the strategy are then assigned between 20 to 25 measures that allow the strategy map to be followed and assessed as a series of measured outputs (Andriessen, 2004).

Although the technique is widely used, it is the actual application of the scorecards, the accurate mapping of the strategy and the identification of the measures to a given scenario that is deemed difficult. Marr & Starovic, (2003) found companies attempting to classify the cause-and-effect relationships between the various drivers of value creation often falter. Their study showed a single process can be isolated sufficiently. However, when viewed as a whole, the intricacies of linking such processes in order to elute a value-based matrix can be difficult. Bontis (2001) suggests that the framework of the BSC is too rigid and provides little scope for expansion outside of the four areas. Attempts by organisations to identify Key Success Factors (KSF) within the cause-and-effect relationships, often blinkers the participants to the interactions of the KSFs. Bontis (2001) also acknowledge that the relationship between these KSFs may not be recognised or mapped accurately.

A KSF may appear in multiple areas of the framework and in multiple processes, but only be reported and categorised within one area. In the case of the measurement of a Knowledge Management schema crossing multiple scorecards, this problem is perplexing and perhaps shows the downfall of the technique as few authors even venture an opinion on this area. Fairchild (2002) places Knowledge Management within the realm of the Learning and Growth card. Spender & Marr (2005) although in agreement, stress the perspective is unclear as the human factors are bundled with the technology aspects, which suggest knowledge is simply another physical asset. Evidently, such a view is against the popular definition of Knowledge Management which is seen as the exploitation of knowledge as an intangible and employee based asset (e.g. Newman & Conrad, 1999). Due to this, many authors regard the BSC as a tool to outline rather than implement knowledge led learning processes (Choo & Bontis, 2002).

Despite problems such as these, the scorecard remains a popular methodology to evaluate intellectual capital. Although as Marr & Starovic (2003) note, the main difficulty is in establishing tangible links between the value drivers, value creation and the future financial results. The four cards are logically linked but the model washes over the processes involved in defining the causal links behind these relationships and hence its usefulness is truly defining cause and effect relationships may be limited (Spender & Marr, 2005).

Du Plessis (2005) concludes by stating that although the BSC technique is important in defining leading and lagging indicators, the use to assess the underlying relationships and reality of intellectual capital is lacking. The reasons relating to this shortfall are that the Learning and Growth perspective only measures the improvement in specific areas, such as competencies, technology and corporate climate, and does not measure the size and value of the intangible assets as they flow within the organisation (Andriessen, 2004).

3.5.5.1.2 THE SKANDIA NAVIGATOR

The Skandia Navigator was initially developed in-house by the Swedish company Skandia to assess and promote the use of intellectual capital within the organisation. The model is depicted in Figure 3.2 and has found favour with other firms and is based upon the work of Edvinsson & Malone (1997):

Figure 3.2: The Skandia Navigator
(Image from: http://www.12manage.com/methods_skandianavigator.html)

The model is based upon a framework that allows the user to navigate through a series of criteria and hence recognise and introduce the principle of managing and assessing intellectual capital against the resources, capabilities and future ambitions of the company (Luthy, 1998). Central to the model is the human focus that denotes the intelligent driver of the process and, in turn, influences and drives the respective outer parts of the model that contribute to the development of structural capital that can be owned and traded (Edvinsson & Malone, 1997; Andriessen, 2004).

The model is similar in use to the balanced scorecard and as such may explain the successes and popularity of the technique (Svieby, 2004).

The model is underpinned by the focus upon renewal and development, through which innovation is encouraged by manager's promoting interactions with the respective components of the model (Choo & Bontis, 2002). Intellectual capital is viewed as a sum of the navigator components (Edvinsson, 2002). Where the deduction of a market value that includes intangibles, allows the measurement of the company's investment in R&D and training, and provides a measure of the organisation readiness to adapt to the future market (Bontis, 2001). Positive metrics are employed to measure the rate of new product design, acquirement of new market places and the rate of introduction of new management techniques to exploit these areas (Edvinsson & Malone, 1997). Edvinsson & Malone (1997) ascertain that the financial focus concentrates upon monetary values, such as share price, past trends and historic financial data and reflects the general financial health of the company. The customer focus assesses the value of the customer capital to the organisation, making use of both financial and non-financial measurements. While, the final process focus is based upon the business processes occurring taking account of measures such as computers per employee.

All in all, the model aims to measure intellectual capital through the use of the five focuses, to which a total of 164 metric measures are applied, with 91 intellectually based and 73 traditional metrics. The metrics are then analysed and reduced to 21 indices, which combine to give a rounded intellectual capital centred picture of the firm (Edvinsson & Malone, 1997; Bontis, 2001). Unfortunately each focus requires the development of its own personal metrics. Edvinsson & Malone (1997) do provide 111 generic metrics based upon their work within Skandia. Yet it is recommended that the critical success factors associated with individual processes, are highlighted and then assigned to one of the five focuses for each individual organisation (Andriessen, 2004).

The process of actually elucidating these metrics and achieving this, is complex however, and unlike the BSC model, the navigator fails as a strategy mapping tool.

Andriessen (2004) ascertains that the navigator only provides information on what is happening within the organisation at that time and provides little notion of the cause and effect relationships that exist between the five focuses. The intellectual capital indices and metrics themselves are also arbitrary and consist of direct counts and percentages rather than monetary values. However, the financial capital aspect does provide monetary value, so is a useful measure with which to persuade management to invest and promote Knowledge Management and intellectual capital measurement (Mouritsen et al. 2001).

3.5.5.1.3 THE INTELLECTUAL CAPITAL STATEMENT

A further aspect of intellectual capital study is the generation of an Intellectual Capital Statement. Mouritsen & Thorsgaard Larsen (2005) suggests this will allow an organisation to visualise and manage its intellectual capital. The model does not intend to quantify intellectual capital, but rather attempts to track management activities that are employed to organise the knowledge resources of the firm (Andriessen, 2004). Of all the methodologies reviewed, this method is most clearly aligned with Knowledge Management activities and practice. Mouritsen et al. (2005) note there is a second wave of Knowledge Management that recognises and includes the remit of intellectual capital. The second wave of Knowledge Management is said to:

"Address how the management control of knowledge resources allows concerns about economising (how much to invest in knowledge resources), organising (where to locate knowledge resources) and modularising (how to standardise knowledge resources)."

In practice the method relies upon three elements to visualise Knowledge Management activities within an organisation, these are derived from Andriessen (2004) and Mouritsen et al. (2001) as:

1. The knowledge narrative details how the company helps its customers, organises its resources and describes the ambition of a Knowledge Management schema.

2. The second element describes the challenges an organisation must overcome to implement the Knowledge Management strategy, these relate to the management of resources which include the employees, customers, processes and technology.

3. The third element comprises the indicators that describe the resource itself, the indicators required to qualify an activity and indicators to describe the effects of an activity.

Mouritsen et al. (2001) focus upon the visualisation of these knowledge activities through the use of narratives. In effect these are stories that link together the resources and networks that are required to understand the knowledge of the firm. The model seeks to analyse where the locus of knowledge creation occurs, whether this lies with the employees or as a result of management activities. So this is highly relevant to the R&D environment where there is a demand for transparency within knowledge activities (Mouritsen et al. 2001). The methodology is intended to provide an overview of the firm's knowledge activities and provides information on where intellectual capital may help the organisation. In this aspect it serves as both a management tool and as a communication aid (Mouritsen et al. 2005). These facets indicate the method may be of interest in advancing the research of Knowledge Management and pharmaceutical innovation and supporting Objective 3.

3.5.5.2 ALTERNATIVE MODELS

The Balanced Score Card and Skandia Navigator are established models, yet there are many models that are based upon, or bear similarities to these works. Research by Hendry & Brown (2005), Spender & Marr (2005), Petty & Guthrie (2003) and Andriessen (2004) outline many of these.

These methods include the Intangible Asset Monitor by Sveiby (1997), which is based upon similar principles to the Skandia Navigator but specifically focused upon the measurement of knowledge. Sveiby (1997) and Andriessen (2004) advocate the measurement of intangible assets or 'invisible assets'. These do not derive from an accounting sense but instead are denoted by three areas.

Namely:

1. Employee competences such as employee expertise and knowledge
2. Internal structures such as computer systems, patents and models
3. The external structure which includes the relationships with customers and suppliers

Although the technique bears similarity to the Skandia Navigator, the matrix based framework, offers a comprehensive solution that allows the publication of intangible assets both internally and externally. However, it is important to note that the metrics used within the system are not monetary and are unique to an organisation. Hence an organisation can only be benchmarked and compared against further successive audits.

Another model discussed by Hendry & Brown (2005) and Andriessen (2004) is the Value Chain Scoreboard (Lev, 2001), which is a method used to analyse the value of the knowledge required to drive innovation. Again the methodology is based upon a matrix arrangement, but has reportedly proven valuable, when analysing the knowledge assets' of large pharmaceutical companies. The method utilises publicly available data that is used to calculate the value of intangible earnings by subtracting the tangible and financial capital from the total earnings of an organisation. The evaluation is obtained when these figures are aligned with a series of lower level matrices that assign metrics to a specific process.

Lev (2001) specifically concentrates upon measuring the value chain within innovative work, suggesting intangibles may only be generated from a new discovery. Hendry & Brown (2005) note these intangibles arise as a direct result of organisational practice or human resources. Andriessen (2004) notes the Value Chain Scoreboard can allow a company to speculatively calculate a return on investment from their R&D practices. In effect, by calculating the potential benefits in intangible capital, a previously impossible task in accountancy based R&D.

In addition to the reviewed models there are a growing number of methods that attempt to visualise intellectual capital. Of note is the Value Creation Map (Marr et al. 2004) and Strategic Performance Management (Marr, 2006) that both map the direct dependencies and relationships of knowledge assets. Also of note is a second Navigator model developed by Neely et al. (2003), which also seeks to depict the relevance and location of knowledge assets with relation to the organisation's strategic aims.

3.5.6 SUMMARY

There are evidently a wide variety of tools, methodologies and theories on how to measure the value of intellectual capital and to review all would be beyond the scope of the review. From the review of the literature, many of the approaches would appear to have merit to the research. Spender & Marr (2005) muse that there are three approaches to measuring intellectual capital, these are broadly classified as an economic valuation, a strategy map (a cause and effect scorecard) and a map of the dependencies, relationships and narratives that describe intellectual capital within an organisation. From a pharmaceutical viewpoint, few studies have been conducted. Hine & Kapeleris (2006) acknowledge the importance of intellectual capital within innovation, yet gloss over its measurement. As such, this research is well placed to advance this field and conduct further research into the use of measurement methodologies.

As Marr et al. (2004) postulate, when the interaction between knowledge resources is known, a firm's knowledge strategy is clear. This section has partially achieved Objective 4 by discussing the evaluation of Knowledge Management, while Chapter 12 continues and discusses Knowledge Management evaluation in practice.

3.6 PHARMACEUTICAL KNOWLEDGE MANAGEMENT

3.6.1 INTRODUCTION

This review has shown that Knowledge Management is seen to be reliant upon the management of a company's intellectual capital (Guthrie, 2000). As the previous section on intellectual capital measurement discussed, there are many ways intellectual capital may be expressed and measured. Innovation is the main focus of the research and Knowledge Management should be a worthy supporting tool to enhance innovation within the pharmaceutical field (Davenport & Peitsch, 2005). Metaxiotis & Psarras (2005) state:

"Productive organisations have the ability to create an environment where the specialised knowledge, skills and abilities of all employees are leveraged to achieve advancements".

However, the practical means to achieve this is disconcertingly unclear. Metaxiotis & Psarras (2005) suggest the use of groupware, intranets, collaborative tools, portals and taxonomies as a means to support innovative Knowledge Management activities. However, the authors also suggest that tools such as data mining and information visualisation could also be employed. Although these tools are common components of a Knowledge Management strategy, it is unclear whether their use can support innovation across an organisation as a whole. Furthermore, does the practitioner employ all of them in a 'scatter gun' approach or are there certain Knowledge Management tools that are more suited to R&D based innovation?

When the literature was researched to reveal the actual reality of Knowledge Management within pharmaceutical companies, very little empirical or practitioner based evidence emerged. In their support of Knowledge Management within innovative processes, Metaxiotis & Psarras (2005) list the Novo Nordisk Knowledge Management project as a positive success story. A story where collaborative dialog with disease sufferers and the company (e.g. the stakeholders), has enhanced the company's innovative efforts.

However, when one delves deeper into the cited article by Skovlund (2004), the actual Knowledge Management implementation is shown to rely upon "an exclusive dialogue tool" of unknown specification or nature. This tool facilitates collaboration between the stakeholders, yet the exact nature of the tool, or how the knowledge exchanged is used to directly influence the R&D process, is unclear. Such vagueness is common within the pharmaceutical Knowledge Management literature, indeed Davenport & Preitsh (2005) conclude:

"There is much more that we do not know about knowledge management in drug discovery than what we do know. The subject has only rarely been studied in the context of pharmaceutical firms and we can only extrapolate a limited number of findings from other industries. Yet, drug discovery is one of the most knowledge-intensive processes, and the ability to create, share and apply knowledge is crucial to its success."

So it is evident that Knowledge Management has a place within pharmaceutical drug innovation (Davenport & Preitsh, 2005; Sundgren & Styhre, 2004) and firms that have taken note of Knowledge Management, have been successful within other areas (e.g. Sher & Lee, 2004; Corso et al. 2001). Yet what academic evidence is available, that specifically links Knowledge Management and pharmaceutical innovation in the academic and practitioner based literature?

As in the Knowledge Management literature, there are two streams of research that often overlap and these are:

- Studies that concentrate upon the use of Knowledge Management technology
- Studies that concentrate upon the human or cultural aspects of Knowledge Management

The review will now attempt to give the reader a clearer picture of how these two areas intertwine, within pharmaceutical Knowledge Management and how the various practical approaches are employed by the pharmaceutical companies.

3.6.2 NETWORKS OF KNOWLEDGE

Pharmaceutical innovation is widely reported to be derived from knowledge networks. These may encompass both internal and external knowledge assets as drug companies' move from an in-house research model, to one of innovation acquisition (Kneller, 2003). Capturing the information concerning these networks has recently taken the limelight of Knowledge Management research. Pharmaceutical companies are now trying to store this information within corporate knowledge directories that capture the nature of information and knowledge assets used, and the employees who take part in the innovative processes (Wakefield, 2005).

Research by Wakefield (2005) continues to hypothesise that there are two types of corporate repositories available. The first is concerned with the creation, storage and retrieval of knowledge within the drug development processes in a repository that allows knowledge transfer between users and the repository. While the second repository functions on a social level, serving simply to facilitate communication and collaboration on a social level or across communicative channels. Davenport (2002) ascertains that such collaborative work requires the workers to co-ordinate their activities and utilise tools on a selective basis as and when they see fit. As attempts to emulate and push knowledge from the employee using automated tools has often failed. Wakefield (2005) on the other hand suggests that a pharmaceutical Knowledge Management System should:

1. Identify the members who actively share knowledge
2. Show the degree of knowledge sharing that occurs in the organization
3. Reveal where the most knowledge sharing occurs
4. Identify high level knowledge sources
5. Determine where each member exerts the most influence in the organisation
6. Indicate the extent to which members seek knowledge.

Wakefield (2005) goes onto suggest a series of 'structural indexes' that facilitate the labelled processes, where the information is captured within a repository and then provides the organisation with a clearer picture of knowledge sharing.

Recent research by Furukawa & Goto (2006) within the Japanese pharmaceutical industry supports the notion that networks of scientists are collaborating to obtain tacit knowledge and actively inducing innovation. Interestingly these appear to be centred upon core scientists or champions, who act as a central point of contact.

The work of Roth (2003) within AstraZeneca Clinical R&D runs within a similar theme and suggests that the use of knowledge facilitators encourages cross project knowledge sharing. The premise is that the knowledge facilitator is in effect a knowledge broker and is responsible for matching employees to other relevant employees from their own personal network of colleagues. Once potential project teams and employees are united from across the R&D domains, one or many brainstorming face-to-face sessions occur that are focused upon a specific problem and directed by the facilitator. The results of the sessions are then disseminated through the organisation via seminars chaired by the facilitator. Roth's (2003) methodology relies upon the experience and wisdom of the facilitator to link and direct the debate and, intriguingly, relies purely upon social interaction rather than technology mediated interactions. In this manner Roth (2003) bypasses the failings of Knowledge Management systems associated with lack of use and the complexities of capturing relevant contextual information (Hayes & Walsham, 2000).

However, it is questionable as to the longevity of a Knowledge Management scheme that relies upon employees being granted time to work on projects outside of their specific role. Indeed McKinlay (2002) notes that knowledge interactions within a pharmaceutical environment is limited by the lack of diffusion across project teams and the tightening of timescales that is accompanying the rapid growth experienced within the pharmaceutical companies. Such pressures are coupled with the knowledge intensive nature of pharmaceutical innovation, as an inherently complex series of processes, where employees rely upon and require access to cross functional and distributed knowledge and information (Zack, 1999).

By far the commonest means to achieve this internally is via a centralised portal system (e.g. GSK and Johnson & Johnson) which is intended to act as a network hub for information dissemination (Wang, 2006; Leavitt, 2003; Koretz & Lee, 1998).

McKinlay (2002) conducted a case study within a large US pharmaceutical company and noted Knowledge Management schemes principally took three forms:

1. The enhancement of established social processes
2. The development of further technical capability
3. Experiments with virtual teams.

On a practical note, the first strategy was associated with a best practice system that aimed to debrief drug project teams once a project was complete, in an attempt to address and capture the lessons learned. The study concluded that after three years, the lessons captured were inadequate and scattered in point and nature. Furthermore the lessons that did exist, on the whole related to problems associated with Standard Operating Procedures not 'critical reflection' on the development processes, as was hoped. McKinlay (2002) found that the intended results were to encourage incremental innovation, where employees could refer to past work and subsequently build upon this base. However, such work rarely occurred, with the lessons on the whole serving to reinforce established organisational practices, rather than spark innovative decisions.

The lessons learnt or best practice system holds substantial weight with many authors. Literature within the engineering field by Wong & Aspinwall (2006) describes a best practice system and work by Park & Kim (2005) also suggest such a system as an ideal Knowledge Management vehicle for innovative work within pharmaceutical R&D. Liebowitz's (2000) quantitative study of Knowledge Management within a large pharmaceutical company, also revealed that there is a definite employee based demand for systems that capture lessons learnt and best practices associated with drug development.

However, the results of McKinlay's (2002) studies, point to a subtle balance between a system, either being a hindrance or playing an effective role as a knowledge asset in the innovative processes. Evidently further research is required in order to elucidate the potential of such systems. This would include an investigation of how companies are successfully converting their intellectual capital and tacit knowledge into codified knowledge, in the form of drug submission data and results. Zucker et al. (2002) propose that as tacit knowledge is codified then the dissemination of the knowledge becomes easier. Although the notion of Furukawa & Goto (2006) that knowledge networks drives innovation, appears to negate the value of the vast amounts of codified knowledge captured within regulatory drug submission systems in late phase development work.

3.6.3 VIEWPOINTS ON PHARMACEUTICAL KNOWLEDGE MANAGEMENT

Attempts to address the issues of information and knowledge extraction within the initial discovery stages of drug development have met with mixed results. The wealth of information generated from the human genome study and molecular biology is being subjected to automated techniques such as information retrieval, information discovery and clustering, although the majority of scientific research is still conducted upon the analysis of unstructured text (Fluck et al. 2005). This process requires scientists and R&D employees to intuitively link a molecular pathway with interacting proteins and a disease state. A task that at present is beyond automated procedures (Fluck et al. 2005). As the research is concerned with the application of knowledge within the drug development processes, such techniques and areas are beyond the scope of the review and on the whole relate to the founding stages of drug development within R&D laboratories.

As Davenport & Preitsh (2005) conclude it is the human factors within drug development that are of interest to Knowledge Management, they classify these human factors as:

- Social networks and communities of practice
- The roles of professional knowledge managers

- The behaviours and processes of knowledge workers
- Management strategies and tactics
- The role of the external work environment.

This research project was well under way at the release of this paper and as will be seen in the later stages of this thesis, the ideas of Davenport & Preitsh (2005) reflect the findings of the research. Interestingly their observations support the notion that the cultural aspects are of most importance to Knowledge Management within the pharmaceutical environment, mirroring the observations of Willmott (2000) and Currie & Kerrin (2003). This idea denotes that Knowledge Management practitioners should address the reasoning behind knowledge sharing and ensure knowledge sharing is aligned with an organisational learning perspective. This approach seeks to address both the means to, and the context of, knowledge sharing within the organisation rather than the technology (Currie & Kerrin, 2003). Although this premise appears worthy, few studies address its implementation. An eminent keynote speaker at a conference on Organisational Learning (OLKC Warwick, UK, 2006), concluded that the current models of organisational learning and Knowledge Management simply do not fit the pharmaceutical R&D environment (Dougherty, 2006). Put in context, the state of knowledge flux required to develop a new drug dictates that little reusable knowledge is generated and hence employees are unlikely to turn to information and Knowledge Management systems as a source of knowledge (Dougherty, 2006). So what Knowledge Management measures are pharmaceutical companies employing to address these issues? And is Knowledge Management a lost cause? The following literature does suggest Knowledge Management can play an important role.

Leavitt's (2003) research within Bristol Myers Squibb reveals the company has recognised the "knowledge network" model. The company has formed teams of 'Knowledge Integrators' who act as central points of contact for drug project teams who require information and knowledge.

They also fulfil an alerting role by notifying their teams of relevant information and knowledge that is being published, crucially, they are said to have achieved a 5-10% reduction on time spent per day by scientists researching material.

Leavitt's (2003) research also points out that the Knowledge Integrators are highly skilled scientists in their own right and have input into project teams. Suggesting that the role requires valuable and senior experience which may prove troublesome in terms of recruitment, as the employee is expected to cover a broad range of issues such as competitor's patent application, and the dissemination of current and relevant scientific and business information (Leavitt, 2003).

On reviewing the literature it was noted that the viewpoint on the issue of capturing the knowledge and information exchange associated with R&D and innovation buy in from biotechnology firms was lacking. Scarce Knowledge Management based literature exists on the subject. Indeed Schweizer (2005) questions the ability of the acquiring pharmaceutical company to 'absorb' the knowledge of the biotech company. Concluding that in many cases, the pharmaceutical company may prefer to outsource its R&D activities to these companies and instead concentrate upon its core competencies of late stage clinical trials, regulatory affairs and marketing activities. Schweizer's (2005) research suggests that the modern pharmaceutical company is essentially acting as a broker. Investing the resource to progress a novel compound to a drug but leaving the biotechnology R&D to external organisations, a situation reversed in Japan where in-house R&D is still largely prominent (Kneller, 2003).

3.6.4 SUMMARY

An interview with Peter Goodfellow the Senior Vice President, Discovery Research of GlaxoSmithKline (Owens, 2003) quotes:

"I think we're on the edge of being able to make drugs more easily, it will take us a couple of years to be certain that is the case, but I'm optimistic".

Contrast this optimism with the current state of knowledge surrounding the knowledge exchange and innovative practices within the industry as portrayed by Dougherty (2006) and Davenport & Preitsh (2005) and a very different story emerges. Yes, drug companies are beginning to adapt to the enormous growth in information from projects such as the human genome mapping through dedicated information management (e.g. Donelly, 2003) and companies now have the ability to rapidly screen chemical compounds through technology such as High Throughput Screening (Owens, 2003), yet just how far have pharmaceutical companies come to embracing the wealth of academic practices covered within the review?

On first glance, work by Hung et al. (2005) suggests Knowledge Management may play a central role within drug development. Although in practice, further research by Wang (2006) within Taiwanese pharmaceutical companies concludes that pharmaceutical companies have been slow to adopt Knowledge Management, even though they *believe* there are benefits. As Peter Goodfellow (Owens, 2003) notes, companies are investing and targeting the problem areas of drug discovery, but there remain many areas that require further work and the benefits are not immediately noticeable due to the time scales of pharmaceutical development. Undeniably the stumbling blocks revolve around knowledge intensive processes. Early studies by Koretz & Lee (1998) suggest that the captured knowledge must remain available to relevant employees in order to promote reliable decision making. These so called "stop/ go" factors determine whether a drug is a failure or viable and marketable. Hence every effort is made to identify the characteristics of the compound in order to cease or accelerate development at the earliest possible stages.

Yet managing the process of knowledge acquisition is at the root of the development process and is essentially a Knowledge Management problem (Koretz & Lee, 1998; Dougherty, 2006). However, unfortunately one that has largely escaped an answer from both the pharmaceutical companies themselves and the academic literature. A fact that is understandable when the sources of knowledge driving pharmaceutical drug development and innovation may be internal, but are just as likely to be from an external and often unknown source (Powell et al. 2005).

The review will now conclude with a synopsis of the research aim and objectives, in order to be certain that the research is addressing the issue of enhancing pharmaceutical innovation through the use of Knowledge Management.

3.7 REVIEW OF TIIE AIM AND OBJECTIVES

The literature review has uncovered many interesting facets of pharmaceutical innovation and Knowledge Management, what is clear is that there is little published empirical and qualitative work that links the two areas. Certainly Knowledge Management literature is widespread and abundant over many areas, but the specific area of pharmaceutical innovation is lightly researched. Furthermore the main research aim of creating a Knowledge Management tool set to enhance pharmaceutical innovation covers new ground.

The objectives and tasks associated with measuring the success of a Knowledge Management strategy also appear to be well founded. Combining Knowledge Management strategy, measurement and innovation offers a unique research perspective and will help to inspire confidence in the research. As such, the research is expected to make a valuable contribution to both the public knowledge and the processes of pharmaceutical innovation within AstraZeneca.

3.8 CONCLUSION

Chapter 3 has covered a great deal of ground that supports and argues a case for conducting the research. The chapter started with the topic of innovation and creativity where the terminology and research scope was clarified, before moving on to address pharmaceutical innovation so as to provide context for the reader to understand the research aim and objectives within AstraZeneca.

The review then covered the fuzzy science of Knowledge Management strategy and tools. This stage provided an outline of the areas and concepts that are important to address when studying innovation. It must be noted that throughout the review, the author has witnessed confused ideas that require further investigation and believe at the minimum, an output of the proposed research will be a clarification of Knowledge Management within an R&D setting. The chapter then progressed to assess the methodologies for measuring Knowledge Management Strategy performance. Before suggesting some of the means with which the developed Knowledge Management tool set of Objective 4, may be assessed at a later date by AstraZeneca.

Finally, the literature review then concluded with a study of the current published Knowledge Management strategies in place across a variety of pharmaceutical companies. Encouragingly, the author witnessed a lack of material which clearly outlined what Knowledge Management tools are required to drive pharmaceutical innovation and as such the research is well placed and novel.

The following Chapter 4, details the research methodology that will be used to achieve the research's aim and objectives and answer the gaps within the existing literature.

CHAPTER 4

RESEARCH METHODOLOGY

4.0 INTRODUCTION

The literature review has shown that the management of knowledge and innovative processes plays a crucial role in the development of innovative behaviour and products. As the use of knowledge and Knowledge Management techniques within the innovative processes of AstraZeneca forms the basis of this research, it is important to choose a research methodology that supports the aim and objectives outlined within Chapter 2. Although the research is unique within the pharmaceutical environment, the methods used to collect and analyse the research data have a number of commonalities with published literature on Knowledge Management, innovation and academic research. The following chapter covers the research methodologies that may be used to conduct the research and explain the rationale behind the final chosen path.

4.1 RESEARCH PHILOSOPHIES

The term research has already been used within the thesis, but what does research imply? Taking the definition of Oates (2006) as a starting point, academic research is described as:

"The creation of new knowledge using an appropriate process, to the satisfaction of the users of the research".

When this definition is placed in terms of AstraZeneca's pharmaceutical R&D processes, the end result is the development of a new drug to combat disease; while in the context of the research within this thesis it is the clearer understanding of the processes and knowledge required to develop the new drug. Oates' (2006) definition also suggests that good research results in the end users of the research being content with the outputs, in this case both AstraZeneca and the academic community will benefit from the study.

However achieving a successful outcome relies upon the researcher successfully communicating why the research is being carried out and what the results may be used for. In the words of Nightingale (1984) this is the successful communication of the 'big idea' of the thesis, an idea that is stated in the early chapters as the principle aim and then rationalised and solved in the following chapters. Oates (2006) hypothesises that in order to achieve this goal, academic research requires a number of stages that should be addressed in turn, these are:

- The identification of a problem,
- The gathering of data,
- The analysis of the data,
- The interpretation of the data,
- The gathering of more data,
- The analysis of the new data,
- The interpretation of the data as a whole,
- Draw conclusions from the data as a whole.

This approach implies that once the context of the research in the real world is known, a problem may be identified and the aim and accompanying objectives to solve and observe the problem, developed in a form of reiteration. Emory (1985) describes this series of steps as the 'research paradigm' which is said to consist of the research question, the research methodology and the output of the research. Hirschheim (1992) refers to the assumptions that underlie the research question and methodology as the epistemology that serves to guide the researcher and the research to a valid conclusion. However, research should be conducted without prejudice and be objective, that is to say preconceived notions of solutions to a problem should be avoided, as good research develops well-founded conclusions that are based on the data collected alone (Oates, 2006).

Furthermore research cannot be conducted without a purpose that is evident from the start (Lindsay, 1995); yet starting a research project is a daunting task and returning to the issue of how this research is conducted yields a bewildering array of approaches. However, there exists common ground, with the positivist, interpretative and critical research approaches well lauded and exercised within both IS and Knowledge Management academic research. These approaches are now examined alongside the views of Miles & Huberman (1994), Myers (1997) and Oates (2006) in the following sections and their suitability to be used as the philosophical basis, weighed up against the research aim and objectives detailed in Chapter 2.

4.1.1 POSITIVISM

Positivism is known as the scientific approach and adopts two principle assumptions; these are that the world is ordered and that we can investigate the world objectively. The first law implies regularity and is associated with assessing the validity of a theory or hypothesis that may be proven or disproved via the formal means of measuring and assessing phenomena. Positivism suggests repetition, in that a phenomena associated with the research environment will occur as a recognisable constant and this phenomena once identified, may be measured through experimentation. The second assumption of positivist research relies upon the phenomena occurring outside of the researcher's cognition, i.e. the phenomena will occur regardless of whether the researcher is present or not. Studies based upon positivism tend to align a theory with prediction and experimentation in an attempt to learn more about why an outcome occurs and to ultimately prove or disprove a hypothesis. An established positivist hypothesis or theory may be read as fact, but the researcher should be aware that the positivist or scientific approaches provides an indication of what is known at that moment. Hence a positivist theory or hypothesis is under constant test by researchers, where theories may be broken down into smaller constituent parts as more knowledge and theories on the subject emerge (reductionism), or tested repeatedly in an effort to elute problems with the researchers objectivity or environmental error (repeatability), or simply refuted where researchers who attempt to repeat the experiment cannot obtain the same result.

Scientific theories and hypotheses are based upon the objectivity and reliability of the research approach and the stronger a theory is, the longer it will withstand scientific scrutiny, yet as this research is based upon the social processes and wiles of knowledge interactions, the use of positivism as a research philosophy is questionable. Indeed, Hirschheim (1992) questions whether social research is truly governed by scientific laws and whether objective measures with which to assess a theory or hypothesis can even be obtained using positivist research.

4.1.2. INTERPRETIVE RESEARCH

Interpretive research is a more open concept, being primarily associated with understanding the social context of a phenomena, a researcher may assume that the means to judge and analyse a scenario may be made through the use of social constructs. These constructs include language, consciousness and shared meanings and divulge a contextual based view of the studied process, due to this it is a popular choice to conduct Knowledge Management and IS research (Myers, 1997). Walsham's (1993) view states that:

"Interpretive studies are aimed at producing an understanding of the context of the information system, and the process whereby the information system influences and is influenced by the context".

The interpretive approach seeks to identify, explore and explain how the social factors of the problem are interrelated and interdependent. Checkland & Holwell (1998) were early advocates of interpretivist research. Their work on the Soft System Methodology describes how the interpretive approach can be used to yield a valuable understanding on how the humans within a problem context, interact and perceive their environment.

In light of this, the interpretive approach would appear well suited to Knowledge Management research as it lacks the preconceived variables of the positivist approach, relying instead on the elution of the sense that a human makes of their environment. This sense is derived from the social meanings and view that there is no single version of the truth; instead an interpretivist relies upon multiple subjective viewpoints that are taken into consideration and not immediately dismissed as erroneous events.

In this light, a single conclusive theory or hypothesis is rarely reached and, as such, interpretive research is often focused upon real world study outside of the regulated laboratory environment

4.1.3 CRITICAL RESEARCH

Critical research centres upon the relationships of the subjects and in many ways harks to the notion of a subject's social and economic status. The critical researcher aims to identify the conflicts, contradictions and the power held within the relationships between people, in order to bring these issues to the forefront where they can be addressed and ultimately eliminated. Therefore a critical researcher may be viewed as a challenger to the established organisational structures by using their research in an altruistic manner to realign the balance of power within an organisation. The critical researcher considers technology as an agent that may be shaped via employees, rather than technology being the agent with which to shape the role of the employee, a mantra in common with recent literature on Knowledge Management and innovative practice (e.g. Darroch, 2005).

4.2 THE RESEARCH PHILOSOPHY

It is clear from the literature in Chapter 3 that Knowledge Management carries both a social and a technological construct. Assigning and uncovering measurable and reliable variables to construct a set positivist hypothesis appears ill founded, as the principle research aim is itself founded within a social context, e.g. the creation of a Knowledge Management tool kit that is useful to employees. Therefore aligning the research with a defined hypothesis and a positivist philosophy could be made to be suitable. However, compelling research by O'Neil (2002) concerning Communities of Practice, suggests that the positivist approach is flawed, when research intends to examine the values, ideologies, political interests and intangibles of a social environment.

As the research within this thesis focuses upon the social context, the rich exploratory data that could be obtained through the use of an interpretive or critical research path, represents a more beneficial and viable route.

Miles & Huberman (1994) stress that it is important for a researcher to make their methodological intentions clear, particularly when conducting human centred research into social phenomena, where the research scope is governed by language, decisions, conflicts and hierarchies. These social factors essentially describe how an employee will think and act within an organisation. Taking these factors into account implies that the use of critical research may be suitable, however, as the research only seeks to analyse and not challenge the power relationships between the employees, the remaining interpretive philosophy is ultimately deemed most suitable. It must be mentioned that choosing an underlying physical framework for Knowledge Management research poses an interesting quandary, as the literature review of Chapter 3 revealed that the majority of published work is either positivist or interpretative. Authors such as Kaplan & Duchon (1988) and Oates (2006) suggest that both are worthy philosophies and even a combination of two philosophical strategies is feasible, but for the sake of objectivity and reliability, the interpretive philosophy is chosen as the underlying framework on which to conduct this research.

4.3 RESEARCH METHODS

Although the underlying research philosophies chosen by Knowledge Management researchers may differ, the means to capture the data to drive the research is often based upon similar means. It is here that the notion of quantitative and qualitative study is introduced. Yin (1994) suggests quantitative research focuses upon data derived from surveys and archives, while qualitative research commonly uses interviews and observation. It must be made clear that the approaches are not mutually exclusive; indeed research may benefit from combining both qualitative and quantitative data collection and is termed triangulation (Mingers, 2001).

Qualitative data may also be codified and hence rendered as quantitative data (Miles & Huberman, 1994), yet it is important to stress that quantitative and qualitative data is the end result of the research methodology and not the methodology itself.

Choo & Bontis (2002) suggest that due to the difficulties of studying organisational knowledge, qualitative data collection is a worthy approach. However, when choosing a methodology that may yield qualitative data, it is important to bear in mind Shaffer's (2000) description of the methodology as:

"A framework within which raw data is placed so that a meaning may be seen more clearly; where the methodology is the transformation of data into information".

Within this research, the desired result is the collection of useful data that has been collected by applying a research framework to study Knowledge Management and innovation within an R&D organisation. The suggestion of acquiring data in an organisation or field is also an accurate description of empirical research, where empirical research is a broad label that is not a philosophy or a method, but is an assumption that research has been carried out in the real world and is based upon evidence derived from experimentation, observation or assessment. Therefore empirical research implies the study of an IT or Knowledge Management system in the field (Oates 2006) and regardless of the final chosen research philosophy or method, may therefore be used to describe the research within this thesis. Indeed, Swan & Scarbrough (2001) state that empirical research provides the means to make sense of the processes and objects that comprise a studied area; particularly advocating the use of empirical research to challenge the common misconception that labels knowledge as a commodity that can be captured and managed with an information management tool.

Although the research may be labelled as interpretive and empirical in character this does little to explain how or what data should be collected, fortunately there are a wide range of methodologies with which to acquire data and answer the research aim within this thesis.

Yin (1994) and Oates (2006) are key figures within qualitative research practice and Table 4.1 details some of the more common research methodologies suggested by the authors to collect qualitative data:

Table 4.1: Common Research Methodologies

Methods	Form of Research	Requires control of behavioural events?	Focuses upon contemporary events?
Action Research	Who, what, why, how many, and how much?	Yes and No	Yes
Ethnography	Who, what, why, where, how many and how much?	No	Yes
Observation	Who, what, why, where, how many and how much?	No	Yes
Archival Analysis	Who, what, why, where, how many and how much?	No	Yes and No
Modelling	How and why?	No	Yes and No
History	How and why?	No	No
Experiment	How and why?	Yes	Yes
Case Study	How and why?	No	Yes

As Table 4.1 reveals there are a considerable variety of methodologies to choose from, some require a rigid and controlled environment, while others, such as historical research, focus on past events. However, as the research requires a contemporary angle, the use of the historical approach may be excluded at an early stage, though the other methods mentioned in Table 4.1 all hold potential merit and application. In order to address this, the following sections now briefly cover the identified research areas and link their use or potential use to the main research aim and objectives outlined in Chapter 2.

4.3.1 ACTION RESEARCH

Action research requires that the researcher both observes and actively contributes to the results of the study. Greenwood & Levin (1998) state that action research is predominantly a social methodology, where the researcher actively sets out to improve the situation for the research stakeholders. In this way the organisation being studied benefits from the elucidation and examination of problem areas that are related to the research aim.

The action researcher is expected to take positive steps to rectify the problems identified and carry out and communicate remedial action. Kock (1997) describes action research as:

"Research methodologies and projects where the researcher tries to directly improve the participating organisation and at the same time generate new scientific knowledge."

Action research is commonly used by researchers who wish to improve their own situation, or by academics:

"Who initially present as experts to analyse, diagnose and suggest change and then progress to become the facilitators of change." Oates (2006).

Despite its applicability to Knowledge Management research, the approach has largely enjoyed success within the social sciences (Myers, 1997). However, authors such as Checkland (1981) and Vigden (2002) have successfully used action research within their IS based methodologies. The use of action research within Knowledge Management is largely under explored, but does present considerable opportunity as it directly utilises the knowledge of the researcher and the employees in order to rationalise a problem area (Avison et al. 2001). Yet this process is also a shortcoming as the results may only be applicable to the studied organisation and attempts to replicate the results of the research will almost certainly differ.

On consideration, action research is certainly a worthy approach and would provide value to both this research and to AstraZeneca. A benefit of action research is that the researcher is immersed within the research environment and actively collaborates with the employees, thus allowing the researcher to view whether the results of this study and the Knowledge Management toolkit is ultimately useful to support pharmaceutical innovation. However, to be conducted properly, active research would require direct participation within the drug development processes in order to assess the Knowledge Management tools that are currently used and may be used.

Although the researcher's Biochemistry background provides an excellent understanding of the drug development processes, the utilisation of the proposed and current Knowledge Management tool kit would require detailed biomedical knowledge, resource and authority, and although promising, the action research approach was on the whole deemed unsuitable.

4.3.2 ETHNOGRAPHY

Ethnography is derived from social and cultural anthropology, where the researcher studies the social and cultural implications in order to elute an accurate description of the people and cultures (Myers, 1997; Oates, 2006). Fetterman (1998) describes ethnography as research of the mundane, where the researcher seeks to analyse the routines of the organisation through extensive fieldwork. Ethnography intends to preserve the natural setting of the study and does not seek to disturb the subject's organisational behaviour, a stance that differs wildly from action research. Instead ethnography utilises multiple data collection tools such as the interview, documents and observations in order to produce a holistic picture of the organisation (Oates, 2006). As this suggests, ethnographers adopt the interpretive approach, relying upon the collation of views and observations across the whole organisation in order to reach valid conclusions. However, this approach is rarely formal and has provoked criticism from the more rigid research proponents (Myers, 1997).

Evidently ethnography may be applicable to the research as throughout the project the researcher was immersed within the organisation and its operating procedures, and hence was in the position to make extensive field notes on which to base an analysis upon at a later stage.

4.3.3 GROUNDED THEORY

Grounded theory is an interesting concept, as it may be used to make sense of the data collected from field research and induce a theory or theories from the data (Strauss & Corbin, 1998). Due to the lack of prerequisites or hypothesises it may be viewed as an ideal tool with which to approach the study of an organisation, particularly from a Knowledge Management point of view.

However, the researcher must be careful, as grounded theory requires the elucidation and generation of theories from the research data and simply describing what was found within the data does not constitute grounded theory (Oates, 2006). The technique relies upon a process of discovery, whereby the researcher has an initial idea of what may be found but is unsure, a initial survey or exploratory study would then be carried out which then leads to further studies and refinement and eventually the elucidation of a validated theory (Oates, 2006). This process of refinement promotes reiteration and the development of firm concepts from an initial notion or a surmise (Denscombe, 2002); in the case of this research, this would be that Knowledge Management does indeed aid pharmaceutical innovation.

Myers (1997) suggests the benefits of grounded theory lies within the continuous interplay between the data and analysis, whereby the data effectively steers the direction of the research. Due to grounded theories loose fitting nature, it has proven a popular research methodology within the IS and Knowledge Management fields alike (Myers, 1997), hence grounded theory represents a worthy avenue in which to progress the research aim and objectives.

Grounded theory does however have its drawbacks, the primary one being that the initial investigations are often vague and lack a clear definition of what or why a sample is being studied. Due to this the researcher may find themselves repeatedly carrying out data collection in a vain attempt to define a theory or reach the fabled point of theoretical saturation, where additional data no longer develops further research but instead allows a theory to be developed (Strauss, 1987). Thus the researcher must be able to collect and analyse useful data that can ultimately be used to derive a theory, the key problem here being that it is difficult to know what exactly useful data is at the early stages of data acquisition.

Problems such as these, compel a grounded theory researcher to codify data in the hope that a theory that has practical relevance to the people involved may be uncovered. The initial stage of codification is termed open coding and requires that the researcher code data according to what is found within the data and not based upon the terms and concepts found within the existing literature, a task that is certainly easier to describe than carry out (Oates, 2006).

4.4 THE RESEARCH APPROACH

The chosen research strategy must firstly address the vagaries of the pharmaceutical domain and from the review of the literature it is clear that few, if any studies, have specifically attempted to create a Knowledge Management tool kit to drive pharmaceutical innovation. Hence the research is a step into the unknown, techniques such as ethnography and grounded theory would therefore represent viable approaches. However, the research is also highly unique in that the researcher has unprecedented access to the employees and AstraZeneca as a whole, and it would be in the interest of both the organisation and academia, to conduct a study that spanned the organisation. Grounded theory would allow a researcher with no previous experience of the domain to conduct studies, yet the researcher's experience of the drug development processes and empathy with the knowledge to be studied, suggests that a more structured methodology will yield greater reliability and understanding.

Ethnography is a serious contender as the EPSRC funded researcher is based full time within AstraZeneca; however, ethnographers must assess and report their prejudices and personal experiences when observing and reporting data, in a process named as reflexivity (Oates, 2006). Reflexivity and the documentation of the personal experiences of the researcher are a necessary part of a valid ethnography study. However, the extra work involved in providing a narrative of the researcher's time within the organisation is deemed to be an unnecessary burden, therefore the chosen research path focuses upon the use of the interpretive case study.

A key advantage of the case study is that the initial investigational stages may be based upon existing literature and can be used to validate and shape existing theories (Oates, 2006). There is a great deal of literature on innovation and Knowledge Management, yet little upon pharmaceutical innovation and the use of Knowledge Management tools. Although the published literature largely applies to other fields, it would be foolish to ignore the existing generic literature on Knowledge Management and innovation.

The case study approach is valuable as it allows the development of an initial conceptual framework, with which to assess the organisation's Knowledge Management and innovation strategy in light of published Knowledge Management and innovation models. Hence the initial stages of this research may be viewed as a bridge, to link the existing literature and AstraZeneca's Knowledge Management strategy. Prior to moving on to develop new frameworks and theories that relate solely to the use of Knowledge Management within AstraZeneca and the drug development processes.

The following section examines the reasoning behind the choice of the case study and the value of adopting the case study approach.

4.4.1 THE CASE STUDY

The case study is used to provide a rich and detailed insight into the studied processes and explore the complex relationships and processes that exist within the study area (Oates, 2006). Yin (1994) is a proponent of the approach as it allows investigation of a real life scenario with loosely defined boundaries. When undertaking this doctoral research, it was deemed vital to adopt a methodology that can embrace the indistinct scope of Knowledge Management, innovation and intellectual capital research. Methods to achieve this are rarely documented, yet the case study is commonly employed within Knowledge Management and IS research as the principle means of data collection (e.g. Carrillo, 2003; Myers, 1997). Benbasat et al. (1987) state that the case study is useful when research is at its formative stages, this is certainly the case within this research project as the literature implies Knowledge Management will aid drug development, but little supporting empirical evidence corroborates this.

Case study research is useful when looking at the 'how's and 'why's (Yin, 1994) and is valuable when the mechanics of a process are unknown, in this case it is the processes and nuances surrounding the use of knowledge within drug innovation which represents the archetypal 'black box' to be explored. Thus an advantage of the case study is that it provides focus and may be used to define the area to be studied.

However, Miles & Huberman (1994) describe this as a loose fitting 'focus' that is largely based upon what will definitely not be researched, rather than what will definitely be covered. In this way the case study is useful to serve as an exploratory tool to define and lead further study (Yin, 2003); however, the case study is also a powerful research strategy where the principle aim is to extract as much detail as possible from the case area in its natural setting. Consequently case studies may take either an interpretive or positivist approach (Yin, 1994), although the interpretive approach offers a subjective dimension where the beliefs and value of the studied system may be constructed and interpreted (Darke et al. 1998). This subjective dimension is a valuable commodity and would both support and develop the primary research aim, by taking account of the views of the employees who utilise knowledge to drive drug development. Walsham's (1995) work supports this notion by highlighting that the interpretivist case study is able to provide an explanation as to what is occurring within the studied processes and the organisation as a whole, which may then be relayed back to the subjects by describing their role within these holistic processes. A further advantage is that the case study develops understanding by obtaining data from multiple sources across an organisation or field, utilising diverse sources such as interviews, field notes, documents and archival analysis in order to make sense of the study as a whole (Darke et al. 1998).Therefore the case study appears to be an ideal approach, but how can the case study help to achieve the main research aim?

This question is partly answered by the ability of the case study to utilise multiple data sources, in conjunction with advice taken from Oates (2006) and Yin (1994), the following qualitative data collection techniques are utilised within the study:

- Interviews
- Direct and participant observation
- Process modelling
- Document analysis
- Field notes

In this fashion, the case study creates a descriptive and exploratory study, identifying and trying to explain why events happen, either by identifying them as unique events or by relating these findings and events to existing literature on the subject (Yin, 2003). How these factors then interrelate allows 'cause and effect' relationships to be uncovered, Oates (2006) also suggests that the case study should target more than one area and, if possible, spread across organisations in order to establish differences and trends within these 'cause and effect' relationships.

In light of the findings of the literature review is it apparent that this research would indeed benefit from cross organisational research, as this would allow the assessment of the impact of Knowledge Management tools within similar innovative organisations and directly support Objective 4 in the process. Darke et al. (1998) cite the use of dialectical hermeneutics as a theoretical framework on which to conduct a case study of the organisational impact of introduced IS systems. What is valuable within this approach is that the study relies upon reaching a consensus of value from the subjects studied, focusing not upon the 'hard' aspects of measurement but on deriving value from the 'soft' social side. In many ways this research follows a similar fashion, as the objectives laid out in Chapter 2 initially seeks to identify and explore the organisational processes of innovative work from the perspective of the employee, showing how and why group interactions and the organisational structure influences innovative behaviour.

As the research process was expected to be conducted over a number of years the case study is of the longitudinal variety. The research seeks to analyse R&D and innovative cases over time, noting and analysing the processes and relationships that are stable and those that exhibit a state of flux (Oates, 2006). However, case studies are not without their critics, in particular they are criticised for their abject specificity as researchers such as Oates (2006) and Yin (1994) suggest it is largely up to the researcher to assess how relevant the results are to other areas. This research was expected to allow generalisations to be made, as a case study regarding pharmaceutical innovation should have application to other knowledge intensive R&D processes.

This is a primary aspect of the research and an achievable aim, as Walsham (1995) suggests the findings of case study research often results in a series of practical implications or the development of a conceptual framework that has wider application outside of the initial research domain.

In order to commence the study, the research is conducted and analysed in accordance with the criteria detailed by Lincoln & Guba (1985) and Oates (2006), who ascertain that for the reader to have confidence in the findings of the research, the issues of internal and external validity, reliability and objectivity should be addressed:

1. Internal validity relates to effectively ensuring that the concepts developed from the researcher's musing may be validated with the subjects themselves and possesses recognisable application.

2. External validity applies to the environment outside of the studied area and emphasises that the research finding should convince an external organisation or subject, that the models eluted by the research will find merit within another context.

3. The reliability or consistency of the research stems from the research results ability to be replicable, where the researcher must be able to convince the reader that the results are repeatable.

4. The final criteria relates to objectivity, which proclaims that the results of the study are obtained from the data alone and not from the researcher's personal bias. Seeking to prove that the researcher did not unduly influence the case subjects or report their own preconceived notions as data (Walsham 1995).

4.5 THE RESEARCH FRAMEWORK

As previously mentioned, the research takes the form of a longitudinal case study coupled with an interpretivist approach, the methods of data collection used are now analysed and their use discussed in relation to the research aim and objectives of Chapter 2.

4.5.1 CASE SELECTION

The selection of the cases or units on which to conduct research is an important point to outline. Oates (2006) describes five criteria which influence what and where can be investigated within a case study and these are:

1. The typical instance displays typical qualities that are representative of a class, the findings from one instance may be generalised to cover a class as a whole.

2. The extreme instance is a sharp contrast to the established norm.

3. A test bed for theory is a case that allows a particular theory or strategy to be examined and then modified, accepted or challenged.

4. The convenience of a case also influences its choice, as restricted access or time related issues may hamper the quality of research that can be obtained.

5. A unique opportunity is one that presents itself while the research is being carried out and may not reoccur, such events often represent the elusive 'holy grail' of research.

In order to satisfy these five criteria the research undertakes multiple case studies across AstraZeneca R&D and two additional R&D intensive industries. Classifying the research as separate case studies recognises that innovation and Knowledge Management is a diverse environment to study.

As the research will commence with an exploratory nature it was envisaged that the case study carried out for Objective 1 would target examples of typical instances of innovation.

A brief outline of the case studies researched, are presented in Chapter 5. Here the reader will note that these case studies represent the extent of what may be conceived of an 'innovation', from the development of an innovative new drug or dosing device, to the development of a new innovative process to introduce a KM system. Innovation and the processes of innovation possesses a wide guise; it was expected that eventually trends would appear that would allow some of these instances to be described as typical, but some cases would remain as extreme instances, while others that specifically relate to the use of Knowledge Management within an organisation would serve as a test bed for theory.

In order to ensure that bias from the author's personal experiences can be minimised, the research utilises multiple sources of data to allow for triangulation, thereby bolstering the case study findings with evidence from similar but distinct areas (Yin, 1994). The results of the studied areas are clearly defined in Chapter 5 in light of the research aim and objectives. Here the analysis will weave a narrative of the findings of the study and provide further validation of the research approach, in line with recommendations by Darke et al. (1998) and Walsham (1995). The following sections cover the steps that were taken to collect the data from each of these diverse areas.

4.5.2 INTERVIEWS

Semi-structured interviews are the primary means of data acquisition and form the mainstay of the research; hence the development of a series of questions to study the relationship between innovation and Knowledge Management was required. The interview is commonly associated with the case study methodology and is an overt approach, where the participants are aware of the rationale behind the conversation and permit the researcher to conduct the study (Oates, 2006).

In all there were four stages of interviews conducted over a two year period, the stages are briefly outlined below:

1. Preliminary Information Gathering

Stage 1 was conducted with five known innovators working within AstraZeneca R&D and was used to assess the validity of the research aim, objectives and the conceptual framework upon which the interview questions were based.

2. Secondary Information Gathering

Stage 2 built upon the preliminary findings and was conducted with thirty two key personnel who are directly involved in innovative behaviour within the R&D wing of AstraZeneca. A further two case studies were conducted within Rolls Royce (Derby) and Johnson Controls (Derby) to assess the value of Knowledge Management within similar innovative organisations.

3. Knowledge Management Tool Kit Design

Stage 3 was conducted with ten innovators who were identified as proponents, expert users and sceptics of Knowledge Management technology in order to provide a holistic view of Knowledge Management within an R&D setting.

4. Knowledge Management Tool Kit Validation

Stage 4 was the final interview stage and required the validation of the research findings with 10 key innovative personnel across AstraZeneca R&D. A series of conference papers and presentations were also used to air and validate the research findings, as and when the study findings were released to AstraZeneca and the academic community.

The knowledge audit work of Coombs et al. (1998) was used as a provisional basis for the questionnaire, while the findings of Stage 1 and the literature findings from Chapter 3 completed the conceptual framework on which to base the semi-structured interview questions. The following components of the conceptual framework are based upon an expanded view of pharmaceutical innovation and Knowledge Management, derived from Cooper (2003), Tether (2003), Scarborough et al. (1999) and Dorabjee et al. (1998):

- Innovation and risk management
- Knowledge Management within AstraZeneca
- Knowledge and information sources
- Knowledge culture, collaboration and knowledge networks
- Knowledge Management/ Information Systems
- Process management
- R&D legal and regulatory influence

The pilot study of five preliminary interviews (Stage 1) was required to align the semi-structured questionnaire with the AstraZeneca operating principles and internal company processes and the final interview structure and questions are detailed within Chapter 5. The framework concentrates on the notion of innovation as both a process and a new product, seeking to elaborate upon existing theory and ascertain the role of Knowledge Management within pharmaceutical drug development.

All interviews were recorded directly into MP3 format using a laptop where possible, when interviews were conducted without recording, at the request of the interviewee, extensive field notes were taken. All interviews were transcribed within 24 hours of completion using Microsoft Word, after transcription the interview transcripts were reviewed with the participant in order to ensure accuracy.

4.5.3 PROCESS MODELLING

Stewart (1997) hypothesises that Knowledge Management will be fundamental to a company's success, yet as the review in Chapter 3 concluded, strategies to achieve this elusive return are rare.

Knowledge Management success stories are driven by companies that integrate the knowledge of the organisation and the business processes with that of the employees (e.g. Dilnutt 2002). Process modelling can be used to benchmark and visualise the existing business processes of the organisation for use with a Knowledge Management system. Nissen et al. (2000) state that before introducing a Knowledge Management strategy it is important to recognise and discuss what exactly Knowledge Management is intended to support and achieve. From the perspective of knowledge as a resource, the models employed to map a process are derived from intellectual capital models and differ from the more traditional Business Process Re-engineering models. Here the Value Creation Map (Marr et al. 2004) and Strategic Performance Management (Marr, 2006) methodologies may be used to visualise a business process in terms of the work flow, the organisational environment, the knowledge interactions and the value of the knowledge used.

Due to the ambiguity of the chosen case study units, process modelling was an integral part of the work, the derivation of an accurate picture of how knowledge contributes to the drug development processes and how Knowledge Management tools may give support was deemed paramount. While conducting the semi-structured interviews of Stage 2, the participants were asked to describe an example of innovative work they had been involved in. These scenarios were then analysed and a map of the knowledge entities and work flow was drawn up utilising the technique of Strategic Performance Management (SPM) (Marr, 2006). Focus groups and further discussions were also held with the participants to ensure that the models accurately reflected the true nature of the knowledge and workflows occurring within the innovative processes. The SPM technique was chosen as it allows the definition of strategy that encompasses the views of multiple stakeholders and allows the definition of how innovation is actually being driven to be uncovered.

Marr (2006) describes SPM as *"an organisational approach to define, assess, implement and continuously refine organisational strategy"*, importantly the method may be used to refine and develop measurement indicators that can be used to reflect the success of a strategy.

Tying AstraZeneca's innovative drug development strategy with a Knowledge Management strategy is seen as an important output of the research (Objective 4) and the application of the SPM technique allowed this goal to be reached. The SPM technique was chosen not only on merit, but also due to the researcher's familiarity with the technique and its application. The researcher was involved in a consultancy project conducted by Cranfield University's Bernard Marr. Following discussions with Bernard Marr, AstraZeneca and the research supervisors, it was viewed that this research would benefit from the benchmarking and mapping of the existing workflows, by specifically employing SPM to map the value creation processes involved in the innovative processes.

4.5.4 OBSERVATION

Observation played a key role in the acquisition of the research data; due to the researcher being based full time within AstraZeneca the opportunities to observe innovative work were widespread. Observation implies that the researcher has a choice on what type of data to collect and when utilising a case study the observer commonly utilises two types, namely direct and participant observation. Both types of observation were heavily utilised, but direct observation played a greater role in the research, as an autonomous observer, the researcher attended numerous departmental meetings, cross functional meetings, AstraZeneca seminars, drug development seminars and strategy meetings over the three year period at the site. Having been granted the status of an employee, the author had wide access to the organisation and interacted frequently with managers, directors and scientific researchers. These informal conversations provided a rich tapestry of data concerning innovation and Knowledge Management.

Participant observation requires a more direct role, rather than passive acquisition of data the researcher possesses the ability to actively participate and instigate data gathering events (Yin, 1994).

Although the author's role within AstraZeneca was largely that of the direct observer, numerous meetings related to Knowledge Management and innovation were conducted over the three years and the author's role shifted from one of observer to participant on many occasions. However, participant observation requires focus as, when participating within meetings and discussions, it is important to remain objective and refrain from bias.

In addition, the role of a participant observer often interferes with the collection of data and, as such, the author found a 'balancing act' between the demands of the organisation and the research was required at times. Over all though, the participant observer approach offered unique benefits to the research by allowing the researcher to empathise with employees, gain an insider viewpoint and highlight areas that were pertinent to the research as and when they arose.

4.5.5 DOCUMENT AND ARCHIVAL ANALYSIS

AstraZeneca is reliant upon the storage and retrieval of documents to support its drug development activities and as the research is focused upon Knowledge Management, it was deemed prudent to utilise the systems currently employed and analyse the documents that are used by employees during their work. The author had access to a number of these systems, including eRoom, GEL and PKT, during the three year project and key documents relating to the drug development work were identified and discussed during the interview processes. Participants were asked to gauge the effectiveness of AstraZeneca's current information and knowledge strategy and comment on areas of strength and weakness. In this fashion the interviews supplied important contextual elements, allowing the meaning and value of the documents held within the innovative R&D processes to be appraised. This allowed the author to judge the effectiveness of the Knowledge Management strategy and accurately model how employee's typically utilise Knowledge Management and information management systems on a daily basis.

4.5.6 CASE NOTES

During the research, extensive case notes were taken in both notebooks and electronic form (Microsoft Word), these notes were largely derived from the interviews, observations and archival analysis and served to provide a 'mental note' of pertinent points that were relevant to the research. Electronic records of the case study were assigned to a 'Hermeneutic Unit' within the ATLAS.ti software in order to map relationships between the collected data and highlight best and worst practice examples.

4.5.7 DATA ANALYSIS

The methods of analysing the data are covered at the beginning of each section in Chapter 5, but on the whole, relied upon utilising the matrix method described by Miles & Huberman (1994) to collate and analyse data with which to support the research aim and objectives of Chapter 2. The research concentrates upon the use of qualitative data to provide context within the fuzziness of the problem area and it is proven that the undefined processes and the importance of social interactions lend themselves well to qualitative analysis (Daft & Lewin, 1993). However, it was expected that after the initial qualitative data collection, subsequent codification of the data would be carried out as suggested by Yin (1994). Preece (2001) and Hague (1994) note, the collection of qualitative data provides insight into the subjective feelings and social interactions of a given environment, and it is believed that insight of this type will be of highest value to AstraZeneca and innovative R&D in general.

4.6 CONCLUSION

This chapter has explained how the research study relies upon the collection and analysis of qualitative data through a series of semi-structured interviews, observations and archival analysis. These steps are designed to uncover the trends, strengths and weaknesses of the current innovative practice within AstraZeneca R&D.

After a review of potential research methodologies and philosophies, the final research approach is based upon the longitudinal case study and the interpretive philosophy, a strategy that is eminently capable of meeting the research aim of creating and evaluating a Knowledge Management tool kit to drive pharmaceutical innovation.

Evidently approaching the tricky subject of innovation and Knowledge Management requires a focused research effort and the means to achieve this have been outlines. A more detailed explanation of the various research stages is provided in the next chapter and their contribution to the research aim is further clarified.

This thesis now discusses the research data acquired from the case studies and explores the how, where and why's of innovative R&D within the case study organisations.

CHAPTER 5:

SCOPING A KNOWLEDGE AND INNOVATION FRAMEWORK

5.0 INTRODUCTION

This chapter is aimed at setting the scene for the research and introducing the reader to AstraZeneca, innovation and drug development. The chapter forms the foundations from which the research is developed and is primarily concerned with establishing what innovation means to AstraZeneca, why innovative work is carried out and how employees are innovative. As the research is based within a real world organisation this stage also allowed the author to empathise with the organisation and made employees aware of what the research project would cover and what it intended to achieve.

As the pharmaceutical industry is highly secretive, relatively few accounts are available that detail how the drug development processes are occurring within the big pharmaceutical companies. AstraZeneca kindly agreed to allow the author access to this environment, so as to benefit both AstraZeneca and the research contained within this thesis. From the review of the literature in Chapter 3 it is apparent that the published academic literature is generic in character. Rarely covering the depth of inquiry necessary to provide concrete guidelines to assist in the introduction and implementation of a Knowledge Management toolkit and strategy too specifically enhance drug development.

In order to analyse innovative practice within AstraZeneca the primary means of data collection chosen was the semi-structured interview. Accordingly, this chapter discusses how a number of AstraZeneca employees were selected to be interviewed in line with the research interview tool outlined in section 4.4.

Hence this chapter is a pilot study, aiming to validate the research methodology and partly reveal the criteria that are central to analysing innovation and Knowledge Management within AstraZeneca. This chapter adopts an exploratory slant, seeking to develop the initial methodology and research framework so as to ultimately support the overall research aim and partly fulfil Objectives 1, 2 and 3.

5.1 THE RESEARCH PROCESS

The overall research process map is displayed in Figure 5.1 and illustrates the sub processes that were followed in order to fulfil the main research aim of developing a Knowledge Management toolkit.

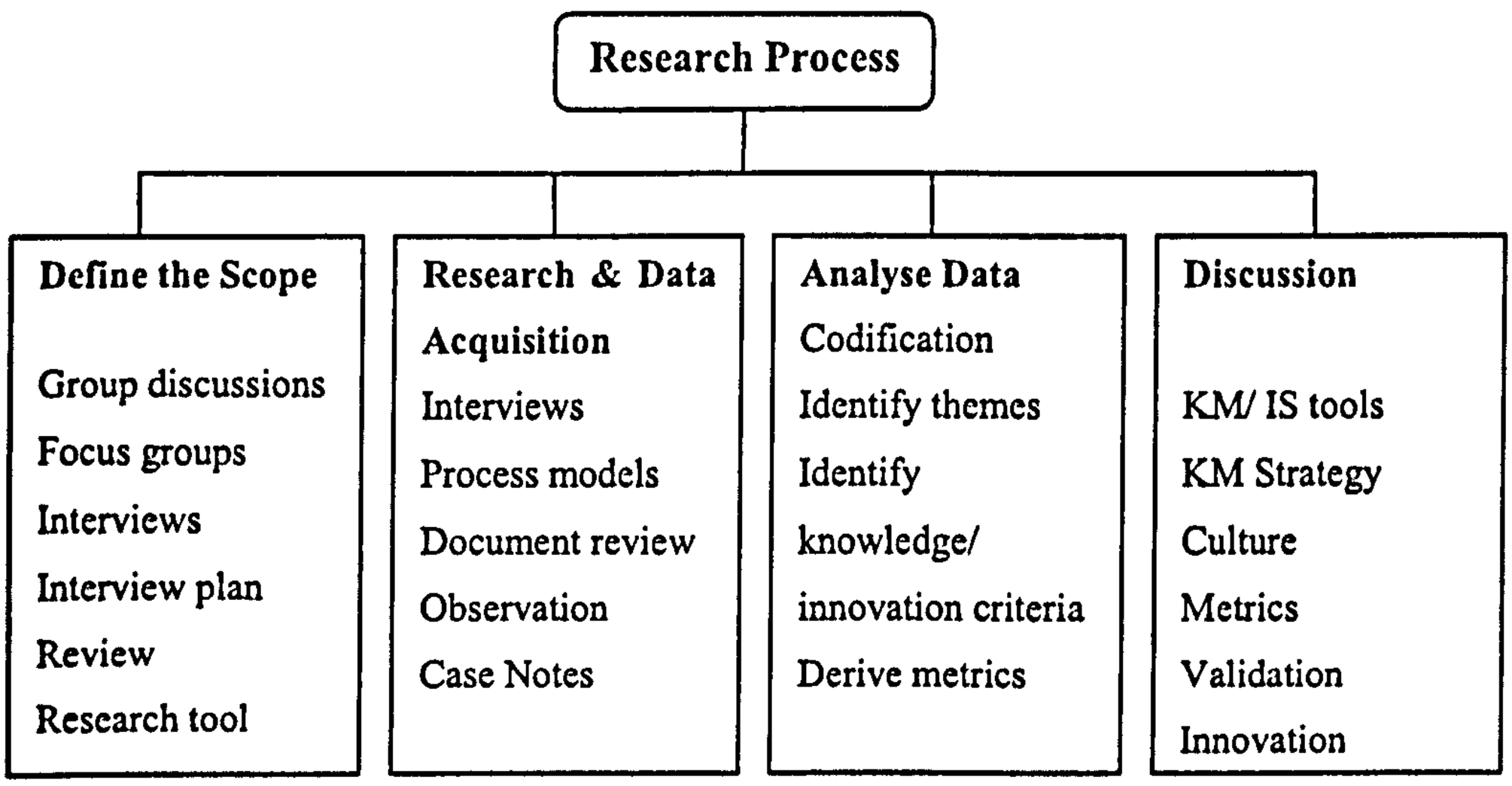

Figure 5.1: The Research Process

This chapter deals primarily with the processes labelled as 'Define the Scope' and 'Research & Data Acquisition', seeking not to collect extensive data, but instead to validate the research approach and create a preliminary tool with which to study innovative practice. Chapter 6 then follows on from this preliminary validation and applies the research tool across the organisation, obtaining a greater depth of data via multiple interviews, direct and participant observation, process modelling, archival analysis and the utilisation of case notes.

5.2 RESEARCH METHODOLOGY

A selection of key AstraZeneca R&D personnel and a Knowledge Management focus group were chosen to question and ground the theory behind the innovation model detailed in Figure 5.3. The preliminary questions were derived from the innovation and Knowledge Management literature and a case study concerning the effectiveness of a Community of Practice within AstraZeneca. The results of the Community of Practice case study were presented at an academic conference to high acclaim. The paper received excellent reviewer's comments and generated a lively discussion with positive feedback from a number of noted audience members. The reference to the paper is included within the List of Publications.

In all, six areas were identified as being pertinent to the use of Knowledge Management to drive pharmaceutical innovation within AstraZeneca. These are illustrated within the model outlined in Figure 5.3. Each step of the model is derived from the literature review of Chapter 3, and combines with the research tool to form the basis of an innovation framework that has been expanded in Chapter 10. Wiig et al. (1997) define a framework as a set of methods, techniques and tools that allow Knowledge Management to be performed in order. Hence the innovation framework developed by this stage of the research, consists of the initial innovation model of Figure 5.3 that is supported by a research tool or question set. Wiig et al.'s (1997) definition of a framework implies that further tools, methods and techniques are required.

Hence this chapter contributes to the research by developing the first tool of the framework that has allowed the author to uncover the subsequent Knowledge Management tools, methods and strategies that together form the innovative framework that is required by the innovators within AstraZeneca. Figure 5.2 outlines how the research tool may be applied to an organisation in order to uncover the specified outputs that may eventually drive innovation forward.

This pilot study concentrates upon the research tool primarily, but also serves to underline where the innovation model sits with respect to innovative practices within AstraZeneca.

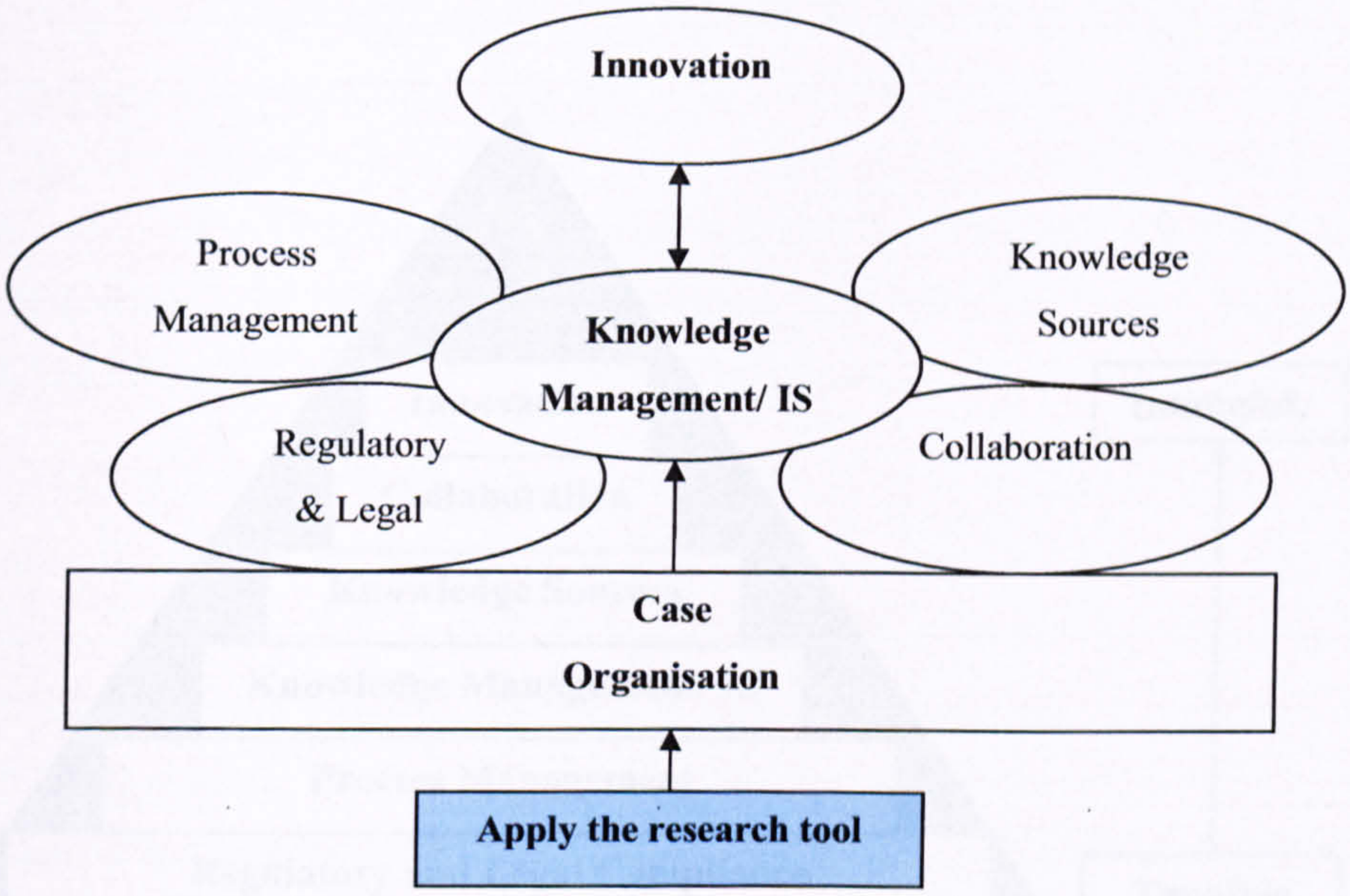

Figure 5.2: Developing an Innovation Framework

The American Heritage Dictionary of the English Language (4th Edition) describes a framework as:

"A set of assumptions, concepts, values and practices that constitute a way of viewing reality."

Thus the assumptions and concepts are derived from the literature review of Chapter 3 and form the Innovation Framework of Figure 5.2. While the values and practices within the innovation framework are themselves derived from the case study within AstraZeneca and uncovered by using the research tool. The use of the research tool has allowed the discovery of what an innovative organisation should look like with respect to processes, information, knowledge and Knowledge Management.

While the innovation framework may be viewed as a structure that allows the visualisation of the knowledge required for innovation and allows the user to examine the potential scope and application of Knowledge Management within AstraZeneca or the studied organisation.

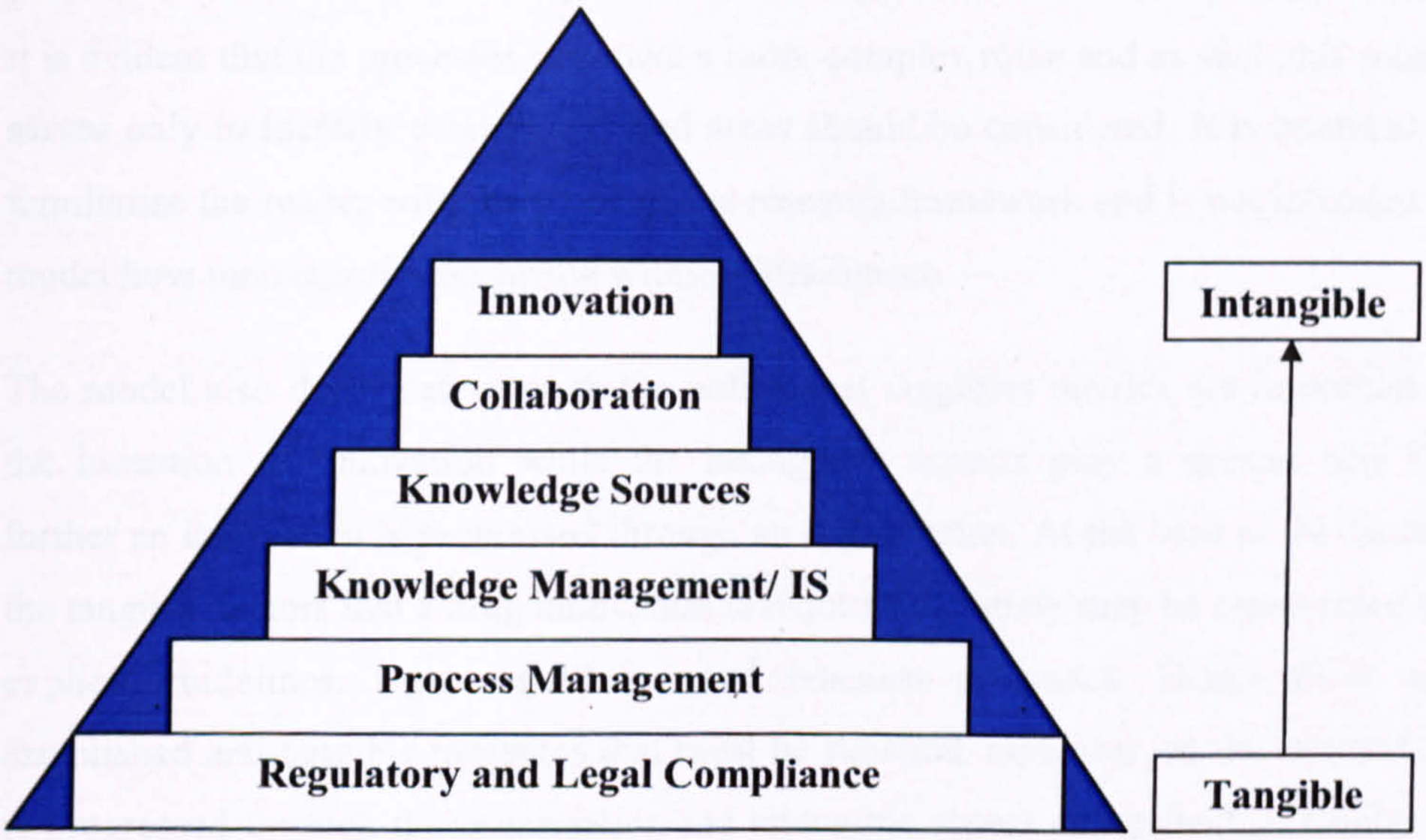

Figure 5.3: Drug Development Innovation Model

To date the model within Figure 5.3 has been used to collect a set of assumptions that are derived from the literature review of Chapter 3 and can be tested by the research tool. Each step of the model forms a component part of the organisational structure that is hypothesised to allow and influence pharmaceutical drug development and innovation. Innovation is visualised as the pinnacle of the triangle and in order for an innovation to succeed it must progress from the ground up. This process is deemed to begin by progressing through the myriad of compliance issues, then only after the innovation has passed the internal processes and organisational structure of AstraZeneca, may an innovator consult Knowledge Management and IS systems to locate the knowledge required to continue.

Failing to find the knowledge there, may lead the innovation to fail or, alternatively, the innovator will consult alternative means of deriving the knowledge from sources such as collaboration. The published literature states that collaboration plays an integral role within innovation and, as such, is close to the peak of the model, indicating that collaboration may be a requisite of innovative activity. Although pharmaceutical development is quoted as a linear process within this model, in reality it is evident that the processes may take a more complex route and as such this model serves only to identify what factors and areas should be considered. It is intended to familiarise the reader with the scope of the research framework and is not intended to model how innovation is occurring within AstraZeneca.

The model also draws reference to the notion that tangibles metrics are important at the inception of innovation while the intangibles aspects play a greater role the further an innovation is progressed through an organisation. At the base of the model, the tangible factors that a drug innovation is required to satisfy may be represented by explicit guidelines, legal regulations and business processes. Hence these are established and tangible measures that must be satisfied. However, as the innovation is progressed through the organisation the intangible aspect of intellectual capital is drawn into play. The nearer an idea is to fruition, then the greater the demand for human capital, customer capital and structural capital becomes. This aspect of the model is derived from the analysis of the literature and suggests that each of these areas of intellectual capital may be required in order to progress, although at this stage of the research it is difficult to draw valid conclusions. For example human capital relates to the knowledge and experience of the innovators, customer capital relates to the demand for the innovation, while structural capital refers to the supporting infrastructure required to realise the innovation. As of yet, no authors have attempted to encompass and explore the relevance of all of these areas in relation to pharmaceutical innovation. Although these factors are derived from an earlier case study and the literature review of Chapter 3, there is scant published material that identifies the intangible drivers and innovative criteria that supports these components.

This observation places this research in a unique position and it is envisaged that by fulfilling the research objectives a worthwhile contribution to the public domain of knowledge will be made. Therefore at this stage the framework possesses a model of innovation and a research tool or framework which will be expanded and developed within the latter chapters of this thesis.

5.2.1 OBJECTIVITY

When conducting interpretive research, it is wise to begin with a loose plan and structure (Oates, 2006), in this case the high level topics of the areas to be addressed by the interviews have been uncovered (e.g. Figure 5.3). However, structure can imply inflexibility and the author is well aware that the act of using a preconceived research tool creates a risk that research tool's specificity will cause a lack of objectivity. Thus it is important to avoid the situation where the researcher dictates both the question and the content of the response, whereby the interviewee elicits responses that they think are required rather than their true opinion (Oates, 2006). However, in order to address Objectives 1 and 2, a degree of specificity is required. Miles & Huberman (1994) believe that in order to conduct effective research you must ask how the research question can be answered, stressing that:

"Simply thinking of the methods of data collection will help clarify concepts and help set the priorities for the actual data collection."

In this respect the innovation model has helped to establish the context that the research will cover, while helping to prioritise the areas that are to be addressed. Rather than serving as an inflexible approach, the innovation model merely seeks to guide the researcher and ensure that the data collected by applying the research tool is both relevant and reproducible.

5.2.2 AN INTERPRETIVE ROUTE

As this research takes an interpretive form, it was decided that the "open-ended" or semi-structured interview would allow the author to uncover new relationships and patterns within the innovation framework (Kvale, 1988).

This is an important point and the choice of the interview as the data collection method signified that this research would be covering new ground. Miles & Huberman (1994) believe that a single exploratory case study of this nature can benefit from a less formal approach.

Yet, although this chapter seeks to explore what is occurring within innovative practice, it is also charged with creating a research tool that can be used to accurately identify the innovation criteria across multiple cases within the organisation. Hence a balance should be sought between the two opposing traits. A balance where the research tool allows the researcher to uncover the innovation criteria that are required to drive innovation across multiple case studies; but also allows the interpretive angle to sit alongside this and identify and assess the characteristics that are unusual within each study. Miles & Huberman (1994) describe the informal approach as little prior instrumentation and align this technique with "basic" research. Due to the nature of the case study, the author was at liberty to embrace both of the approaches (Yin 1994), commencing informally at first and then aligning and strengthening the research tool over time.

5.2.3 GOALS

The goal of this chapter is to develop the research tool in order to study innovation accurately and allow the comparison of innovative practice across multiple organisations and partly satisfy Objectives 1, 2 and 3. The very nature of pharmaceutical innovation is a fuzzy concept and Miles & Huberman (1994) emphasise that when faced with a complex organisational problem, a means to clarify and elute rich contextual data is through the collection and analysis of qualitative data.

It was taken for granted by the author that the data collected would be contextually rich in nature and may be used to ground the research framework and literature, and may also be used on an iterative basis to further enhance and develop the research framework, so as to develop a research tool that AstraZeneca may employ in the future.

To ensure that the needs of the company were being met by the research, a series of discussions took place within AstraZeneca to highlight the areas of importance to the organisation at present. These were identified as:

- The innovation strategy of AstraZeneca
- The knowledge management strategy of AstraZeneca
- The IT strategy of AstraZeneca
- The present functionality of Knowledge Management/ IT systems
- The required functionality of Knowledge Management/ IT systems

Therefore, a secondary overall goal of the research was to provide AstraZeneca with a rich picture of what is occurring within their innovative processes, thus helping to justify the research and ensure that AstraZeneca employees are aware of where and how Knowledge Management practices can help. This pilot study also served to generate interest in Knowledge Management within AstraZeneca and helped to obtain the necessary resource required to tackle Knowledge Management issues. It was envisaged that the analysis and publication of the results surrounding these factors would gain the backing of AstraZeneca managerial staff, with the net result being that Knowledge Management is viewed not as a short term goal, but a long term strategy that can return tangible and financial benefits (see Roth 2003).

The final goal of this pilot study was to build upon the author's current knowledge of the drug development environment and identify other innovative business processes that may be useful to the research. Examples of these innovative business processes may then be used as discussion points and analysed with subsequent interviewees in order to further clarify the research aims and objectives.

5.2.4 LIMITATIONS

As this was a pilot study targeting a small sample of interviewees, inevitably there were limitations.

Therefore this initial pilot study was used as a basis for understanding what is currently occurring and only after additional validation and refinement had been carried out in Chapters 6, 7, 8 & 9 were the results used to model the Knowledge Management toolkit and fulfil Objective 4 in Chapter 11.

5.2.5 ASSUMPTIONS

As the components of the framework are largely derived from previously published studies on Knowledge Management identified within Chapter 3, it is assumed that these represent the key areas that cause the greatest difficulty to an organisation implementing Knowledge Management. Areas such as the organisational culture, working practices and availability of Knowledge Management and information systems are all noted to conspire to hinder the effective working practices of employees. Numerous examples of published studies supporting the basis for choosing these assumptions are provided within Chapter 3, Section 3.3 through to 3.5.

5.3 DEVELOPING THE RESEARCH TOOL

The pilot study innovation model was used as a 'think-tank' and was intended to visualise these points made by the literature on pharmaceutical development. With the ultimate objective being to illustrate that the proposed research tool and innovation framework could answer the research aim. Hence practical application of the research tool was required to identify and address any areas of the research that was poorly conceived or lacking, in line with recommendations by Miles & Huberman (1994). Although components of the research tool had been applied and discussed in a conference paper (see Appendix 1), this round of the research required a greater level of detail and investigation than had previously been employed, embracing not only the work of a single AstraZeneca department, but the knowledge-based work of the R&D wing of the organisation as a whole. In order to apply and refine the model, group discussions were planned and initiated.

During these the author presented and established the goals of this research and Knowledge Management as a whole, in order to draw comment from the delegates. At least 8 of these group discussion sessions were conducted with innovation experts, senior R&D staff, AstraZeneca IS staff and personnel involved with Knowledge Management research and strategy. The sessions ranged in size from 3 people to 10 people and comprised of innovative personnel identified by the author from his time within the company. These sessions were conducted to ascertain the extent of Knowledge Management use within the company and relied upon promoting discussion under the headings suggested in the research model of Figure 5.3 and allowed the clarification of the more detailed interview questions of 5.3.1 through to 5.3.6. The author's role within AstraZeneca focused upon the use of Knowledge Management and hence it was relatively simple to organise these sessions, which were conducted over a six month period and lasted from 2 hours to a full day. The author also undertook the role of a participant observer in at least 11 more meetings centred upon the development of Knowledge Management tools within AstraZeneca that were organised by AstraZeneca Information Systems Department and senior personnel from AstraZeneca Clinical and Discovery.

After the research framework and questions had been devised a total of 15 semi-structured interviews were conducted with AstraZeneca staff over a period of a month, using the interview framework detailed in 5.3.1 to 5.3.6. These interviews were designed to 'set the scene' and identify where innovative practice was occurring and how Knowledge Management was perceived by employees. The interviews also served to identify employees who were involved in innovative practice, both at a managerial level and at a grass roots level in order to gain as wide a perspective as possible. All interviews were recorded into MP3 format and each interview lasted between 45 and 160 minutes, with the typical interview being 60 minutes in length. After the interview, the audio was transcribed and checked with the interviewee to ensure accuracy.

In keeping with guidelines recommended by Oates (2006), when transcribing the interviews the author made a point of utilising italics for emphasis and exclamations marks for heavily emphasised points, laughter or emotions were also recorded as encountered. The criteria by which innovative personnel were chosen throughout the pilot stage discussions and interviews, centred upon the employees involvement within innovative business processes or innovative drug development work. AstraZeneca is keen to highlight outstanding innovation by means of a public award; therefore employees could be easily identified by searching the in-house literature and archives relating to these awards. Additional personnel were chosen and identified via nomination by their peers for their contribution to innovative work. Innovations assessed included, a novel clinical trial, a novel dosing technology, a novel Knowledge Management system and a novel R&D project, amongst others.

It must be noted that this stage does not intend to reach "theoretical saturation" as suggested by Glaser & Strauss (1967), rather it merely seeks to set the scene and familiarise the reader with the case study organisation and ensure the research framework can accurately answer the aims and objectives in Chapter 2. These sessions, the interviews, the Community of Practice conference paper (see Publication List) and the corresponding literature review of Chapter 3, were all used to create the series of questions detailed in 5.3.1 to 5.3.6 and ensure they covered the areas of interest within each component of the research framework.

The questions were also designed to address the goals that AstraZeneca have demanded from the research, as detailed in 5.2.3. The interview structure and scope that forms the question set of the research tool will now be presented and discussed.

5.3.1 INTERVIEW INTRODUCTION

Firstly the author introduced himself to the interviewee and provided a rationale of the project aims, objectives and potential benefits in order to set the scene and address any ethical concerns the interviewees may have had.

A series of initial questions were designed to provide a brief overview of the interviewee's role and background, and provided a rationale as to why they have been chosen as an innovator within AstraZeneca. These questions were:

1. Please give a brief description of your role and job responsibilities within AstraZeneca.

2. What do you believe AstraZeneca's strengths are?

3. Where do you see your role within AstraZeneca?

4. How long have you occupied your role?

As previously mentioned it was envisaged that the interviews conducted in the later stages of the research may focus upon investigating a single innovative business process. Therefore this first series of questions could be used to introduce an innovative work or business process that the interviewee and the author would focus upon throughout the interview.

5.3.2 INNOVATION AND RISK MANAGEMENT

After the introductory stage the research framework seeks to address Objectives 1 and 2, by visualising how innovation is occurring within the interviewee's respective roles, the questions are derived in part from work by Tether (2003), Nieto (2004) and Dorabjee et al. (1998).Throughout the main interview process the author was interested in both the innovative nature of the work and how the knowledge and information was acquired to complete the task or tasks. On providing information regarding the knowledge processes involved within innovative work, the interviewer would draw a rough outline of these processes which were then validated at the end of the interview with the interviewee. The questions used to examine these areas were:

5. What does innovation mean to you?

6. Does your role encourage you to be innovative?

7. Can you describe an innovative process or project you have been involved in?

8. How innovative do you believe your innovation was?

9. Was the end result from momentary inspiration or steady development?

10. How long did it take to realise the idea, from conception to realisation?

11. What barriers did you encounter during the formative era of your work?

12. Was the idea the result of a team or individual effort?

13. What size was the team used?

14. Were you reliant upon previous AZ innovations to achieve your innovative work?

15. Do you believe that innovation within your area occurs through a methodical scientific approach or luck?

16. Do you always build upon previous experience or is it more chance that the right people are there at the right time?

17. In your view, does AstraZeneca build upon previous work or have to reinvent knowledge?

18. Does your work mainly focus upon providing project solutions using existing processes or does it aim to provide an entirely novel solution via "out of the box" thinking?

19. Do you believe that innovation requires risk taking?

20. How do you weigh up the risks involved?

21. Can you mention any positives and negatives associated with these processes?

22. Do you have adequate support from the organisation when undertaking innovative behaviour?

23. Are there any ways that are available so you can publicise and disseminate your work?

24. How easy was it to make the company aware of your work, gain backing and investment?

25. Do you believe you are more innovative in the initial stages of a role or in a long-term position? Please elaborate upon your answer with regards to accrued knowledge, time in the job, fresh outlook, etc

5.3.3 KNOWLEDGE MANAGEMENT WITHIN ASTRAZENECA

KM literature implores that a knowledge culture is essential in order for innovation to succeed within a company (e.g. Darroch, 2005). Specifically this section of the interview was used to fulfil Objectives 2, 3 and 4 by examining the roles Knowledge Management and Information Communication Technology (ICT) play in supporting innovation. As an example, AstraZeneca employees commonly utilise two systems labelled the Global Electronic Library (GEL - a large regulatory document repository) and Product Knowledge Transfer (PKT - a global information repository for drug and project related information across AstraZeneca) to locate information.

The concept of intellectual capital is also raised by the questions and seeks to ascertain what this term means to the employee. Collectively these questions draw upon works by Alavi & Leidner (1999), Scarborough et al. (1999) and Robertson et al. (2000) and pay particular regard to the community and collaborative model of knowledge exchange suggested by Wenger et al. (2002).

26. What does Knowledge Management mean to you?

27. What role did Knowledge Management tools such as forums, information systems, PKT and GEL, etc. play in providing knowledge and support?

28. What are your favoured methods that you use to communicate at a cross-project/ functional level? Examples include: email, phone, intranet, e-room and discussion forum.

29. Are there any particular technologies you've seen or used before, maybe within AstraZeneca or externally, which you believe could be useful? Examples include: databases, discussion forums, blogs or Web Logs and MSN Messenger.

30. Do you have access to a specific budget for IS projects and support?

31. Are your project information and knowledge needs analysed by AstraZeneca IS employees as the project is undertaken?

32. Have you had any IS/ KM projects developed for you?

33. Were you involved within the design and specification of it?

34. Can you elaborate as to the need and success of these schemas?

35. If not, are you aware of how to apply for funding and the potential use?

36. Does the global IS strategy align with your needs?

37. Have you and your department/ team/ organisation received help and training when using new software?

38. Do you take part in IS surveys?

39. As a key innovator, have you been contacted to analyse your needs? If so, has the information you have given been used to provide a solution?

40. Was there a budget assigned to support your case?

41. Are you aware of metrics or measurements used to assess the impact of Knowledge Management within AstraZeneca?

42. What do you understand by the term 'Intellectual Capital'?

5.3.4 KNOWLEDGE AND INFORMATION SOURCES

The following questions were intended to analyse the resource and knowledge bases that are available to AstraZeneca employees and discover whether they meet the needs of the innovators. Although the framework has touched upon these sources previously, this section was used to discover whether the chosen research strategy can accurately answer Objectives 3, 4 and 5.

The questions are derived, in part, from a Knowledge Management survey tool suggested by Coombs et al. (1998) and work by Tijssen (2004).

43. What sources of information do you utilise? Please discuss the sources you concentrated on to develop your innovation, these may include: online journal sources, peer reviewed work, internal data and external data, AZ information and knowledge sources.

44. Within your work, do you believe that AZ offers sufficient specialist knowledge to achieve the task assigned to you?

45. Does everyone who needs it have access to "the right" information sources in order to innovate?

46. Do you value particular sources over other areas?

47. Do you find it easy to disseminate information and knowledge?

48. Do you regularly use external, technology-based knowledge sources?

49. Can you comment as to why you use them, what makes them useful? Is it the content? The layout? Familiarity?

50. Do you utilise similar or the same information systems as your previous role(s)?

51. Do you utilise the information searching capability of the librarian service? Can you discuss your use? Do you value the service?

5.3.5 KNOWLEDGE CULTURE, COLLABORATION AND KNOWLEDGE NETWORKS

This set of questions was designed to explore the collaborative culture that appears to drive the innovation processes within AstraZeneca and addresses Objectives 1, 2, 3 and 4. Zeller's (2002) work indicates that a trusting working relationship is important within an R&D organisation and the following questions were used to ascertain the importance of trust and collaboration within the pharmaceutical R&D framework. The following questions are intended to address these issues and discuss the importance of knowledge that is derived from external collaborations, in line with work by Kneller (2003):

52. What part does collaboration play within the daily processes of your work? This may be related to cross-project teams or cross therapeutic area or research area collaborations.

53. Are there specific tools, which you can use to facilitate this work? These may be net-meetings, email, discussion forums, eRooms, etc.

54. Do you believe that AstraZeneca provides the systems to encourage innovation and collaborative behaviour?

55. Are there specific processes to encourage collaboration within your work?

56. Do you utilise cross-functional teams to enhance innovation? These may be from different project areas within AstraZeneca, i.e. therapeutic areas or research areas.

57. Do you collaborate internationally with R&D colleagues from Sweden, the UK, the US or Japan?

58. Does spatial proximity to your colleagues influence your sources of knowledge?

59. Is there a review panel, which oversees these collaborations? I.e. review boards or steering committee. If so, please discuss the level of information capture; was it thorough or a high level overview? What is the scope of the data captured? (Key players and the key decisions, etc.)

60. What is the accuracy, usefulness, applicability and value of data gained from such collaborations? Can you (or do you) use the data?

61. Do you or your project team use external collaborations with outside firms, such as biotechnology companies to pursue innovative ideas?

62. Can you describe examples of these where such work has led to innovative behaviour?

63. What value does your work derive from such collaboration to drive innovation? Please discuss your opinions on the value and benefit of deriving innovative ideas from external sources; these may be collaborations, journals, seminars and conferences, etc.

64. Can you recount favourable collaborative projects and were there any common processes throughout them?

65. Were you reliant upon any particular method of communication, examples include: meetings, phone, teleconferences, net meetings, etc.

66. Do you have a review panel for external collaborations? If so, please discuss the level of information capture, was it thorough or a high level overview?

67. What is the scope of the information captured? (Key players and the key decisions, etc.)

68. What are the accuracy, usefulness, applicability and value of data gained from such collaborations? Can you (or do you) use the information?

69. Social identity is often perceived as a key facet of a working and innovative environment, can you comment on your working environment?

70. How much prior knowledge and background credibility do you require to conduct a formative working relationship?

71. Do you strive to make yourself heard?

72. Do you believe that a project success is dependent upon who implements it?

73. Do you map the skills and knowledge of the people and departments within your innovative activities? Is this information used in subsequent projects? Examples include: skills used, FTEs, resources, products, costs and the knowledge base used.

74. Is this information published to external departments? Do other AstraZeneca departments know about these maps?

75. Have you undertaken work in other departments or other roles while working for AstraZeneca?

76. Are you encouraged to take positions in different areas or adopt multi-disciplinary roles? Did you find this a valuable experience

77. Within these roles, did you note any working practices that favoured innovation?

78. Did they use tools or systems which would be of use to you? Please elaborate upon these.

79. Can you envisage a Knowledge Management tool to span these areas, or link personnel from these different disciplines?

5.3.6 PROCESS MANAGEMENT

It may be assumed that the drug development processes within AstraZeneca R&D are designed to drive innovation and further research, yet no empirical evidence exists that supports this assumption. The following questions were designed to fulfil Objectives 1 through to 4 and ascertain the knowledge sharing behaviour of the process teams at the forefront of the drug development processes. Concentrating upon the key points raised by McKinlay (2002) and Hayes & Walsham (2000):

80. Do you believe AstraZeneca's drug development processes support innovation?

81. Are your department's/ team/ organisation's objectives clearly defined?

82. Do you map innovative processes and compare them against other similar areas? Do your employees get involved in this process?

83. Do you believe that the information and knowledge gathered at project milestones and reviews is useful and is it available?

84. Have you used such information/ knowledge before?

85. Can you envisage using previous project data when starting a newer project?

86. Do you measure the intangible aspects of project work?

87. Do you believe that AstraZeneca offers a structured review of innovative drug projects after completion, including areas such as: process modelling, information and knowledge flow, intangible metrics, personnel review and appraisal, successes and failures, new skills learnt, task competence on an individual/team level, problems and redundant processes?

88. Do you model processes or review innovative cross-project work?

89. How simple is the process of accessing relevant information/ knowledge on cross-project work? Are there formal guidelines to achieve this?

90. Do you believe the knowledge gained from these processes is valuable? Can you give examples to support your views?

91. Do you believe that a formal process for capturing best-practice decisions exists? Have you ever used best practice software to monitor process or innovation quality? Have you reflected on work that could have been done better?

92. How do you record the risks involved in innovative work?

5.3.7 R&D LEGAL AND REGULATORY INFLUENCE

The pharmaceutical R&D drug development process is a highly regulated and ordered affair. Internal and external guidelines and regulations exert a strong influence upon the various processes. The following questions will analyse the extent to which these pressures contribute to, aid or hinder innovation within the development processes. They are based, in part, upon internal AstraZeneca documents and work by Koretz & Lee (1998) and Dougherty (2006).

93. To what extent do regulation and guidelines impact on your work? Please discuss those that directly impact innovation and are relevant to your area. Examples include the FDA (Food and Drug Administration – American government regulatory agency http://www.fda.gov/), AZ internal guides and external regulations.

94. How important are internal AZ procedures to your work?

95. Do you conduct your work within the guidelines or try to justify a change in approach?

96. Are the guidelines and regulations easily accessible during your work? Do you consult any particular reference sources? Are these sources accurate and clear? Do they include case study information?

97. Do the AstraZeneca Knowledge Management and Information tools you use take account of these regulations?

98. To what extent are they taken into account?

99. Are you aware of any regulatory guideline governing the use of the systems - do people tend to store knowledge and use the tools in the same way?

100. Are you aware of specialist help, services or guidance in terms of Intellectual Property searches, patent rights, internal/ external collaborations, etc. Can you perform these searches without specialist help? Please describe the available tools to search Intellectual Property and the failings of these tools.

5.3.8 INTERVIEW CLOSE

The interview research tool was designed to address the research aim and objectives and, above all, provoke thought and discussion with the innovators targeted. As the interview questions are semi-structured, each topic is intended to allow the interviewee to discuss multiple issues and areas that are successful within AstraZeneca. Time constraints meant that each interview was expected to last up to 2 hours, it was also clear that the interviewee could not be expected to answer all of the questions. Throughout the interview the author used the questions as prompts and, in this way, covered all the aspects of the innovation model (Figure 5.3).

As the question set deliberately employed overlap within the questions, it was expected that the interviewee would 'wander' across multiple topics and such behaviour was encouraged at this preliminary stage, in line with recommendations by Miles & Huberman (1994). The interviewee was also encouraged to highlight areas that they believe affect the innovation processes and raise ideas for process improvements. The interviewees were also expected to voice questions that they believed are important for the research to address. Questions outside of the initial research framework were noted and discussed with the interviewee as they arose.

5.4 PRELIMINARY RESULTS OF THE RESEARCH FRAMEWORK

Cross sections of innovative AstraZeneca employees were initially chosen with which to conduct the preliminary interviews. In order to provide a representative sample, 15 personnel were chosen in total. These consisted of senior managers from AstraZeneca Clinical and Discovery, research employees within AstraZeneca Clinical, and employees from AstraZeneca IS. On completion of the interviews, the transcripts were studied to ascertain if the research tool was viable and if further refinement of the question set in line with the interview findings was required. The results of the preliminary interviews are presented in the next section in line with the innovation model outlined in Figure 5.3.

5.4.1 RESULTS: INTERVIEW INTRODUCTION

The introduction of the research aims and objectives were well received by all interviewees. All interviewees unanimously agreed that Knowledge Management should be a key component of AstraZeneca's innovation strategy. As an initial sign, this is encouraging to discover that, firstly, employees are aware of Knowledge Management, and secondly, they appear to be keen to embrace Knowledge Management within the organisation.

5.4.2 RESULTS: INNOVATION AND RISK MANAGEMENT

The literature review of Chapter 3 discovered that the definition of innovation is rarely typical; instead the definition of innovation is open to interpretation.

From these initial findings AstraZeneca appears to be viewed by its employees as an innovative organisation. However, when interviewees were pressed as to what they believed constituted innovation the majority viewed innovation as a process. This is evidently an encouraging finding as the research aim of linking Knowledge Management with innovative processes would appear to be feasible. This is further reinforced by the notion that an innovative culture appears to exist. A senior figure commented:

"Personnel want to share best practices and learn from others within the company."

Yet, although the outward perspective appears to indicate an innovative environment, many interviewees agreed that while in principle AstraZeneca was innovative, implementing innovation in practice was difficult. An interviewee commented:

"Innovation to me is how we can think outside of the restrictive processes associated with drug projects and use other ways to add value."

Another interviewee viewed innovation as a 'hidden' entity that required considerable groundwork to allow an innovator to 'fit' their innovation within AstraZeneca's existing operating procedures.

This raises the observation that it is the visibility of AstraZeneca's innovators, their innovations and the potential application of their innovation that is most important to study. This is coupled with evidence that AstraZeneca's own internal processes are restricting innovation. These findings provide this research with a sound rationale with which to proceed and address how these issues may be overcome with a Knowledge Management toolset. A factor that requires further investigation suggests that innovation stems from an individual response and that employees are having to operate outside of the guidelines and timelines imposed by AstraZeneca projects. This observation was supported by the finding that the innovators interviewed possessed a degree of autonomy, a senior clinician commented:

"I'm lucky that I don't work on a lot of drug projects, I only work on a few which means I can make them good."

These initial comments indicate that although ideas are stemming from the individual, in order to get an idea up and running, innovators require further guidance and strategic advice when attempting to take a creative idea from conception to implementation. Some of the more senior interviewees had the flexibility, influence and resource that allowed them to evaluate, discuss and implement innovative solutions on their own when conducting drug project work.

Another less senior interviewee suggested that the effort taken to convince senior management to make a financial investment was often far too resource intensive. One interviewee had, however, stuck with their convictions and an innovative clinical study had been introduced as a result. The disparity, observed at this early stage of data gathering, indicated that an employee's seniority directly influences their innovative behaviour; however, this point required further clarification and analysis in order to assess its importance. Overall though, the initial data points to the lack of guidance when innovators are attempting to introduce innovative solutions or work around the established processes of AstraZeneca. However, the process that caused most concern to innovators was the process of evaluating the risks involved in undertaking innovative work. When asked how they assessed the risks an interviewee commented:

"When you see an opportunity you must be able to assess the potential of it, a high potential innovation would be taken and a low potential innovation would be avoided, it comes down to a ratio."

However, there does not appear to be software tools or a documented procedure in place to achieve this, let alone capture or publicise this decision making process. Instead, interviewees felt that it was largely their own responsibility to weigh up the potential benefits and risks. Discussing issues of risk brought the interviewees to begin exploring the provision of knowledge and information sources within AstraZeneca, a topic that is addressed in the second component of the framework.

5.4.3 RESULTS: KNOWLEDGE MANAGEMENT WITHIN ASTRAZENECA

The interviewees were asked to comment upon the potential of Knowledge Management to aid innovation within AstraZeneca and all interviewees agreed that Knowledge Management can play an important role. However, although the concept of Knowledge Management was recognised by all interviewees, the practical means associated with what Knowledge Management entails were unclear. An interviewee commented that:

"I would like to see AstraZeneca making people more aware of what knowledge and information is available to me."

Similar views were upheld by other interviewees, who often questioned the visibility of AstraZeneca's Knowledge Management/ IT strategy. This suggests that this research will provide important insights into how AstraZeneca can address innovators knowledge and information need more accurately. One senior interviewee summed up the feelings of many:

"Science based research generates a lot of knowledge and information that sits in many different forms, and what doesn't happen is the integration - there is no ability to cross these sources of knowledge and information."

Evidently employees feel under-served by the AstraZeneca Knowledge Management policy. However, given the potential scope and role of Knowledge Management within a pharmaceutical environment, this is hardly a surprising finding and further research is required to generate constructive solutions to these issues.

5.4.4 RESULTS: KNOWLEDGE AND INFORMATION SOURCES

The interviewees widely agreed that knowledge and information may be obtained from a disparate range of sources, yet interviewees hinted that the preferred means of information and knowledge acquisition centres upon personal contact. A senior interviewee noted:

"Within the biomedical literature there is a huge amount of slicing and dicing – so to get to the bottom line talking to someone is often much quicker."

Yet one interviewee did favour online databases such as Ovid and PubMed as the primary means of acquiring data and information when conducting innovative work. Hence, there is a variety of knowledge and information sources open to AstraZeneca's employees, yet the use of colleagues and online databases were consistently mentioned and the use of specific Knowledge Management and IS tools provided by AstraZeneca were largely omitted.

A senior interviewee commented on the large amount of disparate information and knowledge sources that is available within the AstraZeneca intranet:

"What we don't do is bring this together. Sometimes we are not aware of the information for months or years even and then suddenly it strikes you that there is a correlation, and some value is made, and the connections are made, and maybe new knowledge comes from this. So what I think is that we have a real problem!"

What is clear is that R&D personnel are required to keep abreast of large amounts of data, information and knowledge and draw valid conclusions from these sources. One interviewee commented:

"This certainly isn't an easy task, if we start from some Discovery effort, there are many project based problems which we try and address and generate scientific knowledge on as we go along; and there are many independent, additional things happening in the world, literature, competitors and within other parts of AstraZeneca...which we must address and keep up to date with."

This was a common theme throughout the interviews and an interviewee suggested that it was not only the breadth and complexity of internal and external knowledge sources on offer that troubled them; it was also the process of weighing up the relevance of sources once acquired and understood.

To overcome this, interviewees often relied upon external consultants to provide them with detailed knowledge regarding a drug's toxicology or pharmacokinetics. Interestingly the internet was also listed as a primary source of information:

"Yeah, I would say I use external experts on a consultancy basis...occasionally if I'm struggling I'd do a general search on the internet to get a basic understanding."

This finding was replicated across the sample population and hints that AstraZeneca's own internal intranet and information sources lack the necessary depth of information and knowledge for innovators to proceed.

At times staff are being forced to look to the internet, yet by the admission of the interviewees, the reliability of information and knowledge on the internet is questionable hence the information gleamed is treated with greater suspicion.

5.4.5 RESULTS: KNOWLEDGE CULTURE, COLLABORATION AND KNOWLEDGE NETWORKS

The research framework then moved on to facilitate discussion on the issues of collaborative working and innovation from the perspective of the employees. A senior interviewee summed up the feeling of the sample, when they explained the notion that innovation was concerned with the process of acquiring knowledge from colleagues or personal networks of external contacts:

"Two of the main knowledge assets are internal people and external people."

This component of the research framework and associated questions appeared to be well placed to address the issues identified by the staff so far.

Having uncovered a level of dissatisfaction with the current Knowledge Management and information strategy previously employed by AstraZeneca, it was expected that, as the research scope and sample was broadened, trends and high priority items would appear as the data was subsequently analysed and codified in line with recommendations by Miles & Huberman (1994).

The reliance upon collaborative working patterns and Communities of Practice is an area that Knowledge Management is well positioned to address and lends further confidence to the main research aim and objectives. The following section briefly addresses the findings relating to the identification of the drug development processes that are driving, and in some cases hindering, innovative work within AstraZeneca.

5.4.6 RESULTS: PROCESS MANAGEMENT

AstraZeneca appears to be typical of large organisations striving to balance the demands of efficient and manageable processes with the elusive knowledge requirements of innovative work (e.g. Dilnutt 2002). An interviewee who had recently joined the company highlighted the potential of AstraZeneca to innovate:

"So I knew AstraZeneca quite well from an external view, but I was a bit surprised to see they had a good early [drug development] pipeline but a poor ability to do anything with it."

Although few interviewees were not overly pressed with regard to identifying specific processes, one interviewee mentioned that introducing a new clinical study design was a lengthy process that required a resource intensive development period of 18 months:

"You know, because it was a learning process as well, it was a new process and we had to write this into study protocols. Consent forms and our ideas about what we needed to look at were evolving as we went along, and this was a result of literature searches as we went along."

The notion of the intensive requirement for resource appears as a central trend to innovative work, interviewees were also unanimous in the belief that AstraZeneca's processes were inhibiting innovative practice:

"I actually think our processes are very inhibitive in some respect. Because we have a complex organisational model, the matrix is complex, levels of accountability are odd and strange and decision resides at multiple levels instead at one clear level...I think having a model like that will always make things harder and slower."

Data such as this suggests that problems do exist within the core innovative ability of the company. From this initial research with senior management and R&D scientists involved in both managing and implementing innovation, the majority appear to suffer hindrance or barriers to innovation of some form.

Although this observation reflects poorly on the existing business processes it also offers this research great scope, with the potential to highlight areas of concern and instigate process improvement activities.

5.4.7 RESULTS: R&D LEGAL AND REGULATORY INFLUENCE

The area of legal requirements and regulations were addressed by questions 31-34. Of the employees contacted all agreed that regulation was crucial to their job. An interviewee noted:

"Regulations dictate what we can and can't do"

He added that the only way of getting work done is to operate and apply knowledge within the framework:

"The driver within this framework is the knowledge that allows us to get things done."

Most interviewees felt that regulations played such a large part in their work that it was 'part and parcel' of the role. Although the established processes allow AstraZeneca to develop and ultimately submit successful drugs, it appears to be the innovative work that is falling foul. An employee noted:

"It is hugely difficult for people who have ideas to improve existing drugs to enter into this system of processes and regulations."

On this basis it appears that regulation will indeed hinder innovation, but it is still unclear whether the guidelines of AstraZeneca are contributing to these phenomena. An R&D Discovery scientist voiced the opinion that adaptation was the key:

"What we're doing now in the early stages of lead optimisation is working within the guidelines for future regulatory submission, in the past we only worked with lab notebooks and now we're entering that data into a system that is already in the form of a regulatory submission."

However, promoting the change from lab notebooks to electronic data systems has been a slow process. In the long term, adopting this change should allow the faster submission of a compound in the later stages of development. Yet, as the literature review revealed, few drugs will ever progress to regulatory submission and demanding that personnel use their stretched resources to prepare data that may never be used is a sensitive area in itself. Employees were often exasperated at the proliferation of what they perceived as misguided internal regulation. An example of this concerned the use of the AstraZeneca GEL system to retrieve project information. In short, GEL is a regulatory document store for data and information that supports drugs that have been submitted for approval. However, employees also view it as a valuable store for project and drug information. A senior Clinical manager was asked to provide advice to a colleague concerning one of their drug projects:

"So I said why don't you just get the document from GEL? He replied 'I don't have access to GEL, well ok tell me the study numbers and I found that I don't even have access to them and I wrote the bloody things!"

While this may be an atypical scenario, further research is required to establish whether this is a common finding. This finding raises two important questions. Firstly, to what extent are the established AstraZeneca processes hampering innovation? Secondly, if employees are relying upon information systems such as GEL to conduct innovative drug projects, can Knowledge Management provide a better solution?

5.4.8 RESULTS: INTERVIEW CLOSE

Employees were thanked for their time and comments and invited to contact the author to discuss the issues raised and any further observations. During the interviews the author asked the interviewees to identify further experts and employees who would be beneficial to contact and interview. At least 35 more potential candidates were identified across AstraZeneca Discovery and Clinical.

These additional employees were then contacted through email and face-to-face meetings, to invite them to the main study carried out within Chapters 6, 7, 8 & 9. A total of 32 employees out of those contacted, agreed to take part in the research. Overall it is fair to say that this pilot study allowed the main research to be conducted by unveiling areas of innovative activity within AstraZeneca that were unknown to the author prior to this pilot study.

5.5 PILOT STUDY DISCUSSION

The objective of this pilot study was to address whether the research framework can address the research aim and whether the data collected by the author appears to supports this notion. The framework will support Objectives 1, 2, 3 and 4 and allow the identification of the drivers and criteria for innovation and analyse how Knowledge Management may be utilised. It is believed that the interview question set may be used as a research tool to assess innovation across a variety of industries. Furthermore, data collected from future studies within other innovative organisations, may also be compared to the findings derived from AstraZeneca.

However, during the interview process the area of intellectual capital was lightly covered. When asked to discuss their knowledge of the topic, no employee ventured an opinion. This area requires further study in order to clarify the intangible drivers, with one interviewee commenting it would be useful for this area to be addressed by this research. However, although no intangible assets and drivers were implicitly mentioned in this preliminary research, it is an area that should be addressed in order to satisfy Objective 3.

5.5.1 PRELIMINARY INNOVATION CRITERIA

Innovative practice within AstraZeneca appears to be a complex process, one where employees have the individual incentive but require the organisational resource to progress their ideas. Without the backing of senior management, innovative ideas may fall foul at a number of milestones with resource appearing as a critical factor within each component of the framework.

However, the area of the perceived risks and benefits of an innovative approach and its ability to comply with legislation also weigh heavily. There are areas of AstraZeneca's innovation policy that are successful and others that are less so and determining what factors are crucial in driving these processes is a prerequisite before undertaking any further action.

The innovations studied at this stage included two innovative clinical trial protocols and a novel process to overcome a process development problem within the early stages of Discovery R&D. Table 5.0 lists the commonalities found across these processes, yet many themes were unique to the individual processes. Further research and a greater reach of data collection were required to clarify these trends but the research model and research tool appeared well founded to achieve this task. Table 5.0 details the areas within the research framework that were deemed to be the preliminary Critical Innovative Factors at this early stage of the research.

Table 5.1: The Research Model and Critical Innovative Factors

Area of Model	Critical Innovative Factors
Innovation & Risk Management	Knowledge Information Data Resource Collaboration Experts Perseverance Perceived Risks/ Benefits Autonomy
Knowledge Management	Access to Knowledge, Information and Data Collation of Knowledge Capture of Knowledge Resource
Knowledge and Information Sources	Literature Colleagues Internal/ External Consultants Experts Internet AstraZeneca Intranet Resource
Knowledge Culture, Collaboration and Networks	Communities of Practice Internal and External Experts Resource
Process Management	Flexibility Resource Guidance Support Resources
R&D Legal and Regulatory Influence	Clear Guidelines Explicit Boundaries Guidance Receptive to Change Security and Access Rights Resources

The Critical Innovative factors listed in Table 5.0 may also be used as a managerial checklist, serving as a high level guide to the identification of the pertinent areas within drug development. Although the author acknowledges that at present, these factors are limited by the amount of data collected.

Nonetheless they serve as important pointers or *themes* that may be used as the basis for the codification of the subsequent data collected within this research (Miles & Huberman 1994). As these factors underpin innovative behaviour within the innovation model of Figure 5.3, they were also used as a basis to develop the innovation framework which is subsequently revealed in Chapter 10. It was also noted by the author that these criteria form the basis of a research tool that may be used to assess *how* innovative a business process or project is, a fact which was discussed in greater detail within Chapters 10, 11 & 12.

5.6 CONCLUSION

This chapter has partially fulfilled the first, second and third objectives and has primarily served to 'set the scene' by familiarising the reader with the environment that is being studied and the chosen research path. This chapter has also served to validate the research technique and methodology employed, providing a context to the research and exploring the real life constraints within pharmaceutical innovation. This section of the research has also met the secondary objective of promoting discussion and raising interest in Knowledge Management within AstraZeneca. The initial results are encouraging and a number of preliminary innovation factors raised within Table 5.0 present a checklist of areas that should be addressed when assessing innovative activity. The semi-structured questionnaire can now be considered to be a research tool with which to assess the ability of employees to innovate within an environment. The questions will also serve to highlight areas of the company's innovative strategy that are performing well or failing, in addition to revealing the nature of how employees are deriving their innovative knowledge.

In conclusion, this chapter has laid the foundations on which to link the concepts inherent within innovative strategy and touches on the knowledge sources required to create a long term Knowledge Management strategy for AstraZeneca. In order to address these areas further, the author began to collect data in earnest, focusing upon analysing the areas within the research model to ultimately fulfil Objectives 1, 2 and 3.

Chapters 6, 7, 8 & 9 concentrate upon the results of a further 32 interviews conducted across the organisation with the key innovators identified within this pilot study. These interviews built upon this pilot study and question the nature of innovative behaviour, thus allowing the author to answer Objective 4 and a design a Knowledge Management tool set to drive innovation across AstraZeneca.

CHAPTER 6

THE INNOVATION AND KNOWLEDGE CRITERIA

The following results chapter utilises the observations of Chapter 5 as a starting point and seeks to expand upon this limited study by examining the interplay between innovation, Knowledge Management, risk, process management and regulation.

6.0 INTRODUCTION

This chapter examines innovation within drug development and plays an important role in analysing the differences between the innovative structures within AstraZeneca and those published in the literature. The chapter builds upon the framework published in Chapter 5 (see Figure 5.2) by seeking to conclusively define the innovation and knowledge criteria by drawing upon multiple case studies conducted across AstraZeneca. The aim of this chapter and the proceeding Chapters 7, 8 and 9 are to satisfy Objectives 1, 2 and 3 and partly fulfil Objectives 4 and 5 by validating and elaborating upon the preliminary innovation criteria outlined in Chapter 5. In order to present the research coherently, the results are spread over four chapters in the following fashion:

- Chapter 6 displays the generic innovation drivers that are not specific to AstraZeneca
- Chapter 7 covers the innovation drivers from an AstraZeneca specific perspective and concentrates upon the culture of the organisation
- Chapter 8 examines Knowledge Management within AstraZeneca
- Chapter 9 details a case study conducted within AstraZeneca with regard to innovation and Knowledge Management

The following section will briefly discuss the data collection and analysis method employed throughout the remainder of the results chapters.

6.1 DATA COLLECTION AND ANALYSIS

6.1.1 COLLECTING QUALITATIVE DATA

A critical part of fulfilling the objectives of Chapter 2 is to identify the innovative criteria that are essential for innovative drug development work to occur. The initial case study described in Chapter 5 has outlined that the research framework is a valuable research tool with which to study innovation; while Chapter 3 outlined that the available literature rarely tackles this area in the depth required by this study. In order to address this, the following chapters utilise the case study approach described in Chapter 5 over a greater number of innovative processes and with a greater number of employees. In all, 32 additional semi-structured interviews were conducted with renowned innovative employees across AstraZeneca R&D in line with the research tool framework detailed in Section 5.3. Each interview lasted between 1 hour and 2½ hours with the conversation and observation transcribed in full by the researcher after the interview. Although the initial case study of Chapter 5 served to define the boundaries and 'set the scene', the nature of innovation still requires a degree of flexibility and the case study approach was again chosen as the principle methodology to achieve this, in line with recommendations by Rowley (2002). In the interests of the ethical guidelines stipulated by Loughborough University, all employees and departments chosen will remain anonymous. So as to ensure the results and comments associated with this research cannot be identified with a single individual.

The sample population of 32 innovators was derived from a large workforce of over 10,000 personnel and was chosen to provide a broad representation of innovative practice within the organisation. The chosen interviewees consisted of senior managers, physicians and research scientists within the company and, as such, represented a broad cross section of the organisational culture. A primary criteria for inclusion within the study focused upon an annual recognition award for innovative behaviour, where the nominated candidates had performed work relating to the development process outside their remit to result in an outstanding contribution.

The study also included key innovators who were identified in the initial interviews of Chapter 5. Many of the chosen interviewees are people who are renowned for providing maverick answers to difficult problems. The interviews sought to elaborate and reveal the knowledge sharing behaviour of the staff, discussing their role within the development process, their use and sourcing of knowledge and information, and their use of KM based technology within such activities. Above all, the aim was to uncover the real life context of the actors within the social tapestry of the case research areas (Yin, 1994).

Throughout the case studies, supplementary supporting data was derived from direct and participant observation as described in Section 4.5.4. Where possible, the author attended meetings and focus groups specifically concerning innovative development projects and acted primarily as an observer, but on occasions this role turned to one of a participant observer when the topic being discussed turned to a Knowledge Management nature. Attending these meetings has provided a valuable contribution to this research and provided a rich data source of detailed case notes. These principally relate to how the employees utilise and derived information and knowledge within their normal working environment.

Due to the researcher's emersion within AstraZeneca, it was possible to access to a wide range of internal data and information sources with which to supplement the interview data and these are acknowledged when used. A process of analytical induction was employed in line with recommendations by Miles & Huberman (1994), to identify and discuss the key themes that ran within the research framework. The interpretive case study requires a constant process of refinement, in that the themes identified were constructed in line with the research framework in a process described by Klein & Myers (1999) as dialogical reasoning. This approach is based upon the work of Gallivan (2001), who successfully identifies a number of key themes from a similar qualitative research project, which centred upon innovative practice and, as such, provides a worthy example of how to conduct such research.

The researcher chose to group themes in accordance with either an innovation- or a knowledge-centred slant. As this research concerned the use of Knowledge Management to enhance innovation it was a natural choice to utilise this methodology to explore the research data. This was grounded by the literature review of Chapter 3 which shows that models of innovation often include innovation as a consequence of applying knowledge (e.g. Alavi & Leidner 2001); while Hicks et al. (2006) perceive innovation as the pinnacle of what can be achieved once knowledge has been applied. Chapter 5 identified that knowledge is required in order to innovate and as this research aims to develop a Knowledge Management toolkit to promote innovation, the researcher deemed it wise to suggest both an innovation and a knowledge grounded theme. These themes are based upon applying each of the following definitions to the points raised.

The definition of innovation chosen is:

"A process of creating and developing new products or services through collaborative team processes and mechanisms that utilise and empower the skills and knowledge of the people" (Terziovski & Morgan, 2004)

The definition of Knowledge Management chosen is:

"A *discipline that seeks to improve the performance of individuals and organizations by maintaining and leveraging the present and future value of knowledge assets"* (Newman & Conrad, 1999)

Each definition has been used to ground the themes generated during this analysis. Innovative themes will concentrate upon defining the drivers and criteria that utilise the knowledge and skills of the employees; while the Knowledge Management centred themes concern the utilisation of the knowledge within these innovative processes and highlight areas of success and concern for Knowledge Management discussion within the discussion chapters. Above all the rationale behind the following chapters is to:

- Answer Objective 2: Identify the drivers, the criteria for innovation, the outputs of the innovation and the themes associated with innovation specifically within AstraZeneca.

- Answer Objective 3: Examine and evaluate the Knowledge Management strategy and existing tools in use across AstraZeneca R&D.

Utilising this approach has provided sufficient data and discussion points to answer the research objectives within the discussion of Chapters 10, 11 and 12.

6.1.2 PRESENTING QUALITATIVE DATA

Upon analysing the data obtained throughout the research project, it became clear that attempting to categorise findings into the distinct subsections of the research interview framework would result in a biased picture of what is truly happening. From the previous definitions of Knowledge Management it is evident that what may be construed as a Knowledge Management problem, may also be construed as an innovation problem. At this point of the research the researcher was faced with the decision to either mimic the results of Chapter 5 and elaborate upon these findings; or analyse the interplay and correlations between these areas. Rather than simply state a linear series of findings in strict categories, a conscious decision was taken to adopt the latter approach and weave the findings into a narrative concerning:

- The innovations studied

- The use of Knowledge Management

- The risks taken and the regulations that affect the process based stages of drug development studied.

By adopting both innovation and Knowledge Management centred "themes" throughout the presentation of the research data, Objectives 2 & 3 were satisfied throughout these chapters and this negates the need to devote a chapter to each respective theme.

This approach is in line with recommendations by Maxwell & Miller (1992) who state that qualitative data may be loosely categorised around a number of conceptual elements, in this case the innovation and Knowledge Management themes.

This means that, examples of a particular event serve to ground the data within conceptual elements, while the qualitative data and accompanying narrative reinforce the resulting themes. In this case, the high level categories developed within Chapter 5 serve merely as guides to ensure that the data can be selected, condensed, transformed and displayed coherently within the following chapters (Miles & Huberman, 1994).In addition to utilising themes, the research findings are presented in a conceptually clustered matrix which allows a number of important concepts to be clustered. In this case, matrices concentrate upon the type and location of the innovative aspect being assessed, the drivers behind the innovation, the criteria required to fulfil the innovation and the outputs of the innovative process. Clustering the individual concepts avoids the lengthy process of reanalysing the data over and over again to satisfy each individual research objective present within Objectives 2 & 3. Miles & Huberman (1994) recommend this technique when informants are presenting similar responses to similar questions or "tying together" concepts as a whole.

In order to make the data coherent the following data presentation structure, suggested in part by Chenail (1995), is employed:

- Section heading
- Present the finding
- Introduce the first data exemplar of this finding
- Display the first data exemplar of this finding
- Comment further on the first data exemplar of this finding
- Make transition to the second data exemplar of this finding

- Display the second data exemplar of this finding
- Comment further on the second data exemplar of this finding
- Make the transition to the next data exemplar of this finding and repeat the pattern
- Present the corresponding innovation and Knowledge Management themes
- Present the conceptually clustered matrix: innovation, drivers, the criteria & outputs
- Closing of the section and introduction to the next section

In this way, the data is presented coherently and accurately and provides the reader with a narrative that can be used to ground the data in particular areas of innovation within AstraZeneca. Interviewees' comments are always represented in italics while observations are built into the narrative. It should be noted that due to the context of the data, the content of Chapters 6, 7, 8 and 9 are at times, largely worded for someone who has an understanding of the drug development processes. However, every effort has been made to make these sections understandable by a range of readers, so the level of detail expressed has been reduced somewhat and generic findings presented. The following sections commence the presentation of the results in this format and elaborate upon the findings so far.

6.2 IDENTIFYING THE CRITERIA AND DRIVERS OF INNOVATION

6.2.1 THE BEGINNINGS OF INNOVATION

This section assesses how novel drug development and innovation commences within AstraZeneca. Earlier within this thesis, pharmaceutical innovation was defined as "the series of processes that yield a new medical drug", yet this definition does not consider the knowledge requirements that are critical within these processes.

It may be taken for granted that novel drug development requires innovation and a good deal of supporting knowledge, yet the knowledge processes within this model are poorly understood. Figure 6.1 outlines the high level drug development processes where the interviews took place:

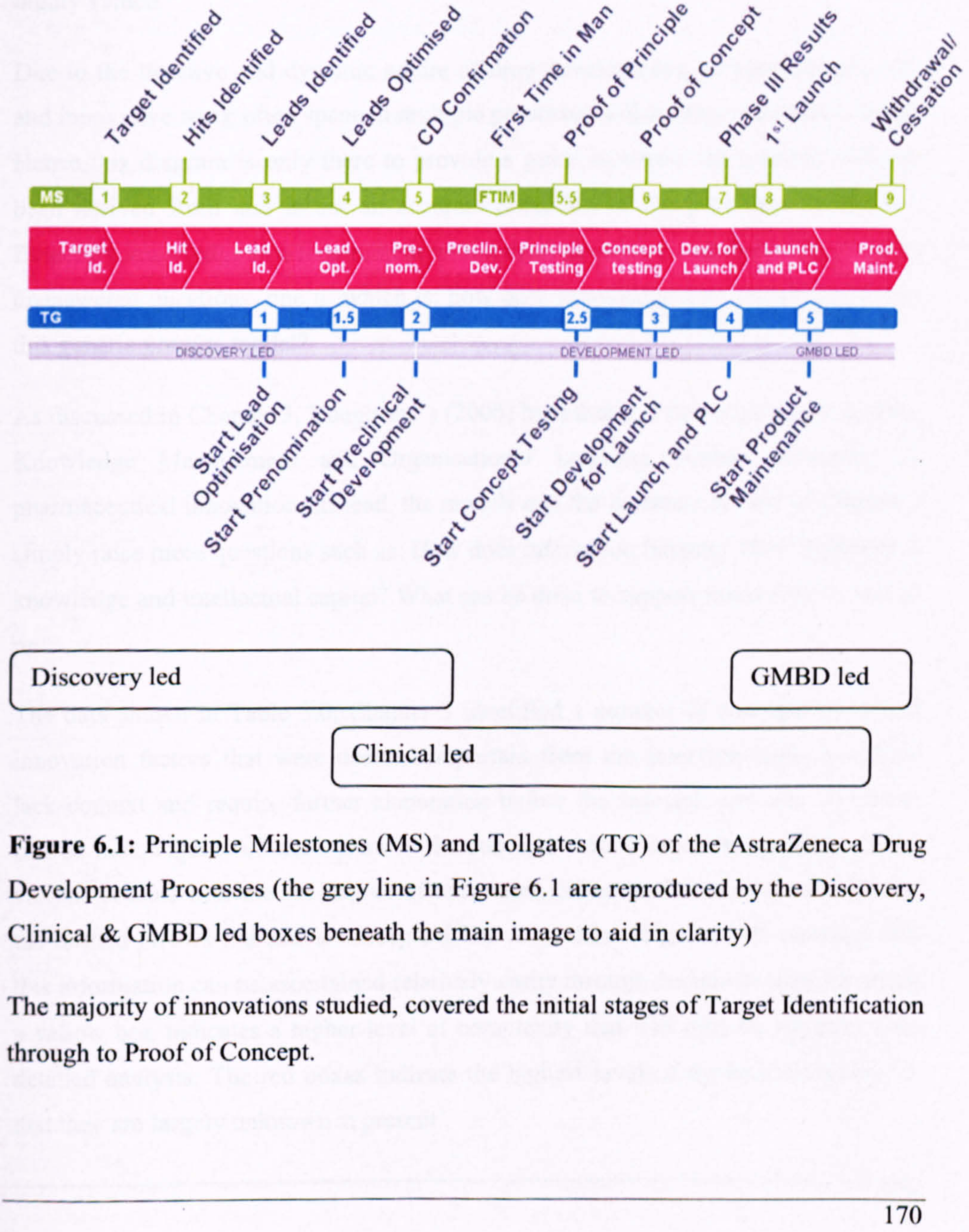

Figure 6.1: Principle Milestones (MS) and Tollgates (TG) of the AstraZeneca Drug Development Processes (the grey line in Figure 6.1 are reproduced by the Discovery, Clinical & GMBD led boxes beneath the main image to aid in clarity)

The majority of innovations studied, covered the initial stages of Target Identification through to Proof of Concept.

It is important to note that although the majority of the researcher's time within AstraZeneca was within the Clinical wing, Discovery innovators were also interviewed extensively so as to provide a broad cross section of innovation. Due to the "snowballing" nature of the interview process, a large number of interviewees also operated at the interchange between Discovery and Clinical and their views were highly valued.

Due to the iterative and dynamic nature of drug development, an interviewee's role and innovative work often spanned multiple processes within Discovery and Clinical. Hence this diagram is only there to provide a guide to where the research data has been derived from and is not an accurate reflection of the processes themselves. Evidently knowledge is a requirement within these processes, yet there remain many unanswered questions, one of which is: how does knowledge and innovation fit into this generic process model?

As discussed in Chapter 3, Dougherty's (2006) hypothesis is that none of the existing Knowledge Management and Organisational Learning models accurately fit pharmaceutical innovation. Instead, the models and the literature review of Chapter 3 simply raise more questions such as: How does innovation happen? How important is knowledge and intellectual capital? What can be done to support innovation? ...and so on.

The data shown in Table 5.0, Chapter 5 identified a number of concepts or critical innovation factors that were deemed important from the interview data. Yet these lack context and require further elaboration before the research aim and objectives can be met. Figure 6.2 demonstrates the concepts this research has addressed. The various colours indicate the degree of uncertainty associated with each concept and the dashed arrows indicate a conceptual link may exist. A green box indicates that this information can be ascertained relatively easily through document analysis, while a yellow box indicates a higher level of complexity that will only be apparent after detailed analysis. The red boxes indicate the highest level of dynamic behaviour in that they are largely unknown at present.

Chapter 5 indicates these concepts are in a state of flux and essentially change in accordance with what innovation is being carried out. Detailing the concepts identified from Chapter 3 and Chapter 5 and identifying any unknown concepts (marked by the "Unknown" concept) is central to this research and occupies the bulk of this chapter.

The green and yellow data and information concepts indicate that AstraZeneca is relatively content with their current strategies. The results from Chapter 5 indicated that this research should specifically address the knowledge required to enhance pharmaceutical innovation as the areas of data management are beyond the scope of this research. However, if promising data is divulged within this area that could better support an overall Knowledge Management strategy, then this will be noted for discussion in Chapters 10, 11 and 12.

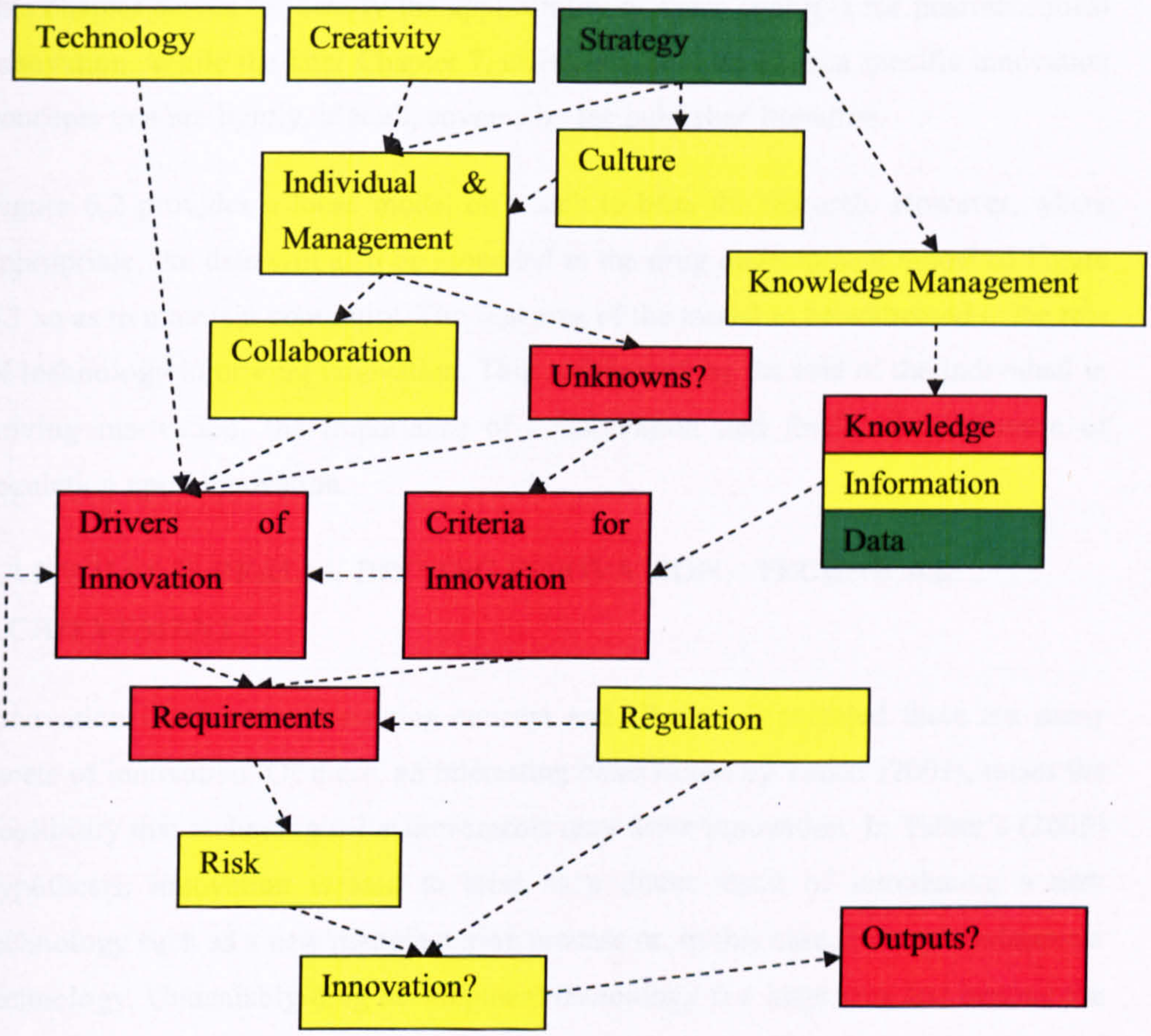

Figure 6.2: Conceptual Diagram of the research areas studied

The aim of the following sections of this study is to address these concepts and analyse innovation and knowledge from the personal perspective of the innovators themselves. The objective is not too identify specific problems but to highlight areas where applying a Knowledge Management toolkit may be beneficial. As such, the observations identify areas which the literature review of Chapter 3 would consider to be knowledge and information intensive areas.

This chapter considers the concepts that are derived from the literature review of Chapter 3 in the context of innovation within an organisation. These concepts include technology, individual creativity, collaboration and regulation.

Each concept is strongly associated with innovation across diverse organisations and this chapter serves to identify the applicability of these concepts for pharmaceutical innovation. While the later Chapter 7, considers the AstraZeneca specific innovation concepts that are lightly, if at all, covered by the published literature.

Figure 6.2 provides a loose model on which to base the research. However, where appropriate, the data will also be grounded in the drug development model of Figure 6.1 so as to maintain continuity. The first area of the model to be addressed is the role of technology in driving innovation. This is followed by the role of the individual in driving innovation, the importance of collaboration and finally the influence of regulation upon innovation.

6.2.2 WIIAT IS REALLY DRIVING INNOVATION – TECIINICAL ACIIIEVEMENT?

Innovation itself is an interesting concept and Chapter 3 revealed there are many facets of innovation. Of these, an interesting observation by Tether (2003), raises the possibility that technological achievements may drive innovation. In Tether's (2003) hypothesis, innovation is said to arise as a direct result of introducing a new technology such as a new manufacturing process or, in this case, a drug development technology. Undeniably drug development technology is a huge area and beyond the scope of this research, yet when grounding the data within the initial stages of "Target, Hit and Lead Identification & Optimisation" (represented in Figure 6.3) there are specific technological advances that have had a significant impact:

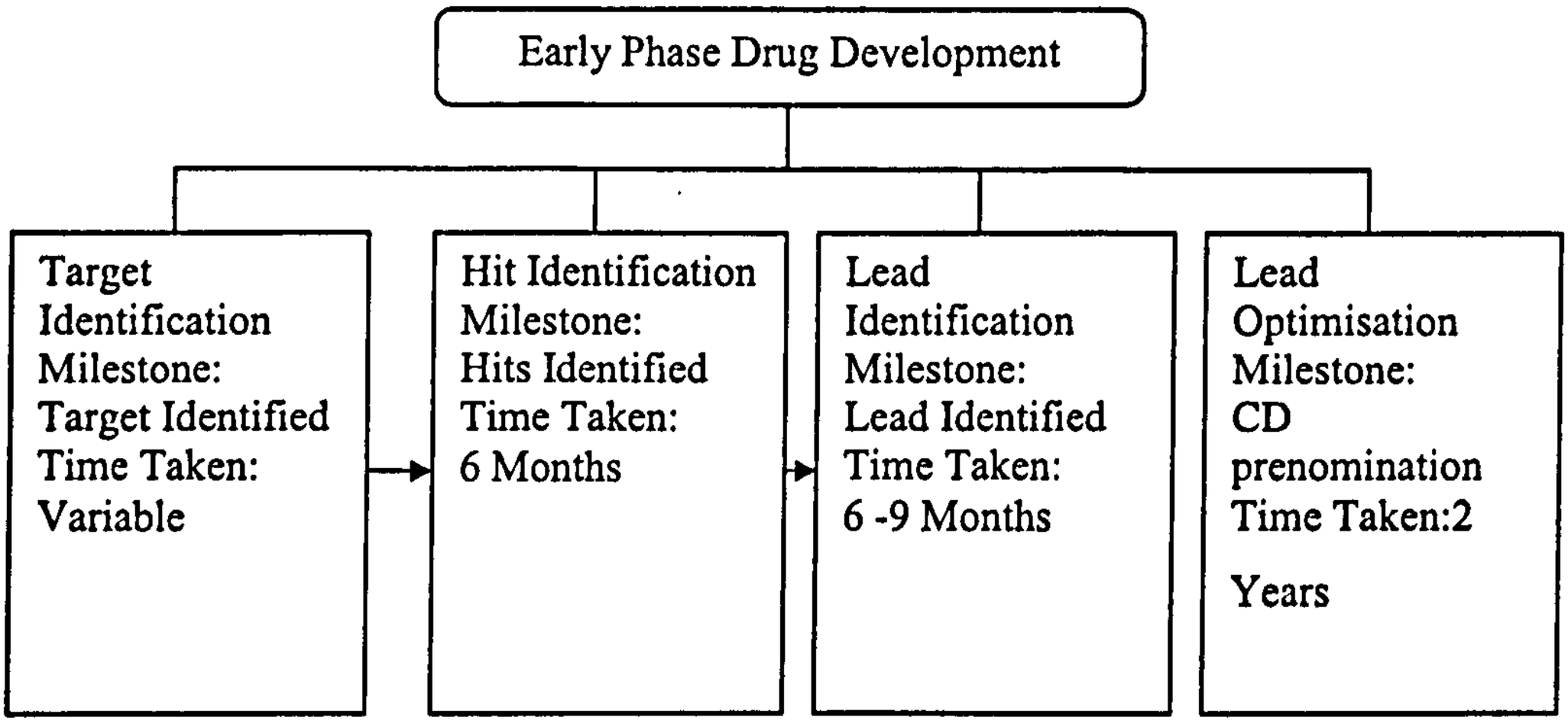

Figure 6.3: The First Four Milestones of the AstraZeneca Drug Development Process

Watson (2004) notes that, within the last few decades, technology, such as high throughput chemistry (HTS) and automated screening, can now assess potential compounds extremely rapidly. As the principle goal of the AstraZeneca Discovery wing is to firstly identify promising biological targets and then supply compounds to assess, Discovery interviewees quickly agreed that these technologies have made their roles easier. Discovery chemists can assess many hundreds of thousands of compounds per year, which is an unparalleled ability when compared to two decades ago, yet the hard truth is that almost all of these compounds will fail to make a marketable drug (Dodgson et al. 2005).

One interviewee commented that although these technologies have made their work quicker, it is the development of the novel compounds to test against a biological target that has remained the sticking point. Hence, in this case, the technology is not directly driving innovative compound development; it is merely helping the process. The technology itself does not give rise to innovation; instead it is the knowledge that is required to supply the "right" compounds to assess using the technology, which is the overriding rate-limiting factor.

A senior Discovery interviewee commented that this study should be concerned not with the technology that drives this process, but with the knowledge behind the innovative ideas that leads to a novel compound that can be tested. They commented that chemistry is an established science so physically creating a new compound is not the hard part:

"Chemistry is a mature discipline, if I want to find something out...I can go to text books that are 40 years old and the knowledge is still relevant, but clinical knowledge is different"

Another interviewee commented that the early stages of drug development were fairly traditional until Clinical knowledge was applied:

"Once they (the chemists) have a structure then it's a fairly defined area...we've got 70% that's conventional and then the other 30% isn't and that's the interesting bit."

Hence, even though computer aided drug technology has evolved rapidly (for further details see Horrobin (2001)), the interviewees stressed that it is not this which is holding back drug development. Interviewees explained that AstraZeneca possesses a library of many millions of compounds and the necessary reserve of Intellectual Capital to develop many more. Current technology can quickly screen whether these compounds are applicable, yet the chemists must have an idea of what type of compound can be applicable. HTS effectively allows many thousands of compounds to be assessed yet, without the application of knowledge; the whole process is akin to looking for a needle in a haystack.

So is technology really aiding innovation? Although technology can aid drug development, it is the creativity and knowledge of the employees or "a result of the firm's dynamic capabilities" that results in the initial stages of innovative drug development. In light of the first stages of the drug development processes, these observations give rise to the first two themes:

Innovation Theme 1: Technological advances in drug development is not one of the main drivers of early stage drug innovation. On the whole it quickens the current "weight in numbers" approach but does not give rise to new compounds.

Knowledge Management Theme 1: Pharmaceutical innovation is heavily reliant upon applying technology and knowledge to develop a refined approach to discovering a viable compound at the early stages.

An interview conducted with a Discovery research scientist ascertained that although, on the whole, technology was a positive and driving force of drug innovation, conversely, drug processes could become overly complicated through the introduction of new technology.

Technology is a vague concept and may refer to a wide variety of concepts such as machinery, data mining, IT or even Knowledge Management systems yet, in this case, individuals associated early stage drug development technology specifically with HTS and screening technologies. As will be seen throughout the stages of this chapter, technology has many meanings, yet all do not directly result in innovation without the application of knowledge instead they aid innovation. A clear example of this related to the introduction of a novel method of dosing drugs in a First Time Into Man (FTIM) study:

"A few years ago our head of department saw an advert for a machine that weighs drugs into capsules, but we saw it and had no idea what we could use it for, but he made us buy it!"

The interviewee went on to explain the reasoning behind why they bought the machine:

"There was an assumption that in the pharmacy business you couldn't just use a capsule to dose drugs, but this company had said you could - so we tried it and for some compounds it worked really well and for others it didn't"

Further comments by the interviewee explained that if the technology did work it could save a huge amount of resource:

"Even though it's not a launch submission, it's three man months effort to formulate a tablet and this can do it in an hour."

Therefore although this project ultimately failed, interviewees who were part of this work stressed that this allowed the capture of knowledge and information around a project that would have otherwise been disregarded:

"Now as it turned out this compound didn't perform particularly well - but from my point of view the real innovation is we've enabled a project that otherwise would have become reprioritised down."

Therefore in this case technology was a driver of innovative work. It did not actually result in an innovative product; instead it enabled innovative work to happen and influenced the direction of innovation. However, in order to acquire this technology a considerable financial risk was taken by the head of department to acquire the technology without a specific project need, requiring an investment somewhere in the region of £100,000 on a "hunch". This case was a rarity and the majority of innovations studied had trouble acquiring any budget. These observations give rise to the following themes:

Innovation Theme 2: Technology can drive innovation within the right environment, an environment that is open to change and welcomes innovative ideas which do not have a specific application.

Knowledge Management Theme 2: AstraZeneca possesses sufficient knowledge and intellectual capital to adapt and exploit innovative technologies that have no specific need when purchased, although this is difficult to achieve, as the financial risks are increased by taking this approach.

The findings of these two innovative areas are captured in Table 6.1. The findings are certainly interesting as they compare two distinct poles: one where technology fulfils a definite need and one where technology results in an innovative process. Evidently there will be traits of both areas when a technology is applied within a highly innovative environment. Yet these findings do provide justification that technology can influence and act as a driver of innovation:

Table 6.1: Conceptually Clustered Matrix: Technology

Area Studied	Discovery	Phase I - FTIM
Innovative Aspect	Technology - HTS, automated screening etc	Technology - dosing technology
Drivers	• "Technology to speed up the process" • The need for information quickly • Commercial, strategic and project necessity to discover viable compounds	• Potential innovation • Unmet and unknown need in the future – proactive approach • To acquire supplementary knowledge • Expand their R&D capabilities
Required Criteria	• Clinical and chemistry knowledge to refine the compound being studied • Information and strategic direction • Multiple potential compounds	• Resource – both financial and time • "An unknown use" • A risk embracing environment
Outputs	• A viable compound • Information and data • Limited "new" chemical knowledge	• Knowledge • A greater understanding • The potential to innovate
Underlying themes	• Innovation at this stage requires established "text book" knowledge and "unknown" clinical knowledge • Technology is not a key innovative driver • Limited new chemical knowledge will arise from these process	• Availability of technology does not directly drive innovative behaviour but can influence the direction of innovation • Technology can create "new or innovative knowledge" by utilising the untapped adaptive knowledge of the employees

This section's most significant conclusion is that technology is simply an enabler of innovation and does not result in an innovative product.

Hence, if technology is simply an aid to innovation in the early stages of drug development, then how is innovative work started? The previous example demonstrated how one creative and farsighted manager eventually sparked an innovative drug dosing process. The following section will continue this along this theme and examine the role of the innovative individual within AstraZeneca.

6.2.3 WHAT IS DRIVING INNOVATION – INDIVIDUAL CREATIVITY?

Sundgren & Styhre's (2004) previous study of innovative practice within AstraZeneca, suggests intuition may play an important role within both Discovery and Clinical, but many interviewees were sceptical of this. Many voiced that "intuition is only developed by a scientist when they become a master of the knowledge within a particular drug domain". Knowledge Management literature describes such people as 'knowledge workers' whose main role is to use their own competencies to convert information to knowledge (Sveiby, 1997).

Existing Knowledge Management research suggests that once an employee is a 'knowledge worker' then the individual begins to play a key innovative role. Yet within pharmaceutical innovation (i.e. target identification and onwards), a team bias emerges, which is a rather different observation to the creative individual as the principle source of innovation. Interviewees suggested that it requires decades of experience to reach the level of a 'knowledge worker' and, due to the depth and breadth of knowledge within the pharmaceutical field, this was considered "impossible". All employees interviewed felt that an innovative drug rarely, if ever, stemmed from one creative individual:

"Not nowadays - you can have the conceptual link, but nowadays no. There was a guy who was asthmatic and he'd test the drugs on himself! You can't do that anymore"

It is perhaps evident that one person cannot develop a compound alone, it is simply impossible within AstraZeneca, yet what of suggesting and moving an innovative idea forward? Comments by interviewees also stated that there had to be group backing and a consensus. This is a stark contrast to the early laxly regulated drug development environment of the 1970s, when interviewees noted that creative ideas were often taken forward by their creators alone. These comments and observations are captured in the following themes and matrix:

Innovation Theme 3: Pharmaceutical innovation is reliant upon collaboration and teamwork. An individual may have the initial idea but without co-operation it will ultimately fail.

Knowledge Management Theme 3: Pharmaceutical innovation relies upon assimilating the complimentary knowledge of the individuals. Specialist knowledge workers must act in synergy in order to innovate.

Table 6.2: Conceptually Clustered Matrix: Discovery & Clinical

Area Studied	**Representative findings across Discovery & Clinical**
Innovative Aspect	• Drug development through creativity
Drivers	• A conceptual idea • Scientific knowledge • The combined efforts of knowledge workers
Required Criteria	• Detailed clinical & chemistry knowledge • "Consensus" • Team backing • Collaboration
Outputs	• A group consensus • Collaboration
Underlying themes	• Innovation via a creative individual requires collaboration • Requires many specialist "knowledge workers" who work together

The idea of loosely formed communities of practice and collaboration resonates strongly throughout this section's themes. A notion underpinned by the need to obtain financial resource and identify the Human Capital resources, e.g. the crucial people within the organisation, who you must see to take the idea forward. Hence, there is little doubt that innovation stems from collaboration with the "right person", whether this is an individual or a team of employees who have sufficient influence. However, can AstraZeneca rely upon collaboration as the principle means to drive innovation?

These results indicate that gaining acceptance of an innovation is a tricky affair, but nonetheless, AstraZeneca is a highly innovative company and the following section examines how AstraZeneca is promoting innovation through collaboration.

6.3 NETWORKING AND COLLABORATION AS THE IDEAL MEANS TO DRIVE INNOVATION?

Collaboration can cover a wide variety of formats, from face to face meetings to teleconferences to email conversations, and plays an important role within AstraZeneca and organisations across the board (Wenger et al. 2002). AstraZeneca has chosen to drive innovation by establishing networks of innovators and collaborators and at first glance this appears to be a valid business model:

"We have strengthened our pipeline in 2005 and 2006 will see the continuation of our pipeline replenishment, whether the opportunities come from our own laboratories or from outside. The future security and success of our business demands that we are open to the vast array of opportunities for healthcare that exist now and in the coming decades." (AstraZeneca Strategy Report 2006)

The interviewees revealed that the typical means to promote collaboration, internally and externally to the organisation, rests in the medium of the face-to-face meeting, telephone and videoconferences (VCs). Overwhelmingly face-to-face meetings were considered to be the primary means to achieve this by the interviewees.

A clinical employee expressed the view that the majority of their personal innovation stemmed from face-to-face meetings:

"I have to say that most of the inspirational ideas come from meetings - they don't come out of things like teleconferences [TCs] and VCs [videoconferences]-they're quite restrictive and can misrepresent people's views; you can't see the body language behind that. Every time something good has come out, it's been [from] a face-to-face meeting."

However, in order to drive innovation, AstraZeneca is seeking to go beyond the simple sharing of information and share, capture and reuse knowledge within collaborations, which, in turn, is hoped, will drive innovation. Yet there are two sides to a debate and basing an innovation strategy upon face-to-face meetings creates a scenario where prior preparation of information is the key, which interviewees acknowledge is difficult when dealing with early stage drug development work. Forcing this explicit link between collaboration and innovation raises the issue of bias. As one interviewee commented:

"The only problem about face-to-face is it doesn't give the protagonist a chance to think about it and come up with their counter arguments."

Interviewees mentioned that face-to-face meetings relied upon both parties being adequately prepared. The outcome of a meeting rests with how prepared both parties are. Just as AstraZeneca have a strategy designed to attract research within its principle disease areas, the research organisations and companies that it intends to collaborate with also have a set agenda to attract investment. As interviewees explained that balancing and recognising the bias between these two sides is a critical part of advancing innovation:

*"We may say we're [AstraZeneca] as open minded as possible but it's not the case. We all have a world view of what's possible and the way things work...you know there's nothing that's clean of bias- particularly data. There's bias in the way you generate it and present it. You know you ask the Paxman question - what is this lying b*stard lying to me about? That's the point of it, nothing is without strengths."*

The last point implies bias exists to persuade a potential stakeholder that an innovative idea is worth pursuing, both from the point of AstraZeneca attempting to drive research that complements its aims and from the point of the biotech company trying to "fit" their research into AstraZeneca's future portfolio.

However, interviewees explained this type of bias will always exist and it is important to recognise this "world view" when "weighing up" the majority of scientific research. Hence, interviewees recommended that to counter this they had to use their own knowledge to assess the self-interests of both parties. Yet interviewees expressed that this knowledge intensive aspect is often overlooked. Particularly within the stages of early drug development meetings where one point of view will be championed over another:

"Usually you have two conflicting opinions that oppose each other and I don't see a conscious effort to consider the two. I think the word is triangulation - there is no deliberate attempt at the start of the presentation to say "right" this other way didn't work."

Interviewees noted that presentations rarely covered both sides of an argument in sufficient depth and essentially noted that this was due to a lack of time within meetings. Others noted that in the context of innovative activity it is often in the protagonist's interest to place their point of view above others, even if it is to the detriment of scientific rigour. Interviewees also noted that in many cases it was their job to assess this bias and the act or further discuss this accordingly.

A further warning by a Clinical manager questions how easy it is to truly capture and discuss both sides of an argument within AstraZeneca, let alone between AstraZeneca and external organisations:

"Networking and collaboration - on the outside it looks pretty straight forward as we're all working in a company and it should work seamlessly but it's not. It comes down to where you are sitting in the organisation and what's your position."

Therefore, AstraZeneca's strategy to actively pull ideas from internal employees, academia, scientific literature, biotech's and licensing agreements requires innovation to be discovered and is reliant upon both employees and these organisations being able to put ideas forward. These case studies revealed that internally, collaboration is reliant upon overcoming a distinct hierarchy which can limit access to the employees able to progress innovation:

"If you are a manager, sitting at a group level, then you have a higher chance, but if you are actually doing the [innovative] work then it [access] is very poor – you may get one [person] in your department but beyond that, no."

While externally the element of cost and scientific bias may adversely affect the success of each innovative project, these findings are represented in the following themes:

Innovation Theme 4: Collaboration both internally and externally are expected to play an important role within AstraZeneca future strategy and portfolio. However, there are difficulties carrying out collaboration across the organisation, let alone externally.

Knowledge Management Theme 4: AstraZeneca are seeking to drive their future strategy through collaboration and extended external Communities of Practice, yet, in order to progress beyond simple information exchange, a knowledge centred strategy that reduces the bias that exists within scientific research is also required.

The Knowledge Management Theme 4 emphasises the need to address the knowledge aspect, yet how this will be achieved by AstraZeneca is unclear, other than the basic proposition that collaboration will play an important role. It has already been ascertained that collaboration takes a number of guises, and furthermore, it is implied that internally, an innovator must be able to effectively collaborate across the management and stakeholder hierarchy in order to succeed.

Therefore interviewees stressed that it is "who you know" and how good your "political skills" are in convincing management and the associated stakeholders, that results in the financial backing of an innovative project. The comments of an innovator reveal the extent of the frustration caused by the need to convince and consider multiple stakeholders:

"Say you've got an invention, well you can't really sell it, unless you sell it to a project manager, and I guess that's right, but you need to alter your communication style to suit someone who may not understand the science, because they come from lots of different backgrounds."

While there are an abundance of highly specialised and technical proficient people within AstraZeneca, finding the one person with the political and social influence and the necessary scientific background to understand the potential of an innovation was rare:

"I mean, there are so many levels of people that you have to influence, in order to play the influential game. You've got to understand the mesh and the grid, sadly - so that's a very important part of the learning process."

Innovators commented upon the existence of an unseen grid or matrix across the organisation that differed from the published organisational charts, implying that the apparent hierarchy can be circumvented by knowing the right people. Therefore, collaboration with these people can significantly improve the chances of developing an innovative project. Yet when asked if it was clear who these people were and what people could help them, many replied:

"No it isn't, and that's because it's a 3 D grid. It's not even a grid it's a spiders web in three dimensions so you can be interacting with people all over it and that bit is a bloody nightmare."

While others gave more explanation of just how difficult it was to truly identify who could help them and where they operated within the organisation:

"Getting a feel for the entirety of the grid and where you lie in it is mind boggling and is a distraction from what you need to do - and it is pointless to learn because it's a moving structure because its not like it'll be fixed like this forever - the next reorganisation will move it again."

In this statement the sense of frustration is heightened by the sense of fluidity which arose from a recent reorganisation of the functions and departments within AstraZeneca. However, it appears that collaborating with these "innovation champions" is critical to maintain innovative activity. As one Clinical scientist explained, their social networks are vitally important:

"For me there are two dimensions, one is protecting my innovation and the other is progressing it. Some collaborators I use just to keep my innovation alive and there are others who help to aid it. The smaller group who keep my innovation alive - they're quite hard to find actually."

These observations give rise to the following themes and matrix, which are based upon the frustrations felt by innovators attempting to tackle the complexity and dynamic nature of AstraZeneca's collaborative structure:

Innovation Theme 5: Innovation relies upon an unpublicised and unseen grid of "innovation champions" who hold the influence to drive innovation forward.

Knowledge Management Theme 5: The unseen "innovation grid" implied by the employees is not publicly known and relies upon personal networks of collaboration to achieve results. The knowledge and information generated from this grid is rarely captured and shared.

Table 6.3: Conceptually Clustered Matrix: Collaboration and Innovation

Area Studied	Representative findings across Discovery & Clinical
Innovative Aspect	The acceptance of innovative ideas through collaboration
Drivers	• Networking – both internal and external • Collaboration – primarily through face to face meetings • External organisations vying for funding • Scientific bias to concentrate upon innovations that fit the portfolio • The "unseen grid"
Required Criteria	• A promising idea or innovation • The means to collaborate i.e. face to face, TC or VC • Sufficient scientific knowledge and information to "weigh up" and recognise scientific bias • A "feel" for the organisational grid • A knowledge of who within the grid can help to drive innovation • Knowledge of who can "keep an organisation alive"
Outputs	• Tacit knowledge and information (rarely if ever captured) • Political influence • Frustration felt by many if they failed in their bid for support
Underlying themes	• Difficulties in effective collaboration • Poor knowledge and information capture • Organisational matrix underpinned by an unseen grid • Poor capture of the collaboration, knowledge and innovative potential within these grids and social networks

AstraZeneca is relying upon its ability to draw in knowledge and skills as it requires, yet to an extent, this model relies upon the location of the necessary internal resource and skills to drive an innovation once an idea appears promising.

Interviewees noted that compound attrition is incredibly high within the pharmaceutical industry and higher still when new disease areas are being considered. Hence, being hampered by these internal factors related to innovation take up, only enhances this problem. As this research has discovered, adapting to factors, such as the changing "3D grid" requires considerable flexibility in terms of organisational intellectual capital. However, it also raises the question of what happens when a project is highly regulated and flexibility is difficult? In order to explore this area further, the following section considers the extent to which regulation drives AstraZeneca's innovative abilities.

6.4 THE IMPACT OF REGULATION UPON INNOVATION

6.4.1 INFORMATION AND REGULATIONS

Throughout the series of interviews and the observation gathering phases of this research, employees' comments indicate how the regulation of drug development has progressed from the early days of relatively lax regulatory influence, to a state where regulation effectively controls how innovative a company and the eventual drug can be. All interviewees unanimously agreed that regulation was a key factor throughout innovative drug development, yet their own understanding of how regulations affected their own work was clouded by inadequate information. When asked about the influence of the regulatory bodies a Discovery director exclaimed:

"Yes! That's another aspect which we have to look at, more a regulatory aspect...So it's very complex in our organisation"

The regulatory influence is so widespread as to be omnipresent, in that the interviewees commented that the complexity of regulatory influence is such that it affects almost everything that an employee will and can do within AstraZeneca.

Research by Moerman & Van Der Laan (2005) provides further information in relation to how regulatory agreements such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) effectively govern the global extent of innovative drug development. To further confound this problem, interviewees noted that accessing the relevant regulatory information that directly affected their work, could be difficult, with no clear guidance on which one to utilise:

"Again this is something you'd want to access through the internet, not talking to the regulatory agencies directly. They obviously have websites, where you have access to the guidelines, documents, processes, the regulation and their interpretations and so on, which again are quite useful – but really [there are] so many different [regulatory] sources which aren't very intuitive to use."

These observations are summed up in the following themes:

Innovation Theme 6: External regulatory bodies (i.e. the FDA) have a powerful and controlling influence on how innovative drug companies may be throughout the development processes.

Knowledge Management Theme 6: The provision of external regulatory information is poorly handled; employees are unaware of where to find and how to interpret information that is applicable to their roles.

The data suggested that even though regulation is omnipresent, it does have differing degrees of influence on each respective stage of the development process. One particular highly regulated area is Phase I clinical trials, where it effectively shapes how innovative an individual's role can be.

6.4.2 REGULATIONS AS THE DRIVER OR THE BARRIER TO INNOVATION?

Innovators within Clinical were particularly vocal on the affects of regulation, with one interviewee involved in Phase I Clinical Trials stating: *"My role is a well defined role by legislation and regulation".*

He continued to explain that their job was a balancing act between carrying out a clinical trial in accordance with these regulations and acquiring new innovative knowledge. This observation implies that regulation can inhibit innovative work and, from the interviewee's comments, appears to impact at a highly crucial stage within the drug development processes. Interviewees stated that a higher throughput of successful trials essentially equates to a greater potential profit, so it is easy to see why the balancing act between running a successful trial and acquiring supplementary innovative knowledge is tipped in the favour of profit and a low risk Phase I clinical trial. However, the interviewees always strived to include innovative work within the stages regardless of these barriers:

"All the processes are one - strictly regulated and two - there are some ethical restraints and all the processes have to go through the process of informed consent. So the innovation is difficult, so it sometimes occurs in a different type of way, so maybe from an observation in a study or experiment we learn something on how to improve things, so it's more evolution rather than innovation - it's incremental."

Therefore the highly regulated pharmaceutical environment means that employees treat their governance with differing degrees of interpretation, as one interviewee commented:

"You can have a wide comprehensive knowledge of the regulations, but a lot of it isn't clear. So for many people, depending on where they work, they will have an extreme interpretation and this may be unreasonable in legal terms. But generally speaking, there will be a range of what is possible and people will be toward one end or the other, and that gives you an opportunity to negotiate"

Stringent regulation certainly affects innovation but as one interviewee stated it gives rise to incremental innovation carried out within the bounds of what is legally feasible. Hence as one interviewee commented, permissible innovation is simply a case of knowing, how and which regulations govern your work:

"What I class as innovation is to make best use of what's already there [the regulations] and come at it from a different angle."

On a more pressing note little knowledge capture was noted to occur around these "incremental innovative processes" typically employed within clinical trials. This research suggests that within pharmaceutical innovation, the regulations impact an employee's ability to apply their knowledge to such a degree, that they are both simultaneously a driver and an inhibitor. These comments, observations and the previous comments give rise to the following important themes:

Innovation Theme 7: Creativity and innovation arise as a result of negotiating the rules and regulations implied both externally and internally. Without this foundation of external regulation, some innovative practice would not occur.

Knowledge Management Theme 7: External regulations govern the degree of additional knowledge that may be applied and acquired from conducting supplementary drug development processes, and in many cases the knowledge surrounding this process is poorly captured.

These comments also raise the spectre of risk avoidance in taking a "straightforward and safe path", particularly in risky areas such as Phase I Clinical trials. Hence innovators also stated that it is not only the external regulations that govern innovation but AstraZeneca's internal interpretation of these regulations that prescribe how innovative they may be.

6.4.3 EXAMINING THE EFFECT OF EXTERNAL REGULATION AND INTERNAL PROCESSES

A study by Schmid & Smith (2004) explains that the increase in regulatory pressure has caused R&D costs to rise steeply. This may explain why the safer option is the preferable option, from an economic sense at least. As regulatory bodies demand ever greater detail on a prospective drug's safety, efficacy and differentiation to other existing products, so the costs associated with meeting these demands rise.

Yet this research has revealed that there are differing levels of regulations and differing impacts associated with these regulations.

Employees perceive that in many respects not only do external regulations set by the regulatory bodies, sway their innovative ability, but the internal regulations of AstraZeneca are unfairly hampering their innovative ability as well. A "tongue in cheek" comment by one interviewee was:

"I've spent most of my life trying to avoid the procedures and processes that are already there in order to get on and do things. There's nothing particularly innovative about that, apart from how you can get away with it - I just ignore the rules and try to get away with them."

AstraZeneca's company mission statement (AstraZeneca, 2006) maintains that creativity is the key through the offering of 'an environment that allows employees to exercise and reward their creativity'. Yet the results of this study question whether employees are being allowed to exercise their creativity in the innovative stages of drug development. The interview data implies that AstraZeneca does possess a creative environment, although there are strong hints that creativity is being stifled across the organization:

"I think it's about putting more emphasis on creativity and making sure it's rewarded, but in the same time you have to have tolerance if a democratic decision goes wrong. If they bang around when something goes wrong then people will not do it again."

Hence, employees are wary of a "blame culture" with regards to regulations, erring on the side of caution. Furthermore, this suggests that an employee's innovative ability is governed by their environment and the direct management associated with their role. Although the data collected by this research was comprehensive, it would be unfair to label AstraZeneca's management as directly stifling innovation.

However, this research concludes that there is evident disaffection and this arises from the difficulties in effectively balancing the need to innovate within regulations and the need to generate a profit. Interviewees commented that creativity and their innovations often arose from the need to circumvent an AstraZeneca management process:

"Creativity comes out of needs, sometimes quite desperate needs, and you have to have an environment that gives you a certain degree of freedom, but if you have an environment [like AstraZeneca] that has very clear restraints, then you will become creative in solving the problems that arise."

So for some, innovation is born out of the necessity to adapt to ambiguous regulations, their innovation is simply adaptive and raises the interesting observation that internal regulations are also both a driver and an inhibitor of innovation. The issue of innovation always led the conversation to one of prohibitive regulation, a fact that is seemingly inescapable within modern drug development.

When a senior research scientist was asked if they could obtain previous development work that had occurred within AstraZeneca, they commented:

"Yes, I have access to some that has been done. Sometimes I get it through people who are good enough to show me what people have done, and sometimes I rely on the literature that covers those areas."

The interviewee continued to state that these two internal and external sources of knowledge and information are essentially the same:

"To a large extent these are the same and the reason that these are the same, is [regulatory] bodies like the FDA don't want innovation, they want validated proof of principle."

This comment implies that regulatory control is highly significant and controls how innovative personnel can be, as by their observation, the published literature and internal

AstraZeneca work is highly similar because it is subjected to the same regulation. The interviewee proceeded to explain that although their work was corralled, there was still scope:

"But within that system there is room and scope to be innovative and to develop biomarkers [measures] that not only talk about the efficacy of the drug but the mechanism and mechanisms of classes of drugs as to why they are successful or not. So yes, we're getting information, but we're not getting all the information we should be."

Many innovators were quick to point out that regulation was significant in influencing their behaviour:

"Regulatory is an issue. For the innovative things I've tried to do, regulatory has been a hurdle rather than a help."

The regulatory environment may be construed as omnipresent within AstraZeneca. An innovative Knowledge Management tool the researcher was involved with in AstraZeneca was also subject to these constraints, as information or knowledge captured effectively created an audit trail. However, at a fundamental level, interviewees agreed that regulation will always hamper innovation. Yet, it is the view of many innovators that AstraZeneca's approach to regulating their drug development processes may be a further unwarranted constraint:

"There are people there [regulatory] now who are approachable, but I think that because we've possibly got such a poor track record with the guys like the FDA, there's a paranoia around regulatory which I have a hard time getting my head around, probably because I don't understand it"

So far this research indicates that both internal and external regulations play an important role in driving innovation. These observations and comments form the final themes, before the section is concluded with a conceptual matrix of the main findings of this section:

Innovation Theme 8: Innovation can arise as a direct result of the need to circumvent existing AstraZeneca processes in order to fulfil their role yet this carries the potential of blame.

Knowledge Management Theme 8: Knowledge Management may play an important role in addressing the issue of reluctance associated with trying an innovative approach by ensuring that employees are aware of how their innovation could fit in within the regulatory framework.

Table 6.4: Conceptually Clustered Matrix: Regulation and innovation

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	The role of regulations in influencing innovative activity
Drivers	• Strong external regulatory pressure to conform to published guidelines • Strong internal pressures to conform to the interpretation of external guidelines • The need to be innovative within a regulatory boundary
Required Criteria	• Access to information and knowledge with regard to regulations • An understanding of regulations that affect their role or innovation • Patience to adopt an incremental approach to innovation within a regulatory framework • An understanding of how to interpret a broad range of requirements and develop innovation from there
Outputs	• Innovation within the framework of regulation • A drug that will conform to legal requirements across many markets • Potential capture of information and knowledge with regard to how innovation have succeeded • The potential to succeed over the "blame culture"
Underlying themes	• Innovation is heavily influenced by internal and external regulations • A successful Knowledge Management schema needs to draw in the regulatory aspect alongside the need for information and knowledge

As this section emphasises, regulation is an omnipresent factor within pharmaceutical drug development and employees must be aware of how this area affects their innovative work.

A careful balance between innovation and regulation appears to exist and it may be wise to include this aspect within any Knowledge Management toolkit.

The following section briefly concludes this chapter.

6.5 CONCLUSION

Throughout this chapter, interview comments have been used to provide an insight into how innovation is occurring within AstraZeneca. The key concepts studied within this chapter have largely been derived from the literature yet the extent of their influence has been surprising. For example, the notion of the individual 'knowledge worker' driving innovation alone does not apply to the pharmaceutical arena. Factors such as regulation and the need for collaboration all contrive to ensure that innovation is beyond the scope of the individual. In order to clarify these observations further the following chapter examined the innovative culture of AstraZeneca in greater detail, in order to ascertain how innovation is being driven and supported within AstraZeneca at present.

CHAPTER 7

ASTRAZENECA AND AN INNOVATION CULTURE

7.0 INTRODUCTION

AstraZeneca are a highly innovative company and the third largest pharmaceutical company in Europe. In order to understand the complexities of innovation and the potential for Knowledge Management within AstraZeneca, this chapter examines the issues that are specific to AstraZeneca's organisational culture. It seeks to explore the findings of Chapter 6 in greater detail and uncover the innovation and knowledge criteria that are specific to AstraZeneca. The starting point of this chapter is thus the starting stage of pharmaceutical innovation within AstraZeneca and considers the R&D behind the identification of a biological target.

7.1 THE PROCESS OF FINDING A BIOLOGICAL TARGET – A PROCESS OF STRATEGY OR INFLUENCE?

In order to proceed down the drug development pathway a pharmaceutical company must have a biological target on which to develop a compound on which to act. Throughout this research AstraZeneca innovators were questioned as to the roots of pharmaceutical innovation and the extent to which they can influence how and which biological targets are being discovered. From the interviewees' answers to this question, it is apparent that not only do the innovators have scant personal influence on the processes of identifying biological targets, but AstraZeneca itself has little influence. A Discovery research scientist clarified this by commenting on the influence of AstraZeneca on external R&D activities:

"Almost nothing, because that isn't the way it works. You [the research organisation] come up with targets not because AstraZeneca would want that.

You come up with targets because you are working in that area and subsequently you think "Oh yes, AstraZeneca would like that!" So, in a way it's not even market led, it's interest led and academic."

Therefore, when innovators were questioned over whether they could influence the initial identification of targets the majority reply was, unsurprisingly, *"No"*! Other, more senior interviewees explained that they did possess a minor degree of influence:

"There's the Respiratory Strategy Team which is meant to set broad ideas on what where we should be, they also set the disease target and product profiles which will be what we fit our drug to, and then there are dozens of other strategy teams - so you do have some influence in a very broad sense."

Yet in the majority of cases they were tasked with making a drug that *"met predefined expectations"*. Therefore, the degree of influence is dependent upon who is suggesting the idea. More worrying, however, was the opinion of the majority of interviewees that once a target had been identified and information was available (either in-house studies or peer reviewed publications) their influence on which of these promising targets should be brought into the AstraZeneca development portfolio, was again limited. When asked if they could influence this process within Discovery, a senior interviewee commented:

"No! Well sort of - the chemists have so many different groups, all doing slightly different things and quite often not liaising. There's a thing called the Science Group which meets about once a month, but they sit at a really early stage and brainstorm new targets."

The interviewee continued:

"3-4 people will present, which will be based on really early knowledge and everyone will get chance to have their say. Then when it's a bit more developed, we vote on if to progress, so we do have some influence"

This answer implies that there is an avenue for innovators to broach ideas on what targets should be examined within AstraZeneca but it is not open to all, other innovators were unaware of this group or were not privy:

"People do not have an equal chance of influencing the system and that, therefore, becomes orthodoxy of opinions within the company, which is again against innovation!"

Implying that innovation at the early fundamental stages is dependent on who you are and who you know, this edict was a common finding throughout the research and typically reflects this organisational-cultural issue plays a hand in influencing target selection.

The other striking finding is the need for accurate knowledge at this early stage. When discussing the Science Group, the interviewee stated that without sufficient supporting information, a potentially promising innovation could be overlooked. It is the proponent's role to sufficiently research the proposed innovative approach and as this was often based upon early ground-breaking work. Presenting rigorous scientific evidence could prove difficult.

This results in a requirement not only for accurate knowledge but also for an ability to present and pitch information at sufficient depth to gain interest and demonstrate the potential of an innovative idea. These areas are more important when a large conceptual leap is required, and interviewees who were members of the Science Group acknowledge that this generated intense competition between innovators for the limited resources available.

Innovation Theme 9: Innovative ideas that could be of use within AstraZeneca's drug development portfolio are poorly received. It appears difficult for the majority of innovative employees to suggest potential innovative ideas and, therefore, influence the early development work.

Knowledge Management Theme 9: Early drug development innovation requires an entrepreneurial approach to develop interest from limited resource and organisational support, and is reliant upon sufficient knowledge to generate interest.

Failing to provide innovative personnel with the opportunity to suggest innovative targets is indicative of both a cultural and a Knowledge Management problem.

Although AstraZeneca does not appear to be able to directly request work on a specific area, there is still the question of using AstraZeneca's influence to fund work on biological targets that are in line with the company's future desired drug portfolio.

Unfortunately, as a Discovery scientist explained, the way of influencing which targets were being discovered was also minimal. Pharmaceutical companies do fund scientists (i.e. biotechnology, post docs & PhDs) to conduct research into targets that might have application *only* once they have been identified. Furthermore the means of learning the nature of the work that was being carried out, both externally and internally, within AstraZeneca was distinctly hazy. Many employees commented that they relied on direct communication with colleagues as the principle means of discovering past work and promising work:

"I would ask around. I'd probably go to the head of the CPU, head of Discovery and Translational Science - all guys who have been around the block a couple of times and ask "Have you ever heard of anyone actually trying this?""

Above all, there is a focus upon practicality, regardless of how promising or exciting innovative research appears, it must possess a place within AstraZeneca's strategy. As a senior director remarked, it is often relaying messages about the *"right"* innovations that enable innovative work to receive backing:

"So the Global Product Teams (GPT) are very practical, they want something that they can use, and they ultimately can only get better the next time they do it. So they've been very good, but we've not been very good at explaining the messages"

Although there is evidently an innovative culture that drives this initial research, to an extent, it is the act of "*presenting a strong enough business case*" to influence the early stages of innovation, which appears to be hampering the introduction of new ways of thinking and practice.

Innovation Theme 10: Successful innovative practice requires the right information, organisational structure and team commitment at the very earliest of stages to gain momentum.

Knowledge Management Theme 10: Supporting innovation at an early stage can be aided by ensuring that sufficient information is available, presenting a strong business case and having access to the "right" influential strategy groups.

Table 7.1: Conceptually Clustered Matrix: Influencing early phase drug development

Area Studied	Representative findings across Discovery & Clinical, but principally Discovery
Innovative Aspect	Identification of Biological Targets
Drivers	• Relevant targets from external work • The need for innovative biological targets • Strong employee drive to supplement the portfolio with promising areas
Required Criteria	• Clinical and chemistry knowledge to develop a strong business case • Managerial influence and access to the groups that influence future strategy • Promising scientific research – almost exclusively externally derived
Outputs	• A promising biological target • Hitherto unknown data, information and knowledge • Potential lucrative returns if the research is unique
Underlying themes	• Innovation at this stage is reliant upon a structured business case • How innovative the idea is, can be outweighed by the availability of supporting information and data • How innovative the idea is, can be outweighed by the lack of managerial influence • Sufficient support at this stage is essential for innovation

The following section examines the means AstraZeneca as an organisation, is employing to enhance innovative practice.

In order to gain an overview of how AstraZeneca is tackling the problem of broadening its drug portfolio and discovering new biological targets, after recent setbacks (BBC 2006a), the researcher analysed documents across the AstraZeneca intranet and learned that a specific team, named the 'New Opportunities Group', has been set up to promote innovation outside of the normal therapeutic areas. A key remit is to develop innovative drugs that have traditionally been outside of AstraZeneca main disease areas and hence expand the market potential of AstraZeneca's portfolio. An interview conducted with a New Opportunities Group member, sourced from an AstraZeneca internal newsletter, stated:

"Until now, it has been difficult to develop projects falling outside our traditional therapeutic areas of expertise. The New Opportunities Group will address that by providing a home for the ideas that previously had nowhere to go." (Charnwords 2005)

Hence, it appears that AstraZeneca has recognised the need to embrace innovation on a greater scale than it currently does, the interview finishes with a request:

"We really want to hear about creative thoughts and ideas that may not have had the opportunity to surface before." (Charnwords 2005)

An email address is provided where employees may email suggestions and ideas for consideration. The team appears to have senior management backing but at the time of this research, no employees interviewed had submitted an idea, some were aware of the group but others were not. The majority of employees interviewed gave the opinion that unless the proposed group possessed considerable managerial backing, it was likely to fail:

"There seems to be very little interest in innovation in this company, at the bottom line – its all very "be innovative" - but as long as it doesn't worry us and as long as it doesn't interfere with the nominal timelines you can be innovative - but that doesn't work."

Hence, buy-in from all hierarchical levels is required. In essence, innovators surmised that an idea must be *targeted* professionally, scientifically and financially and, if an innovation fell within the remit of the New Opportunities Group or a Global Product Team (GPT), then it could be well received. Yet interviewees noted that this constrains the extent of innovative work possible, whether this is a new biological target or a potential new compound. A Discovery research scientist commented that this relies upon being able to access the groups that decide upon funding:

"It depends on who you have to see. If you come up with an idea that you think is going to add value and help, you need to get funding. If it's going to help a project then you need to approach the global product teams (GPT) or within your team. In my case, I know most of the people to speak to. I know for a lot of other people that certainly isn't the case."

These findings give rise to the following themes:

Innovation Theme 11: AstraZeneca have taken positive steps to embrace innovations that occur outside of their traditional therapeutic areas, but further steps need to be taken to ensure this resource meets the needs of the employees and is as receptive as it proclaims.

Knowledge Management Theme 11: Knowledge Management may play an important role in publicising and defining the innovations that AstraZeneca will specifically fund and manage. As the concept of innovation is perceived to differ according to who is proposing an idea, a common understanding to develop a symbiotic relationship would be beneficial.

The previous section implied that, although AstraZeneca is trying to be a receptive company to innovation within both Discovery and Clinical, the interface between Discovery and Clinical was commonly cited as poor:

"It is better than a lot of places I've worked in... I think here it is very much more open, they may not take any notice of you but at least they're polite!"

This observation is worrying yet confirmed by the majority of employees interviewed, it implies that people are open to suggestion and will listen but then fail to take the suggestions on board, particularly if the suggestion arises from a Clinical employee and concerns a Discovery focused area. As such it is again an area where Knowledge Management could play an important role by ensuring that employees have the opportunity to raise suggestions across the organisation. The findings of this section are represented in the following themes:

Innovation Theme 12: Innovation is hampered by the interchange between Discovery and Clinical resulting in the potential loss of valuable ideas.

Knowledge Management Theme 12: Information and knowledge exchange and reuse between Clinical and Discovery are felt to be poor and can lead to a sense of frustration. Knowledge Management techniques could help to improve this area.

Table 7.2: Conceptually Clustered Matrix: Innovation Acceptance

Area Studied	Representative findings across Discovery & Clinical
Innovative Aspect	The acceptance of innovative ideas
Drivers	• Innovation (and therefore financial reward) may lie outside its traditional portfolio • Employees may drive this process • Market drivers and competition from rival pharmaceutical companies forcing AstraZeneca to utilise its internal knowledge
Required Criteria	• Detailed clinical & chemistry knowledge • A valid idea or innovation • Scientific knowledge and information • New Opportunities Group backing
Outputs	• Financial backing and management support • Potential diversification of the existing portfolio
Underlying themes	• Few innovators implied that the group would be as receptive as it proclaimed • Knowledge Management could help to form the "link" between this group and innovators and ensure mutual benefit • Innovation can be hampered when Discovery and Clinical are involved • Information/ knowledge exchange was felt to be poor across Discovery/ Clinical

This section has examined the acceptance of innovative ideas from the employee's perspective. On the outside there appears to be avenues for employees to broach their innovative ideas, yet this is rather more difficult than AstraZeneca would suggest.

A key factor in this is that recently innovation has largely stemmed from external organisations through a process of acquisition. This paradigm shift from in-house R&D to external acquisition is examined in greater detail in the following section.

7.2 ACQUIRING INNOVATION RATHER THAN GENERATING INTERNAL INNOVATION: A FACT OF LIFE?

The last 20 years has witnessed the large pharmaceutical companies switching to the scenario, where they outsource increasing amounts of the initial R&D work. The majority of innovators questioned, agreed that AstraZeneca was reliant upon acquiring the initial innovative work from external organisations. In the case of Knowledge Management systems, this research certainly detected antagonism to developing complete systems in-house. Although the internal functions were highly welcoming to Knowledge Management ideas that arose "in-house", there is a definite reluctance to progress them:

"Lets take the ontology backed discussion forum, it would be relatively easy to go to a company like IBM and buy it in for say £250,000"

In many ways this is a similar model to how AstraZeneca operates in terms of early phase drug development, it is simply easier to acquire an idea that shows promise and then tailor it to a situation. AstraZeneca appears to be content to encourage innovation, yet relatively reluctant to exploit these creative ideas, with the principle reason behind this being assigned to cost. While this may be counter productive in a Knowledge Management setting, within the early drug development stages it is an absolute necessity. As one interviewee commented:

"It's cheaper to buy in for a huge number of reasons. First of all a lot of the research you do is pointless, you know it happens in academia. It happens in a big project and that bit [of research] is swept under the carpet or it is part of a bigger project and that dies and the people die and you never hear about it!"

In many respects these observations suggest that a dichotomy of innovation exists.

With respect to early phase drug development the preferred model is to acquire novel work, while, outside of that, innovative ideas are widely applauded, yet poorly acted upon. Large scale funding exists to acquire promising pharma-related work but, outside of this, funding is limited to supporting what innovators termed AstraZeneca's "*core competencies*" which, in this case, is drug development. Knowledge Management appears to be very much on the periphery.

However, from a pharmaceutical point of view, is it simply cheaper to acquire the rights to research a biological target or molecule rather than conduct in-house research to discover it? When questioned from a Human Capital perspective, innovators indicated that AstraZeneca no longer requires the ability to innovate at these early stages and instead acquisition and collaboration are the preferential means.

On further investigation of this point many interviewees pointed out that academia fuelled the majority of innovative pharmaceutical related work, although innovators acknowledge that, due to the complexities of biological systems, a percentage of this academic research is essentially useless:

"That's the thing about academia, you don't hear about the failures because you cannot publish - so it's impossible to assess those costs but that is huge - and, in a way, it's why drug companies aren't doing it"

The interviewee continued to say that the capability of the system meant that a huge amount of work was never published, even though it could have potential:

"There's enough redundancy [R&D capability] in the system [AstraZeneca R&D] once you've got a target and made a drug. Imagine what there is when you come up with the target - and because of that, a lot of people will come up with some incredible stuff that has amazing commercial potential and never realise it!"

These findings concerning redundancy are important for a number of reasons, not least because it implies that promising innovation can be overlooked. These findings are represented in the following themes:

Innovation Theme 13: Pharmaceutical innovation relies upon a plentiful supply of innovation stemming from external organisations. This effectively reduces the risk associated with innovation by the costs of the innovation being absorbed lower down the chain.

Knowledge Management Theme 13: The degree of knowledge and information disregarded within these early stages is prolific, as only research that can be published will be shared publicly.

Therefore, as long as there are still viable innovations stemming from academia, interviewees noted that AstraZeneca and the other pharmaceutical/ biotech companies are at liberty to pick and chose what innovations suit their current portfolio and strategy.

However, due to this, competition will arise and inevitably the more potential an innovation appears to have, the higher the price tag will have to be paid. Interviewees explained that it is, therefore, a careful balance between the perceived *risk* and the perceived potential *benefits* of the research being acquired. Interviewees expressed dismay at the number of promising areas of research being heralded as the next big breakthrough and the interviewees mentioned that the popular media is often awash with such claims. Yet the innovators' agreed that optimistic and published research, stands a higher chance of being taken into a company overall.

A senior manager commented:

"Biotech's are fascinating because there's always a perception that it's [their research is] easier to develop, you listen to people [in AstraZeneca] and they say "you get this" and they say "This is wonderful! It'll be on the market in two years" - but it's complete bollocks!"

It has been interesting for the researcher to reveal the innovator's opinions on biotechnology companies and their role within AstraZeneca's innovative future drug pipeline. A senior employee provided a memorable comment when discussing how AstraZeneca sometimes drives itself to acquire research, rather than accept *"in house"* innovation:

"It's like playing Chelsea by sitting in the stands and trying to poke the ball away from them with a broom. You are definitely handicapping yourself before you start, so in that respect it's difficult to be ever truly innovative."

This point referred to the strategy employed by AstraZeneca to largely focus upon compounds that are capable of being dosed by mouth. Recognising that in order to have an affect at the site of the disease the compound must fulfil a greater number of criteria in order to eventually arrive at the disease site. This was labelled by a senior physician as the *"scatter gun"* approach to drug development and was perceived to be relying upon stumbling across a compound that would act on the disease and be administered orally. However, aside from the difficulties of finding a compound that is biologically active against the identified target, many interviewees raised the spectre that the politics associated with what is perceived to be a successful drug, effectively governs how innovative they can be:

"The key decision is what's trendy and can we raise small molecules to it? And there are things that might be trendy but we don't think we can raise small molecules to it, so we don't bother."

While others confirmed that because external organisations were researching the targets that required small molecules, AstraZeneca were more likely to look to this research and ultimately take these onboard. A research scientist of considerable experience indicated that the obvious problem of how knowledge and intellectual property was exchanged was relatively minor:

"Yes, well I'm involved with Cambridge Antibody Technology, but its different - IP [Intellectual Property] doesn't seem to be a problem, there's always some little reservation about doing things."

Many interviewees noted that the difficulties lay in quantifying the benefits obtained from the collaboration.

Yet as a recent news article detailing AstraZeneca's recent acquisition of Cambridge Antibody Technology in May 2006 suggests, if such collaborations do yield a promising drug then the potential benefits are worth the effort and cost (BBC 2006b). Yet when discussing the acquisition by Discovery of the licence to research a promising antibody from a biotech, another interviewee commented:

"There are things that you cut corners on, but there are other things that take longer, so often it's not much quicker to get them [the drug] on the market"

They continued to say that acquiring biotech antibodies was far from a commercially safe way of obtaining a marketable drug:

"You can patent your specific antibody usually, but not always... then someone can come along with a slightly different antibody and put it on the market and there's nothing you can do about it - but it's interesting"

The bemused comment at the end stems from the interviewee's experience of a competitor releasing a drug based upon a similar antibody a considerable time before their own project could be released. Within this lies a clear message, speed is of the essence and the failure to reach market first results in valuable revenue being lost. However, the desire to recoup the substantial R&D investment required to develop a drug, may lead to haste. Innovators noted that the desire to embrace promising compounds, novel target data and licence antibodies from biotech should be carefully weighed up against the risks and costs involved. A process which, at present, is reliant upon sufficient information and knowledge being made available to aid the decision, a situation that interviewees noted was not always the case. The following themes and matrix summarise this section:

Innovation Theme 14: The process of acquiring innovation was perceived to be AstraZeneca's preferential means of driving innovative drug development. However, the benefits from acquiring this research rather than developing it in-house are not always clear.

Knowledge Management Theme 14: Acquiring innovation does not always mean that the knowledge and information is also acquired. In certain cases the desire to acquire cutting edge molecules may mean this supporting information/ knowledge is scarce.

Table 7.3: Conceptually Clustered Matrix: Acquiring innovation

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Acquiring innovation from external organisations and academia
Drivers	• A promising compound or the identification of a biological system • Promising academic research • Strict criteria of what a drug "can be" that effectively limits innovation • The perception that external innovation is "better" because it meets the criteria of what a drug is supposed to be i.e. orally dosed and a small molecule
Required Criteria	• Sufficient published information to drive AstraZeneca's interest • A collaborator within AstraZeneca to drive the relationship • Plentiful academic research • Research that shows promise but is not sufficiently developed to attract a competitor's interest
Outputs	• An innovation that could result in a new drug • A collaboration and funding for an external organisations or academia
Underlying themes	• There is a huge degree of redundancy within the system from both an R&D and a knowledge perspective • Acquiring innovation does not always demonstrate an evident return on investment • Knowledge and information generated via an acquisition may be lost or disregarded

Throughout the discussions on external organisations, interviewees repeatedly mentioned that biomarkers are a highly innovative area. Furthermore it is an area that is heavily reliant upon acquired innovative research from academia and biotechnology firms. The following section details a series of case studies which examined biomarkers in greater depth with regard to innovation and Knowledge Management.

7.3 BIOMARKERS AND THEIR ROLE IN DRIVING INNOVATIVE R&D

In order to examine the innovative nature of work concerning biomarkers, a detailed case study was conducted around this area and the results from this are presented in this section. Although this section presents the results of this research, an introduction is required at the start that draws upon prior research. This part of the research also draws upon published work within this area by an AstraZeneca employee who provided valuable guidance to the researcher (Gaughan, 2006).

When a drug is applied to a biological system, various biological cycles and pathways are invoked or altered and the identification and measurement of these changes is the role of the biomarker. Although exploring the mechanisms of biomarkers is beyond the scope of this research, for the interested reader a review by Seo & Ginsburg (2005) provides a thorough overview of the role of biomarkers. Importantly, within pharmaceutical drug development, biomarkers are amongst the primary means of predicting and measuring the response and efficacy of a drug. Unravelling the clinical and biological characteristics that are present, once a drug is dosed, is the key to planning an effective clinical trial and developing therapies that are targeted to a particular disease area (Gaughan, 2006).

Due to the complexity of the drug development processes, biomarkers fall under a number of categories (Seo & Ginsburg, 2005) and range from a simple clinical marker such as the blood glucose level, to more complex molecules that may be used to profile a patient in order to provide personalised medicine (Gaughan, 2006). The categories suggested by Seo & Ginsburg (2005) include:

- A pharmacogenetic biomarker measures the effect of a drug on a single gene.

- A pharmacogenomic biomarker refers to the effects of all the genes that impact on the behaviour of a drug.

- A pharmacodynamic biomarker assesses, through biochemical measures, whether a drug has reached its intended target

- A disease marker may be used to assess the efficacy of a drug (e.g. how well the drug is performing by modifying a disease state).

However, what appears to be happening with regard to biomarkers is complex, all interviewee agreed the role of biomarkers is crucial, yet their opinion on how AstraZeneca deals with the knowledge and information surrounding biomarkers was far from positive. One interviewee who was partly responsible for the development of viable biomarkers with which to assess the pharmacogenomic properties of a compound, believed that although biomarkers represented a crucial stage in the development process, one where the compound becomes a potential drug, the time and resource devoted to these processes was nonsensical.

This case study followed the work on an innovative drug, which had been assigned a month by the project management team to develop biomarkers. When questioned about the risk involved in not finding a biomarker in this time, an interviewee replied:

"It's an immense risk...The chances of us finding any biomarker that we can use in the month is negligible, about 2-3% - in 3 months we've got maybe a 25% shot, in 6 months it's maybe a 50% shot - but if we ace it it's a big deal, we get a drug for an unmet medical need which is very fulfilling in its own right, it's not a blockbuster - but it'll be financially rewarding for the company."

Many interviewees also suggested that although the identification of biomarkers is a key component of developing a successful drug it is rarely assigned the time it requires.

In many respects biomarkers are a *"pinch point"* or a *"double edged sword"* that can be used to both drive a drug and also effectively end research if biomarker work is unfavourable.

Hence by identifying biomarkers that are likely to highlight rogue characteristics sooner or complimentary characteristics sooner, the likelihood of compound attrition within clinical trials is likely to be reduced. Innovators explained that to overlook the former may result in attrition further down the development line, and to overlook the latter may result in attrition at this stage if the drugs mechanism of action is poorly understood. One interviewee described their role was to both *"nurture"* and *"cull"* drugs at this stage:

"I feel as if I'm a gamekeeper here, whereby I try and slaughter as many new drugs as I possibly can."

Another interviewee summed up the complex task of balancing the risk between the two sides, which was present at all times:

"My understanding is - if you kill a bad drug early then you've got more money to spend on the other drugs, so I'm always aware when I approach a problem of what hasn't been done [innovative biomarker work], that may have relevance to the compound and other compounds like it"

Here the notion of risk and resource is paramount, whereby there is an implication that freeing resource on one project by ending the project earlier, will allow this resource to be channelled into other drug projects. Innovators, who mentioned this, effectively used their innovative talents to develop innovative biomarkers in order to *stifle* drug innovation. Although this appears to be juxtaposition, it is symptomatic of the drug development process. Great lengths are taken to develop novel compounds that meet a defined criteria prescribed by Discovery and Clinical yet, as many innovators voiced, little notice appears to be taken of what happens *outside* of the defined framework of measurement:

"All those drugs that fail, we throw them away as failures. What we should think of them as is test beds of the system not of the drug, so we ask "if we do this to the system why doesn't it do this?""

To put a perspective on this, an interviewee explained that clinical studies take a variety of guises, yet early studies are primarily to assess the risk in taking an innovative compound forward and look at specific biomarkers that can prove a drug's potential to both the company and to also withstand regulatory scrutiny:

"Basically to give the company confidence and see if it can be progressed to a larger study - or stop the whole thing."

At this stage interviewees explained that it is usual for only certain characteristics of the compound to be assessed and interviewees were unanimous in their observation that it was difficult to build innovation into standard biomarker chemical assays. However, the more innovative the compound was the more innovative work was possible when biomarkers outside of the *"norm"* were required.

Innovative compounds require biomarkers that interviewees noted could potentially shed greater light on the expected and unexpected mechanism of action of an innovative compound. For example, a *"routine"* Phase I clinical trial will concentrate upon a defined number of biomarkers and little consideration will be taken of biomarkers or physiology that lay outside of these markers. Even though many innovators voiced the opinion that little extra effort would be required to acquire this greater knowledge and understanding it was rarely instigated. An interviewee commented that this related to the promise of the project and who was managing the work:

"This is when it becomes subjective rather than objective. It depends on who you're working with and who you are trying to convince and what level of risk they are prepared to accept and on the disease itself."

For example, numerous innovators stated that there is a higher degree of flexibility concerning biomarkers, when working upon a drug that challenged an unmet medical need.

However, interviewees noted that drugs that are attempting to challenge brand leaders are set "*higher hurdles*" simply because there appears to be a degree of restrictive thinking that drives colleagues to match and better an existing drug, using "*existing and established mechanisms and measures*" which, in other words, may be construed as a "*standard*". The findings on this aspect are presented in the following section and examine how the standardisation of biomarker work has led to the standardisation of innovative compound development.

The findings of this section lead to the following observations and themes:

Innovation Theme 15: Biomarkers represent a highly innovative and time sensitive area that requires innovative work to both stop and drive further R&D. It is also an area that has the potential to divert resources to other more promising projects earlier within the processes.

Knowledge Management Theme 15: Innovation at the biomarker stage relies upon sufficient knowledge and information to understand the mechanism of action of the drug. Without this, the risk of attrition further down the development pathway increases substantially.

Table 7.4: Conceptually Clustered Matrix: Biomarkers and Innovation

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Developing innovative biomarkers to highlight innovative drug R&D
Drivers	• Strategic drivers to prove that a drug is viable • Existing and known biomarkers – a drug should conform to these (within strict limits) • Promising R&D that requires biomarkers that exist outside of the norm
Required Criteria	• Sufficient time and resource to develop biomarkers that fully capture a drugs potential • An acceptance that novel drugs require greater resource but the rewards are potentially greater
Outputs	• A biomarker that allows a drug to progress • Confidence in the safety and efficacy of the drug • Greater resource availability if a drug can be *"killed"* earlier • Knowledge and information that may provide a greater understanding of the drug's action – if innovation is allowed
Underlying themes	• Biomarkers are an area of intense innovative activity • Without sufficient resource the risks associated with each compound increases, i.e. with inaccurate biomarkers a poor compound may progress, yet on the other hand a compound may be disregarded if its expected actions are not confirmed

The potential of Knowledge Management within biomarker work is evident, but these findings also revealed that there is a push towards large pharmaceutical organisations to develop a standard drug. The following section examines this aspect of AstraZeneca's innovative strategy in greater detail.

7.4 DEVELOPING A "STANDARD" DRUG?

Interviewees pointed out that a drug development project typically falls under three strategies; these are *"first in class"*, *"fast follower"* or *"me too"*. "First in class" represents highly innovative work and requires a drug to be radically different to any other on the market. A "fast follower" aims to seize market share by the introduction of a drug which out performs a recently released drug, whether it be from AstraZeneca or from a competitor. "Me too" drugs exploit commercially available knowledge to create a drug that offers advantage over currently available similar drugs. When questioned over the strategy adopted by AstraZeneca, a Discovery employee commented that each type required a different approach, however, each suffered from the same blinkered and process driven view:

"We don't care how a drug works, just if it does and that's our data. All these drugs that make it [a disease] go slower are as much use as the ones that make it go faster - it's just we've got to find a way of measuring that."

An employee from Clinical noted that the AstraZeneca strategy appeared to gear its drug development work towards "first in class" whereby the drug meets an unmet medical need or approaches a disease from an innovative angle. Although the precise data concerning the extent of AstraZeneca's drug strategy is unavailable, innovators were of the opinion that it was significantly easier to work within the boundaries of a "first in class" product. However, a "first in class" drug places heavy demands upon resource and many employees again voiced the opinion that this could be futile. A researcher commented that, although AstraZeneca devoted great resource to its projects in order to be "first in class", in effect the end result was a "me too" as it's competitors were all drawing from popular research and hence working upon similar areas:

"20 years ago companies seemed to be a lot more secretive because they were doing the same sort of stuff, but nowadays everybody is doing a 'me too' as they're all using the same sources, and so we have a lot of X antagonists, so we're all competing for the same market. In effect, we're making a 'me too' right from the word go."

Although AstraZeneca may be developing drugs that are 'first in class', interviewees noted that the competition is also highly likely to be developing compounds along similar lines. Therefore, when the drug is released it is likely to face stiff competition from rival drugs and become a 'me too', perhaps inadvertently. Employees raised concerns that not only were there competitors working on similar biological targets, but other AstraZeneca departments could be, and in some cases *were*, working on the same area and target. A senior physician raised this as an unavoidable scenario of the *'scatter gun'* approach adopted by AstraZeneca:

"The other thing we're in danger of doing is because we're not being so specific anymore, there's a risk of duplicating effort – You may find out that the GI [Gastro Intestinal] people are working on the same target and you don't know about it - and that's a difficult thing to know what's going on."

This is an alarming comment when the expense and resource of developing a drug are taken into account. However, all interviewees commented that this situation can exist due to the closed project mentality adopted by AstraZeneca. When interviewees were questioned over the extent of how collaborative working patterns have been introduced to stop this, an interviewee noted:

"Well we try to [collaborate], we were tasked with looking at X [established AstraZeneca drug on the market] for broncho inhalation and we thought we'd ring up the guy at X and look to see if there was any hint that it had an action on COPD - and they just wouldn't give us the data."

The interviewee continued:

"It was a sort of "it's ours, its proprietary"- they've only just agreed to send the data and that's 6 months later - it's crazy!"

This outcome resulted in a tangible 6 month delay in the process of accessing project data that, by the accounts of the interviewees, should be available to all (or most) employees within AstraZeneca. Yet all innovators were certain that delays of this kind were rarely reported or more importantly acted upon, they fell under the banner of *"the way we do things round here."* A fundamental reason why this may be was proposed by an interviewee:

"The way we do research around here is what we call hypothesis driven, so we have a hypothesis that we test."

The interviewee continued to comment that hypothesis driven research was at the root of why compounds or even drugs were steadfastly applied to one disease area alone. Rarely, if ever, would a compound be investigated across Therapeutic Areas (TAs). This is certainly a common finding and essentially arises due to the hypothesis being *"restricted"* to a certain area. Other interviewees commented that other potential ways of research could be effective in driving innovative work across TAs:

"There's another complete way of doing research which is the engineering approach and the way we do it is to tweak something to see if it goes faster or slower."

Yet interviewees stressed that the current situation can and does result in the people and teams working on the project becoming disinclined to accept research outside of the hypothesis:

"Team processes are very discrete groupings. Because we're working with some people who are very innovative in their thought processes - working with them is a no-brainer. Others are starting to come round but in the same department some are so mechanistically entrenched that it's beggar's belief."

When referring to *"discrete groupings"*, the interviewee clarified that, within teams, a distinction of innovative behaviour existed, however the extent of entrenched behaviour exhibited, varied in accordance with the *risk* associated with being innovative. This juxtaposition in behaviour by employees may be explained by the proposition of risk and the management of risk.

Once a compound has been identified as a potential drug, then AstraZeneca must have confidence in the safety and efficacy of the drug which involves weighing up the perceived benefits and the *known facts*. An interviewee explained that promising drugs could generate unrealistic expectation, particularly if it was highly innovative, a factor that certainly causes a change in people's reactions to sharing information and knowledge:

"If it's an unmet medical need then the hurdles are lower. Even in my own thought processes, working for the unmet medical need project, the processes are completely different, not easier but different. The only thing that gets to me in terms of ability to do things - is unrealistic expectations."

The following themes and matrix condense the findings of this section:

Innovation Theme 16: Hypothesis driven research restricts the extent of innovative activity possible by narrowing the viewpoint of the employees involved. As a result, innovative research and data is poorly shared across AstraZeneca.

Knowledge Management Theme 16: The hypothesis driven approach results in duplication that may or may not be uncovered. Adopting a "systems engineering" approach may avoid duplication of effort and wasted resource.

Table 7.5: Conceptually Clustered Matrix: Standardisation and hypothesis driven research

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Developing innovative drugs that are differentiated from the competitors
Drivers	• Strategic drivers – the drive to be "first in class" • Competitors' drugs • Financial drivers • Promising external research that could lead to a competitive advantage and a less "*risky*" product development route
Required Criteria	• External research that promises differentiation • A hypothesis that is flexible and allows innovative thought within its bounds • The innovative vision and freedom to drive a differentiated product • Access to work across TAs within AstraZeneca • A lack of competition within AstraZeneca – or at least co-operation concerning compound data
Outputs	• A potentially innovative drug that is first in class • A drug that adopts a "me too" or "fast follower" stance – either should provide a degree of financial return
Underlying themes	• Hypothesis driven research may result in a standardisation of the developed drugs which results in *"similar"* drugs being developed • Hypothesis driven research results in a duplication of evidence as it fails to take into account areas outside of the boundary of the hypothesis i.e. other disease areas

While this section has examined how hypothesis driven research can adversely affect pharmaceutical drug development, the following section continues to explore the criteria and drivers that allow innovation within AstraZeneca.

7.5 CONSIDERING THE CRITERIA THAT DRIVE INNOVATION

7.5.1 INNOVATION OUT OF NECESSITY OR LUCK?

As this research has shown, innovation arises out of a number of areas including collaboration and acquisition amongst others. However, of the innovations studied, *all* were driven by a need to either solve a specific process related problem or improve the way a process was carried out. For example, one interviewee, who developed an innovative way of running a clinical trial, had the opinion that unless you had a solution to a known problem within a current project, then you were unlikely to receive funding:

"He [the project manager] had a real problem in that he didn't have the resource to run the study and so called upon us to fix it - and only then was he interested in it [the innovation], but maybe if you tried to sell him that technology generally then he'd be like "I'll see you later"".

Although this comment is tongue-in-cheek, it sums up the feeling of many in that their problem solving abilities and skills are often overlooked and only needed when projects hit a dead end. Others said that a way they could bring their own innovative behaviour to bear would be by analysing their current ways of working, and processes, and highlighting the areas that caused the most problems:

"So the innovation is in doing a proper gap analysis and then actually working with all those projects that are coming through to work with these new methodologies. So every time we have a new project we bring it onto the radar of the Global Product Team [GPT]."

In this manner innovation stands a higher chance of being accepted as it meets a defined need and will be highlighted to the senior strategists, which in this case is the GPT. These observations are represented in the following themes:

Innovation Theme 17: Innovation typically arises as a result of a defined need by a project. Innovation that lacks specific and immediate application outside a project is highly likely to be disregarded.

Knowledge Management Theme 17: There is a lack of appreciation of the knowledge capabilities of the employees and this is manifest in the levels of discontentment felt by innovators who may struggle to progress their innovative work.

The previous themes are relatively self evident but important, none the less. They indicate the importance of defining a problem to spur collaboration and to attempt to meet a previously unknown need. However, many innovators broached the interesting idea that serendipity or luck plays a major role in AstraZeneca's dynamic ability to cope with highly varied problems. As one interviewee commented:

"Yes, serendipity, that's how you find most things in life. Most things in life happen by luck, it's all luck, and its being in the right place at the right time - you meet one person."

While another Discovery interviewee emphasised how at odds this reliance upon luck was within a scientific organisation:

"I believe this is very dangerous for an innovation led industry that the chance element plays such a big part and is so prevalent. It is dependent upon the right people making the right connections at the right time, and that's a problem."

The role played by luck within drug innovation is startling; with many innovators believing it is a necessary factor of drug innovation. Luck certainly plays a key role in the beginning cycles of drug development as innovators' suggested that this process appears to rely in part, upon employees stumbling across the work of others in journal papers or at conferences. Furthermore, the research data suggests that luck is apparent *throughout* the drug development stages.

A clinical scientist commented that their idea, which had won an AstraZeneca innovation award, initially stemmed from academia, but a passing comment had allowed it to progress:

"I would say that the initial idea came from academia but then I took it forward and presented it to the project teams for agreement. So it was just a chance remark when they asked "have you considered doing an IV and an oral dose on the same day?" and I thought, yes, that's going to work."

While it is difficult to gauge the influence of luck within the daily work of the employees, it is evidently a valuable factor within many of the cases studied and has been responsible for driving the innovation itself on occasion.

When coupled with a *"slow and incremental"* pace of innovation suggested by many interviewees, it provides a good indication of the amount of risk involved within AstraZeneca's innovative processes. Without a degree of luck, many of the innovations studied would not have been possible, yet of the innovations studied, almost all resulted from the innovator's personal network of acquaintances. While the degree of managerial influence that formed these connections cannot be measured at present, the research data gathered from managerial staff suggests that the innovators are placed in the right place at the right time through the structure of the organisation.

A senior director explained:

"It's not what I do, but how I do it that is the innovative aspect....two of the main knowledge assets are internal people and external people. The people that work for me directly and I interact with offer me the most knowledge, and knowing who to interact with and what they do and don't know, is to me the most important aspect."

From a Knowledge Management perspective this firmly equates to the description of a Community of Practice facilitator, yet from an innovation perspective this managerial influence equates to a *"guiding hand"*, but the extent and effectiveness of this guidance is rather unclear. This observation also contradicts the observation in chapter 6 that an employee's capabilities can be overlooked.

On one hand there is the innovative manager attempting to utilise people, while the reality for some innovators was markedly different. When interviewees were asked if the relationships in their personal network were ever written down or captured electronically, innovators resoundingly replied *"no"*. This suggests that without an innovator's personal network the concept of luck would play an even greater role.

Innovators also raised the point that employees who were new to the organisation lacked this network and in a large organisation, such as AstraZeneca this was essential to innovate. These observations give rise to the following emergent themes and matrix:

Innovation Theme 18: Luck plays an essential role throughout the early stages of drug innovation, yet may be guided and created through effective management practices.

Knowledge Management Theme 18: The community-of-practice model plays an integral part in bringing potential innovations to the forefront. However, this process may still be reliant upon an element of luck to make these initial connections.

Table 7.6: Conceptually Clustered Matrix: The drivers of innovation – necessity and luck

Area Studied	Representative findings across Discovery & Clinical
Innovative Aspect	The role of necessity and luck to drive innovation
Drivers	• A specific and defined problem within a project • A problem that can prevent a milestone being reached, i.e. inadequate means of collecting clinical trials data • An opportunity to introduce innovative work • A need for a greater awareness of what could be achieved
Required Criteria	• A defined need and a vision of what could happen • A degree of luck • A personal social network of colleagues • The knowledge required to form worthwhile social connections • The initiative to challenge what is the *"norm"*
Outputs	• Meeting a specific need through innovative behaviour • Stronger bonds within the network - greater awareness of the capabilities of people within the organisation
Underlying themes	• People's capabilities can be overlooked unless a manager explicitly performs a *"gap analysis"* • Poor knowledge and information capture surrounding the personal networks • The Community-of-Practice model is widely employed to acquire innovative knowledge, yet relies upon an element of luck

The role of luck and innovation out of necessity brings an element of risk to the innovative ability of AstraZeneca. To explore this further the following section examines how innovations are either embraced or discarded dependent upon the perceived risk associated with the novel approach.

7.5.2 INNOVATION AS A RESULT OF CONSERVATISM?

A Discovery director proclaimed that effective innovative practice is dependent upon mitigating the risks involved within pharmaceutical development and making the connections between disparate *"bits of information and people"*. However, the extent of how much this cautious interplay between risk and innovation should be managed was a contentious point. On one hand, interviewees were quick to point out the successes of AstraZeneca and describe the innovative drugs they had been involved in producing. Yet, on the other hand, the risk adverse organisational culture was described as a handicap by all on occasions:

"There is reluctance in AstraZeneca to do these things, and it's interesting - again a very rich and innovative early portfolio with all sorts of new mechanisms, but a relatively conservative development organisation."

Other interviewees also suggested that the conservative approach to drug development arose through the need to *innovate* to *avoid* crises:

"Not innovation in products or technology but more innovation in processes, so you know how to deal with specific issues - so you know that's how to avoid getting into problems or crises."

Hence, innovation was viewed not as a tangible end product, but as a response to avoid or side step a potential crisis. Yet, even when faced with considerable pressure to innovate, the existing status quo exerts a strong force with little capture of the reasons and decision as to why this would be so. A Clinical physician commented:

"I found out that more recently there has been an initiative to shift certain behaviours, but even within a meeting of a short span, perhaps an hour, within the presentation, the questions and the conclusions -there's a kind of return to the status quo."

All innovators voiced this opinion and the majority remarked that rarely is the knowledge and information around these discussions captured - a situation which arises due to the pressure to work quickly and at times against their better judgements. Many innovators remarked that Phase I clinical trials was an area where this was greatly felt, because its aim is:

"*Basically to give the company confidence and see if it can be progressed to a larger study - or stop the whole thing*".

This is evidently a crucial point and can lead to a considerable pressure on the employees involved to take a calculated and innovative risk rather than the *"safe route"*. As one manager remarked:

"The ultimate aim is to get better by doing these technical studies in a more innovative way, so cheaper, quicker, better and not necessarily at the same time"

Innovators voiced that the continual managerial pressure to quickly react and complete projects in the shortest possible time was an unrealistic means to develop products. In many ways, interviewees said that a cycle existed where innovative work was a necessity to overcome problems as they arose, yet on the whole it was difficult to gain acceptance even though it was necessary. This was a common finding across the interviews and the resulting themes and matrix from these findings are:

Innovation Theme 19: Innovation is required to allow employees to overcome traditional working practices, yet the conservatism of AstraZeneca can prevent innovative work from succeeding.

Knowledge Management Theme 19: The knowledge and information generated from the discussion of potential alternatives and innovative work is rarely captured and rarely disseminated organisation wide.

Table 7.7: Conceptually Clustered Matrix: A conservative approach to innovation

Area Studied	Representative findings across Discovery & Clinical
Innovative Aspect	Organisational culture and acceptance of innovation
Drivers	• A specific and defined problem/ process that creates a demand for innovation • Pressure to work ever quicker • Pressure to be more productive
Required Criteria	• A defined need or process to change • An *"open attitude"* to accept that change could bring about benefit • A means of convincing people to take an innovative route – meetings, face to face discussions, etc. • Convincing information to take the innovative route • Determination to see an idea through
Outputs	• Meeting a specific need through innovative behaviour • At present a return to the "status quo" on the majority of occasions
Underlying themes	• Conservatism is rife within AstraZeneca and may hamper innovation • Poor knowledge and information capture concerning the decisions on whether to take the innovative or conservative route

The reasons that are hampering innovation are many, and the discussion of these factors that are returning the organisation to the status quo, produced some strong feelings amongst interviewees. In particular, a lack of resource and a lack of appreciation of an employee's skills are discussed in greater detail in the following section.

7.5.3 INNOVATION OUTSIDE OF AN EMPLOYEE'S SPECIFIC ROLE?

As this research has already revealed, the lack of financial resource pushes innovative work aside and leads innovators to perceive that their skills are underutilised. Many interviewees voiced that *"outsourcing"* was the route drug companies such as AstraZeneca were using to save resource and *"speed up the development processes"* instead of utilising the employee's in-house skills. However, interviewees mentioned that outsourcing cannot solve AstraZeneca's internal problems; it merely results in a short term alleviation of the problem. Interviewees commented that outsourcing was seen as the panacea to solve the problems faced by AstraZeneca and the industry as a whole:

"More and more and more people are "externalising funding" - because in effect, if you've got a good group of bright people, they could do more and cheaper than you could in-house. It's cheaper to buy a post doc than to work in AstraZeneca!"

This observation was also raised by other innovators who voiced that they felt their work was of little value to the organisation. Employees perceived that it was preferential, in terms of resource, to outsource innovative early development work, yet this often led to innovative work being carried out within the company being overlooked to the detriment of the innovators:

"Its not really about where it [the innovation] has come from it's about who gets credit for that. For example, X's [name of innovator omitted for privacy] work – why should we develop it? Why can't we just buy it from the company who is providing XYZ [name of innovation omitted for privacy]? And then that hurts – it doesn't hurt the company it hurts the innovator."

They continued to raise the interesting point, that the innovators themselves could be viewed as external collaborators in order to drive innovation:

"I think we need a mechanism whereby you have an idea and you know what you can do with it and you can suggest to the company or how you can push things forward. In that case you are treated as one of the [external] collaborators."

As another interviewee explained, employees have traditional roles which are the mainstay of the company. Within these roles the emphasis is upon performing tasks quicker and not necessarily in a more innovative fashion:

"So it's about doing things in a narrow area and knowing exactly how to do things and how to do them better - but keeping a similar standard, but I think that innovation goes off when you deal with the professional element."

Few innovators felt their innovative ability was truly valued within their role, an interview explained that once their innovation had been funded their principle role in its inception was overlooked:

"That's the thing that kills innovation .... You've got to be quick and protect your idea, as once these things start happening it's very easy to get crushed under bigger things."

Another commented that there were no clear benefits to being innovative, unless you had to specifically solve a problem:

"Do you do it for research or for recognition from your peers? It comes down to protecting your Intellectual Property within the company."

Therefore, interviewees also raised the traditional adage that handing over an innovative idea also handed over power, as it was their personal knowledge and tenacity that provided the ability to progress drug projects and generate a financial return for AstraZeneca:

"There is an element of knowledge, but there is the element of the human dimension. The element of power, where certain people will share up to a certain point where that gives them power - if they completely release that to any given point, they relinquish that [power] - so in any Knowledge Management strategy that cannot be completely underestimated or ignored."

The interviews also focused upon exceptional innovations outside of the traditional arena of drug development and this raised some interesting responses.

A number of Knowledge Management systems were developed within AstraZeneca and achieved recognition, yet winning the support to continue this work was often hard:

"It's difficult to try and prove it's [the innovation is] worthwhile. Yes, it depends on your background – if you have a successful track record then it's easier, but if you have just come into the company, then I think people are a bit scared of the risk."

Others with the *"successful track record"* noted that although it is difficult to gain management backing, part of the problem with Knowledge Management also lies in ensuring the end users support the project:

"It's quite difficult in the company to get any kind of backing especially from management - so the real driver is not management it is the users. When you approach an idea to the users and they say that this idea is good and then, yes, you get a team around you"

On the whole innovation within an individual's role is acceptable but when it lies outside of an employee's recognised expertise it becomes increasingly difficult. These observations give rise to the following themes and outline the dynamic nature of knowledge required to innovate within AstraZeneca.

Innovation Theme 20: In many cases innovation occurs outside of the individual's traditional role, yet attempting to progress these innovations is particularly difficult as it relies upon both management and the end user (i.e. project team or software user) accepting the innovation.

Knowledge Management Theme 20: Innovation requires an exchange of knowledge where the innovator feels valued and rewarded for knowledge outside of their job remit. Sadly, in AstraZeneca, this sometimes is not the case.

Table 7.8: Conceptually Clustered Matrix: Driving innovation outside of an employee's role

Area Studied	Representative findings across Discovery & Clinical
Innovative Aspect	The acceptance of innovative employee behaviour
Drivers	• A specific and defined problem that requires an innovative angle • The availability of *"outsourced"* knowledge and information • The perception that external innovation is *"better"*
Required Criteria	• A defined need • A persistent innovator who does not *"give up"* when external innovation is sought over their ideas • The ability for the employee to broaden their role beyond their normal duties • A means of convincing people to take an innovative route – primarily management, but also users for Knowledge Management innovations • The ability to make yourself heard in the organisation • The people to accept internal innovation over external innovation
Outputs	• The Intellectual Property associated with the innovation • Recognition as an innovator • An innovation that meets a defined need – developed by people who are part of the process
Underlying themes	• Innovations often lie outside of an employees role or expertise • Innovative behaviour demands appreciation, which is not always forthcoming

The previous findings illustrate how innovation may stem from areas outside of an employee's role. The role of the highly talented individual within AstraZeneca is, in many ways, restricted and this leads to innovative ideas outside of their role, as has been witnessed within this study. Yet if such innovations are poorly accepted, how is AstraZeneca trying to encourage innovative ideas? As the previous findings suggested, the answer appears to lie in providing the employees with the ability to innovate, through organisational change.

7.6 INNOVATION THROUGH A PROCESS OF CHANGE

The research has revealed that AstraZeneca is largely reliant upon acquiring innovative research that has reached a certain stage, e.g. one where there is confidence that a new drug can be eventually marketed. The research has also shown a tendency for these drugs to essentially be a "me too", which is evidently less risky and less expensive to develop than a "first in class". The reasons behind this are largely financial. As an example of the expense associated with "first in class" drugs, the industry giant Pfizer recently acquired a biotech company that was developing a HDL-raising (good cholesterol) drug for $1.3 billion (Barrett, 2005). Such expenditure is becoming commonplace amongst drug companies, but acquiring creativity at this stage where there is good supporting scientific knowledge that a viable "first in class" drug can be marketed is exceedingly pricey, but it does remove an element of risk, as does the development of a "me too". As mentioned previously in sections 7.4, the traditional model of in-house drug development is now largely redundant, and in many ways the AstraZeneca strategy to diversify its pipeline outside of its standard therapeutic areas is an approach that is not an option but a necessity. When interviewees were questioned as to how innovative drug development can continue and how AstraZeneca can diversify with the financial costs associated with acquiring "first in class" research, many interviewees recognised that fundamental organisational change was required.

While the researcher was working within the organisation, a whole-scale change in the R&D Clinical organisational structure occurred, which was designed to improve efficiency and innovative activity.

As expected, the results of this change met with varied opinions, some in favour while others distinctly less so. The majority response ventured by innovators within Clinical was that the change had resulted in a lack of resource, with personnel expected to cover more work than they had previously with less human resources available to them. All interviewees who ventured this opinion had experienced the need to change their working structure and felt an increased pressure. As one commented:

"Having people in positions where they are so stretched is also a waste, you know someone of that standard [a consultant physician] should be given something that deserves their full attention...but to be brutally honest, the new Clinical operating model stifles innovation full stop. It's a thoroughly biased objective opinion but I truly believe it!"

The interviewee was a senior researcher within AstraZeneca Clinical and they continued to give the reasons behind their views:

"By trying to rush things and doing things without adequate and appropriate resource, you make mistakes and that is very bad for the profile of the company. Its one thing to take risks but it's another thing to make mistakes.

They continued to blame this upon the differences in how scientific and non-scientific personnel across AstraZeneca perceived the risk/ benefit model:

"Now you can say by stripping down available resource and available expertise, that is an acceptable risk, but it's something that I don't see at all. The process people will probably see that as an acceptable risk but I don't - the logical, scientific mind just sees it as stupidity!"

Again, the majority of interviewees focused upon insufficient resource - failing to provide employee's adequate time to complete their new work were the most cited reason. Others felt uncomfortable because after the reorganisation their role was less defined, effectively being told to learn new skills in order to maintain their position and hence, to an extent, loosing their specialist knowledge of one critical step within the drug development phases. As one key innovator within AstraZeneca broached:

"When I think of my drug development experience, when I give advice and expertise to teams - I'm mainly relying upon my experience in previous drug development"

However, they continued to mention that adopting a *"generalist"* model could extend AstraZeneca's innovative abilities:

"I'm more relying on lateral thinking - I've got very broad interests. I wouldn't say I've got all science knowledge to a certain depth but I'm very broad, more a generalist. I think I can take my creative energy out of the breadth rather than the depth of a certain thing."

Hence, there is a clear disparity between drug development knowledge which is specific and a valuable *subjective* resource, against innovative knowledge that occurs from applying unrelated knowledge to a problem. The tail of the previous comment explains that if innovators are generalists, it raises the question to what extent can drug development specialists entrenched in one part of the organisational process, ever be truly innovative? When interviewees were questioned as to the extent of their background research prior to joining a drug project, a research scientist commented:

"I believe that you should read as little as possible, because you cannot help but be influenced by what's been written. So, if you want to be truly innovative, you take the biological system you've got and think about it to find out where it is leading."

However, the interviewee noted that this went against Knowledge Management principals and could result in the duplication of work:

"It's a bad way of doing something, as you can then find "Oh yes, someone has already done that!"...But if you go down papers [academic literature] as the first route you become seduced into ways of looking and thinking about things - that may or may not be true. OK, so if you have to be truly innovative then you have to be without influence."

Thus a characteristically complex scenario emerges, one where the purported benefits of Knowledge Management, e.g. knowledge capture and reuse, may inhibit innovation!

A subtle balance is therefore required between avoiding the reinvention of knowledge and retaining a basic level of knowledge that may prompt innovation. Yet, as Section 7.5 noted, personnel simply do not know *what* is occurring within AstraZeneca, both with regard to international colleagues and to drug projects that fall outside of their immediate project work. The new Clinical operating model places employees within multiple projects and, therefore, multiple teams that span the organisation, in an attempt to promote collaborative behaviour in this respect. It would appear that the reorganisation attempted to address the entrenched culture, but through the introduction of more work and less resource, innovation has been inadvertently stifled. Furthermore, the majority of innovators noted that organisational change occurred whether they wanted it or not, prompting employees to question whether another round of organisational restructuring could ever bring about the result of increased productivity required by senior management:

"They almost see organisational change as a way of gaining more productivity - and that may be true in some artificial way - in terms of management metrics where we measure the productivity. However, if we measure it in terms of innovation then I'm not sure that this happens in a clear way. I don't think the connection between an organisational change and innovation is clear."

Undoubtedly Knowledge Management and intellectual capital can play a role here. However, even though the restructure has *"streamlined"* the resource available to the project teams, many interviewees were still expressing that this new model would still lead to an ever greater waste of the available resource within these restructured project teams:

"You'd have to fire half the people in AstraZeneca to make it more efficient! I mean I've been working here for three years and I don't know who two thirds of the people in this building are and I certainly don't know what they do - are they actually doing anything useful?"

Another interviewee commented on the convoluted processes being made worse by the number of *"hoops"* that employees had to pass though to proceed.

Again, it was a question of *"too many good people"* working in the wrong organisational structure that did not utilise their key skills:

"The more people you have the more it generates more people and more waste of time. I worked for a small American biotech for a while...We had time off to go to the pub, go for lunch and we did it because there were only six of us, so we didn't have any meetings, you know you could just go on and do the job."

The interviewee ended this comment by adding:

"To be fair life was a bit easier as this was 15 years ago and you didn't have to comply with so many things, but I think the same model would hold true here to an extent."

Evidently there are issues that are causing concern to the employees interviewed for this research and within a large and highly regulated organisation these views would be expected. However, even after a reorganisation there are still concerns within project teams, most notably the perceived waste of resource of skill and expertise of the employees. These key observations and the qualitative findings of this section are captured and represented in the following themes and conceptual matrix:

Innovation Theme 21: Organisational restructuring is intended to increase productivity and drive innovation. However, in certain cases, the increased responsibility and realignment of the employee's roles leads to a decrease in potential innovative ability.

Knowledge Management Theme 21: Organisational change causes a distinct change in the relative information and knowledge needs of the employees as they learn new skills and take on a different role.

Table 7.9: Conceptually Clustered Matrix: Organisational change and innovation

Area Studied	Findings across Clinical
Innovative Aspect	Examining the affect of organisational change upon innovation
Drivers	• Organisational change as a perceived means of driving innovation • Redefinition of roles to cover a broader remit • Strategic drivers – development of a "first in class" • Financial considerations
Required Criteria	• Employees capable of adapting to their new roles quickly • Sufficient knowledge and information to make the transition • Sufficient resource (financial and time) to encourage innovation within their new role
Outputs	• Potential increased productivity • A leaner organisation that utilises less resource • The potential development of drugs that are "first in class"
Underlying themes	• Organisational restructuring is difficult to achieve correctly without stifling innovation • Information and knowledge requirements for innovation may be hampered by an ineffective reorganisation strategy

It was apparent throughout these interviews, that a clear dissatisfaction with the organisational structure existed and in many ways interviewees mentioned that the management drives to increase efficiency and productivity can act *against* innovation. The following section discusses this relationship in greater detail and examines the means employed to measure innovation and productivity within AstraZeneca.

7.7 MEASURING INNOVATION

7.7.1 MEASURING THE SUCCESS OF INNOVATION THROUGH PRODUCTIVITY

As the last section revealed, organisational change does not necessarily lead to innovation. In this case, the transitional stage posed considerable problems for the interviewees as they adapted to their new roles and, on occasions, a lack of resource. A number of interviewees concluded that this could be a result of how innovation was perceived and acknowledged by the relative parties. One interviewee explained that the strategic vision of management differed from theirs:

"That's the difference in the definitions of innovation. For some [management] it's doing things quicker. For me it's just about creating and doing something new!"

Others noticed that reorganisation and management in general, firmly linked measuring innovative activity with the speed a project or development progressed, regardless of the difficulties associated with carrying out a project, whether it is innovative or not:

"You know whether it's an easy or a hard process...I mean people say "be innovative, be faster", but it's often "be innovative, take your time""

Certainly all AstraZeneca employees strive to be productive, yet the research findings question whether productivity and innovation are linked to the extent that is perceived by management organisational strategies. The views of innovators varied but the majority viewed innovation as a separate entity:

"Although I think organisations can facilitate innovation and we [AstraZeneca] should do - though this would be very difficult to quantify and demonstrate that this particular organisational change has done that, is not so easy, but there might be a productivity ratio you can measure - but these are not necessarily the same things and they are not equivalent [productivity and innovation]"

Of the innovators interviewed, only one interviewee commented that *"innovation and productivity go hand in hand"*, but continued to state that they viewed innovation as *"designing the best solution"* - in effect, the most productive solution.

However, the majority of interviewees felt that pharmaceutical innovation sat aside from productivity, and stated that increased productivity rarely meant increased innovation. However, all interviewees agreed that innovation often results in a tangible outcome that is distinct from creativity:

"I see it differently from creativity. Innovation is really the proof of concept; you take the idea and prototype it. Innovation is not just about being creative, you have to show that it might work and for me that is important. So that has implications - the company really has to allow prototyping if you foster creativity, if you don't allow the next stage - then you're stuck with your innovation process."

What was also apparent was the apparent disconnect between the measurement of innovation and productivity through Key Performance Indicators (KPIs). Although innovation can result in a tangible end product, interviewees noted that the metrics associated with this are different to those used to measure productivity. All interviewees stated that AstraZeneca's KPIs simply did not cover innovative activity and, worse still, they are often unrealistic, with many expressing the opinion of the following employee:

"We have our KPIs and we have no role in setting these up - on the record, these are people who don't have a clue! I would like to say that the company is looking at realistic planning - but it doesn't. It's the same for everything, you put forward a realistic plan and it's cut in half - It's stupid!"

This study certainly generated emotional answers concerning this subject and although there is a divergence between measuring innovative activity and productivity, the data suggests this leads to a worrying difference between what is planned and measured and what can actually be achieved.

This was a consistent observation throughout the interviews and appeared to stem from the fact that staff at the *"shop floor"* lacked the "*voice"* to assist in setting realistic KPIs that reflect their true working environment. As an example, this illustrates this point:

"When you are told [by project managers] that there's no reason why you can't write a protocol [Clinical Trial protocol] in the afternoon and in fact it takes 6 weeks - when you've got that level of disconnect then it's very, very difficult – it's just totally pathetically unrealistic. The reality [of what is possible] versus the mission statement [measures and metrics] – there's a huge difference."

Interviewees frequently mentioned this type of unrealistic expectations and mentioned that it was, therefore, difficult to measure innovation effectively. The reliance upon standard KPIs to assess productivity and therefore act as a measure of innovation is at odds with the review of Chapter 3 which covered intellectual capital methods. When innovators were quizzed concerning the use of intellectual capital assessment methods almost all were unaware of the available methods. A number of senior directors had, however, heard of the term, yet expressed that the current measures did not address this issue:

"No there isn't and that is a worry, there is no way or formal audit process to capture this information."

Of the methods suggested to the interviewees the Balanced Scorecard was recognised though its application and use was confined to one Clinical department. Overall however, the innovators recognised the need to concentrate upon this area further to link innovation, productivity, the people and the knowledge required by drug development projects. Yet due to the unforeseen needs associated with a project as it progresses, this approach was viewed as difficult. A comment by a director summed this up:

"Yes, interesting. That would always be the best way, and have all the people operating in the same framework - but sometimes the looseness of the requests, we don't work out what is the job of the person on that team, with no definition of what the project requires, prevents that from happening."

They continued to note that this difficulty stemmed from a tendency to improperly plan projects:

"So people don't always spend the time to work out what is being requested, and work out what really is the job of the person on that team, and identify the people with the right skills, background, knowledge, experience. It's more that there's a team here that needs this resource and this person's available - if it's at that level, then it fails to address the real fundamental aspects of the project work."

This section gave rise to the following themes which centre upon the measurement of innovation within AstraZeneca.

Innovation Theme 22: Innovation and productivity are markedly different in the scope of drug development. The current measures and KPIs employed within AstraZeneca often fail to take account of the breadth of innovation occurring throughout a project and focus upon reducing the time required to complete a task.

Knowledge Management Theme 22: There is a need to employ intellectual capital assessment to measure the innovative activity occurring within AstraZeneca; yet also a need to develop a framework that accurately supports innovation within the organisation so as to encourage further innovative behaviour.

Table 7.10: Conceptually Clustered Matrix: Measuring innovation within AstraZeneca

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Measuring innovation within AstraZeneca
Drivers	• The need to develop drugs faster and more efficiently • Intense commercial pressure to reduce development costs • Management and reporting metrics to show progress through development
Required Criteria	• A sound recognition of the processes employed within the organisation • An appreciation of where innovation has helped to drive these processes • Separate measures that accurately reflect both innovation and productivity as separate entities • A framework that both supports employees and allows measurement • Sufficient resource to meet expectations • The resource to allow prototyping – whether it succeeds or not
Outputs	• Currently metrics (KPIs) that measure the cost, resource and outputs of a project based on tangible milestones or tollgates alone • Potentially a greater understanding of the processes with intellectual capital measurements and the ability to identify and aid innovation
Underlying themes	• Innovation is rarely measured within AstraZeneca, instead the measure of success of a project is based upon productivity and efficiency • A framework that provides measures to support innovation is required

The following section questions the role of the patent as one of the few common tangible methods employed to measure pharmaceutical success (Furukawa & Goto, 2006).

7.7.2 THE INFLUENCE OF PATENTS ON THE PROCESSES OF INNOVATION

Measuring productivity occurs at many levels, but a tangible measure that is reported for financial analysis is the number of patents or patent applications submitted by a company. To the pharmaceutical industry patents are the means to protect the considerable investment a new drug requires. As a measure of success they are relatively easy to assess, yet the process of acquiring a patent is far from easy and requires innovation. A Discovery physician explained that:

"The key thing that gives you your patent, is that it has to be something that isn't a logical conclusion of other things, so it's got to have popped out of the woodwork and, of course, you've got to be the person who supplied the principle intellectual and how's your father - otherwise, if you're not, the other person has the rights to the patent."

Therefore, the balance between creating an innovative drug or discarding it, lies not only with whether it is possible to patent the research or final molecule, but also with who the instigator of the research was. As the previous sections have noted, developing R&D that is unique is increasingly difficult when so many companies are drawing their work from the same sources.

Interviewees also explained that once a patent is granted it can be a telling signal of what disease areas and biological mechanisms a company is researching. From there the need to generate a marketable product is driven by strong commercial pressures to *"make good"* on the promise of the patent:

"You can imagine how long the gap is between a patent being granted and you actually having a product, a huge, huge, huge amount of time. But it doesn't stop you of being aware of other molecules - so you could do [patent] searches and it will tell you the way other people are thinking and it may be applicable to you."

In many ways the use of an external research organisation is an attempt to again minimise risk. A Discovery employee, who had spent considerable time within academia researching novel targets before joining AstraZeneca, noted that he had approached his research based upon patent and literature analysis.

He concluded by saying that this method was commonly employed, but is expensive and "*constitutes a huge gamble*" in that it may not yield a viable and *unique* research project. In addition, there is no clear cut way to assign a cost to this process and measure its success, other than a patent. Yet interviewees explained that the act of striving to develop a patent narrowed the innovation possible.

The interviewee explained that developing a number of compounds that acted upon a specific target derived from the literature was a vastly expensive process, one that by their accounts could be approached from a different angle. Other interviewees summed this up by questioning the drug development model employed by AstraZeneca, stressing that rather than looking to raise a compound that specifically acts upon a target, pharmaceutical companies should instead be seeking to understand the disease in greater detail:

"If we do that this way and the other, we'll actually come up with key components of this disease and these components and their related chain of activities. This is where we should be going and, to me, that is the next huge intellectual challenge that drug companies should be addressing."

The viewpoints of the innovators stems from the *way* disease is viewed, to clarify this, a senior physician explained:

"The way disease works if you think about it - is how many ways can it be manifested? Because "it does this", doesn't mean it's this type of disease, and that really is doing yourself a huge injustice. Until we think beyond that complex, then we're never going to go any further because we're constraining ourselves by things we don't need to."

Therefore, the act of 'pigeonholing' a disease along with the target that is *believed* to affect this disease was viewed by many innovators as flawed, certainly in terms of innovative activity. When interviewees were questioned as to the major hurdles that affected the generation of patents from innovative work, one replied:

"So when we're talking about the whole areas of innovation they're huge. Where we give drugs to, when and how we give drugs, how we decide which drugs to give, how we monitor those drugs properly, how we make best use of the compounds we throw away because they have huge amount of utility to be fed back into the processes - all of this is missed out on as far as I can see."

Unfortunately swaying the processes of AstraZeneca away from producing compounds to target a specific biological target and focusing upon the wider picture is, by the admission of the interviewees, exceedingly difficult. Due to the complexities surrounding drug development and the biology of a disease, it is often taken for granted that a drug that works on X disease will *not* work on Y disease. On the whole this was deemed a fair assumption, yet innovators complained bitterly that this knowledge as to why this was so was considered irrelevant and largely worthless when a patent application was sought:

"Well its not that they [compounds] have other application, it's what they tell us about that disease."

Innovators frequently called for the means to review past work and in particular any failures associated with trying new compounds within multiple disease areas.

As one innovative Clinical physician commented, innovation that generates a patent is generally reliant upon prior yet elusive work:

"Yes, if you look in terms of innovation and work [R&D patents] that has been previously done, there is never actually, let's say....an easy connection, between something you do now and something that's truly ground breaking concept tomorrow.

They continued to say that patent data, previous R&D and the employees within the organisation provide the *basis* for innovation:

"There is often a good ground base of information, knowledge and experience which you need, and then to make the right connections at the right time and make that big leap always has a very big part to play, indeed, as innovation can't occur without them - so we need these things to exist."

Hence, it appears a fine line between relying upon prior information and generating a novel idea which is patentable. As prior data has suggested a fine line also exists between having too narrow a scope to be truly innovative and developing patentable research. Additional knowledge and information that has been generated from R&D that lies outside of the patent may also be useful, but may be disregarded as employees are too constrained by the need to register a tangible and measurable patent as an output. The following themes and conceptual matrix summarise this section:

Innovation Theme 23: Patents are a tangible means of measuring pharmaceutical R&D but may not recognise the amount of innovation required to reach that stage. Furthermore, the process of patenting research may constrain innovation.

Knowledge Management Theme 23: Conducting patentable R&D results in additional knowledge and information than is not required to submit a patent and consequently may not be captured effectively. Measuring and using the information and knowledge generated outside of the patent may be more valuable than the patent itself in some cases.

Table 7.11: Conceptually Clustered Matrix: Assessing the influence of patents upon innovation

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Patents as a means of measuring innovation
Drivers	• Commercial pressures to develop patents from stakeholders etc
Required Criteria	• Access to patent databases and business intelligence • Research that is novel enough to warrant a patent • The ability, the knowledge and the information to generate a patent
Outputs	• A patent which is a measure of R&D "*potential not success*" • Detailed chemical or clinical information and knowledge that supports a patent and the associated research • Supplementary innovative knowledge and information that has driven the process, but is rarely recorded • In some cases a limited understanding of the disease itself, due to the constraints associated with filing a patent • Information to competitors on your R&D strategies
Underlying themes	• Patents can both protect innovative R&D yet constrain the innovative activity possible • Supplementary information and knowledge that lies outside of the formal patent application, may in some cases, be more valuable than the patent itself

As these previous sections have noted, measuring and assessing innovation is a tricky, yet important part of the development process.

Interviewees stated that an organisation will evidently be reluctant to invest financial resource into an innovation that does not guarantee a tangible return. This chapter now ends with a brief set of concluding remarks with regards to the observations within this part of the research.

7.8 CONCLUSION

This chapter has explored a wide range of criteria and drivers that are critical to innovative activity within AstraZeneca. The findings analyse an area that is poorly represented by the literature and clarify the extent to which innovation is driven by external influence across the pharmaceutical industry. Overall the concepts within the innovation model suggested in Chapter 6 have been expanded to specifically address the effect of the organisational culture upon the reuse of knowledge to drive further innovation. In particular, the findings relating to the success of organisational change, the acquisition of innovation, the role of luck and the perceived strategy by AstraZeneca to develop a "me too" drug and avoid excessive risk were notable findings.

Throughout this chapter the interviewees placed a strong emphasis upon the generation of information and knowledge that was rarely captured. Noting that although AstraZeneca was highly innovative, aspects could be changed to capture the innovative nature of the individual employees and fundamentally change the current means of developing innovative drugs by avoiding a hypothesis driven approach. It is the researcher's view that the observations within this chapter will form the cornerstone of a successful Knowledge Management tool set, as required by the research aim and objective. In order to discuss the development of the tool set further, the following chapter now turns to examine the present role of Knowledge Management within AstraZeneca.

CHAPTER 8

KNOWLEDGE MANAGEMENT AND INNOVATION

8.0 INTRODUCTION

Throughout the presentation of the results a number of themes that have detailed the requirements for knowledge and information that drives innovation have been outlined. This series of Knowledge Management themes has focused specifically upon the innovative processes knowledge requirements. Yet AstraZeneca's current Knowledge Management strategy that supports these aspects has been lightly explored. This section explores this aspect and details observations and qualitative data derived from the research results, seeking to examine the role of the current Knowledge Management tools within AstraZeneca as an aid to innovation.

A conscious decision was made by the researcher to avoid a consultancy type report which simply listed AstraZeneca's Knowledge Management strategy and the tools used. Instead the focus was upon how innovation occurred using the Knowledge Management tools, which then allowed the development of an innovation centred Knowledge Management tool kit described in chapter 10.

During the researcher's time within the organisation, the Knowledge Management strategy was evolving and therefore the issues raised here may have been addressed. Nonetheless, the results presented here are not intended as a criticism of AstraZeneca's current strategy, but merely highlight areas that could be addressed from an innovation perspective.

8.1 KNOWLEDGE MANAGEMENT TOOLS

AstraZeneca is typical of a large multinational organisation, having many repositories of information that fall under a combined KM/ IS strategy. Of these, the more commonly used tools include:

- PKT: an information library for project based documents and information
- GEL: a regulatory information store that is designed for the submission of regulatory information and supporting documentation
- eRooms: a recently introduced collaborative and document management tool designed to facilitate project based collaboration
- Our Discovery: an information and document store
- An email service utilising Outlook
- A number of departmental, independent discussion boards
- The Autonomy search engine system
- An expert location service
- Numerous databases associated with departments throughout Clinical and Discovery - many are in proprietary format
- E-learning tools for staff training and education – topics range from medical to ethics
- Numerous other proprietary Knowledge Management websites, departmental websites and document/ information stores, examples include Process R&D and Global Safety Assessment

During the three years this research was undertaken, AstraZeneca IS launched a strategy to pull in all the disparate intranet sites and Our Discovery under the umbrella of a single portal, namely the R&D Portal. While the researcher was conducting this research, interviewees were asked on their opinion of the strategy after the portal had been running for a period of approximately six months.

The results were surprising as it showed that innovators and employees are *more* reliant upon *external* information sources, than internal sources such as the R&D portal and intranet. The combination of resources needed to innovate was wide and innovators noted that it was beyond the scope of one particular Knowledge Management based tool:

"We have multiple sources that we use, medical scientific literature, multiple internal repositories holding different information and knowledge in many diff forms...we have the Global Electronic Library or GEL, PKT, Our Discovery, R&D portal, eRooms and shared drives – an old fashioned way of saving information."

The interviewee continued to note the complexity of the currently available systems:

"So we have all of that existing at the same time – and that makes it not very useful because you can't bring it together in a clear way!"

What was apparent is that the R&D portal cannot link the broad array of potential sources of information and knowledge, there are simply too many that have a "*potential*" use. An interviewee noted their reliance upon external patent databases as a basis for innovation:

"I use these databases, because these sources are not widely available through the company...these are databases like Pharma Projects, Scrip, R&D Insight, R&D Focus, Global Project Database and a few others - so these are commercial databases which capture things which aren't in the medical journals."

The interviewee continued to explain that these external sources were so important because they aggregated diverse information sources:

"They use various sources such as companies, conference proceedings, abstracts, external stuff which you don't necessarily find in the normal literature."

A number of interviewees stated that because of the bewildering array of sources, their first choice source of information when beginning innovative work would be external literature sources such as PubMed. Many innovators expressed regret that the R&D Portal model had (at the point this data was gathered) missed what was perceived as its key goal of bringing these disparate sources of information together. One senior interviewee noted:

"So the intention is to bring quite a bit [information sources] together - but not all, as PKT and GEL will still remain independent. Our Discovery will sort of stop and be transferred to the Portal KM systems of the portal project and eRooms - so that will be transported, but there are many, many systems and things which will remain outside."

Hence many interviewees believe that AstraZeneca have missed an opportunity to collate these diverse sources under a common access portal:

"I think at a strategic high level, the company has created a relational hierarchical system for linking all of these things [with the R&D portal]. However, what happens within the company is that there are many independent things going on and they're generating specific solutions for specific groups, yet there is no direct link to this relational hierarchy that exists."

Other interviewees were rather more complimentary, but again described the R&D portal as a strategic information repository rather than a store of drug development information and knowledge. On the whole most utilised internal sources such as the R&D portal, along with a combination of sources:

"One of the key sources would be journal searches to get background info. The other searches we would do would be internal, because often they are centred around projects, project and compound information, background information and then people, using one-to-ones [meetings or telephone] - going to people who have got that bit of expertise."

It is important to note that the key reason behind employees failing to consult internal IS and Knowledge Management sources is due to the difficulty in finding any relevant information.

All employees, including those who could be considered highly skilled in the use of computers e.g. programmers, complained that locating information across the AstraZeneca intranet was far too laborious:

"From a pure Knowledge Management point of view it would be absolutely wonderful if, for each of our drugs, there was one place you could go to and you could find everything in one place. That's not exactly innovative; you would have though it was common sense."

Interviewees were particularly vocal upon this point and viewed that, although the goal of Knowledge Management and AstraZeneca IS were positive, very little help had been given to them with regards to their knowledge needs:

"We've been harping on about Knowledge Management and how it can help and very little has been actually executed."

However, many were realistic as to what a Knowledge Management strategy could achieve. Of particular concern was that a system or tool should make the process of keeping up to date with the inordinate amount of current pharmaceutical related research easier than it was now:

"Certain types of information we must keep up to date with, in this industry it is very important to keep up to date with on a day to day basis, particularly the scientific Medical literature and journals. These discuss new mechanisms, new clusters, new compounds and ideas, so you have to be on top of this on an almost day-to-day basis."

Hence, there is reliance upon external sources that, as the previous sections have explained, will always remain:

"Well in reality a lot of ideas come from many different sources...no one source provides the single idea...I would say, over my career, the main innovations, from which we've produced valuable blockbuster drugs - they've come from many different sources. Sometimes we've read literature and distilled ideas from there."

Unfortunately, as one interviewee noted, without detailed background knowledge and the ability to compare the proposed research with "what is already out there", the prospect of reinvention is very real:

"Well, you have to have a reasonable amount of knowledge to make sure you don't invent something that's already been invented a few years ago - I would say that half an hour in the library would save you, say, three months in the laboratory."

Another interviewee noted the need to keep abreast of all the various sources throughout the life cycle of a project in order to avoid duplication of effort, although some sources were more valued than others in this respect:

"I guess you see we use all of them, some at certain times depending what stage of the project we are in... I guess if I have had to put a value to each one of them, I would say sources like PKT [and] Our Discovery. Our Discovery is really quite useful and then recently the emergence of the eRooms which are very useful when they're actually populated."

While others preferred to consult favoured journals for innovative ideas yet found that setting aside time to achieve this was difficult:

"The external scientific and medical journals provide information and knowledge that are very valuable when you access it."

Yet interviewees noted that although it is vital for them to read specific journals to gain broad understanding, they often have to focus upon a particular target due to time constraints:

"There's a journal, but I don't have time to search or review journals, which is what I'd like to be doing. I tend to look at them and go after a specific target or you could take in some news and reviews in specific journals."

Once the information on the target was discovered then rapid progress could be made:

"It's fairly easy and mostly obvious, so if you identify a target you can either make a molecule, or an antibody or whatever and so you decide on various reasons to do what ever you can."

This comment explains that, with the correct information and in sufficient detail, invoking the early stages of drug development was relatively straightforward. Others noted that a Knowledge Management system that could provide a link to the underlying research data derived from both Discovery and Clinical and the published literature, could provide a valuable insight and potentially drive innovation. When asked what a Knowledge Management system should provide, an interviewee commented:

"Things we've done...there are times we've pursued experimental work to obtain new novel data, and this new novel data has been pursued and this had led to a product at some stage down the line, yet this is a long protracted process, but that's often where ideas come from."

Another interviewee noted that with the ability to link data, information and knowledge, potential problems could be foreseen earlier:

"It was preclinical data that indicated there would be non-functionality with a particular genotype for the receptor, emerging biomarker data from the clinical studies and potential genotype data in the literature which indicated there could be issues with the metabolism of the drug, absorption, distribution – a combination of sources"

Therefore, in many respects innovators concluded that access to sufficient information and knowledge is critical, whether it be from academic journals or pharmaceutical databases. However, on a more social note, interviewees noted that collaboration between colleagues and externally was just as likely, if not more likely to provide them with the information or knowledge they required easier and quicker. These observations are captured in the following themes:

Innovation Theme 24: Knowledge Management can play an important role in driving innovation by providing the means to access cutting edge research, both internally and externally to AstraZeneca.

Knowledge Management Theme 24: Innovation requires multiple and disparate sources of information and knowledge. Many are available within AstraZeneca but keeping abreast of the important sources is paramount to promote innovation and avoid reinvention.

Table 8.1: Conceptually Clustered Matrix: Assessing the role of Knowledge Management upon innovation

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Knowledge Management Systems and their role within innovation
Drivers	• Knowledge Management/ IS Strategy to provide relevant information and knowledge • Acknowledgement that pharmaceutical R&D requires multiple cutting edge sources of knowledge and information • Acknowledgement that a range of Knowledge Management tools are required
Required Criteria	• Access to information and knowledge as and when required • The infrastructure to support the systems • Knowledge Management tools that provide sufficient information and knowledge to drive information • Sufficient knowledge of the individual to know when and how to use research information and knowledge • The ability to locate and make sense of the multitude of sources required to innovate • Access to scientific data to support rationale and hypothesises
Outputs	• Innovation if the *"correct"* information and knowledge can be located • The capture and dissemination of information and knowledge – to a limited extent • The identification of which sources are key to innovation
Underlying themes	• Knowledge Management could play a greater role in providing innovative knowledge • Innovators require to keep abreast of multiple sources and as such a Knowledge Management schema should take this into account

8.2 KNOWLEDGE MANAGEMENT AND COLLABORATION

Throughout this research, the aspect of collaborative knowledge has been strongly evident. Without internal and external collaboration innovation would certainly falter, if not entirely fail (Section 6.3). Interviewees regarded fellow employees and collaboration as an important aspect of innovation that could be overlooked by the current Knowledge Management tools. While others noted that it would be highly useful to review the knowledge sources used within a project, both as contributions from colleagues and information sourced from the various Knowledge Management/ IS systems within AstraZeneca:

"A review of the people involved and the knowledge [used] then yes, it comes back to the idea of one store. I'd just like something really logical - so if we had the invitro pharmacology, the animal pharmacology - and you could just type in [a search for information or knowledge across all sources] and get back something that you wanted."

Hence innovators are requiring a Knowledge Management system that can supply information, knowledge and the means to instigate and record collaborations as they occur. As one interviewee noted, their personal network of collaborators is essential to drive the initial processes of innovation:

"Obviously there are a lot of interactions with the guys in Discovery and Clinical, trawling the literature trying to see the knowledge around the target and looking at what people have measured previously which is related to the disease process or related to the mechanism of the target we're looking at."

Other interviewees believed that, prior to the lead optimisation phase, drug development is essentially an established and documented process reliant upon chemistry that may be obtained from any textbook. However, the managerial interviewee noted that the further down the development phases a compound passed, the greater the need for clinical knowledge and information became.

They noted that this may be the arena that Knowledge Management could posses the highest impact, when a compound has proven its worth but clinical knowledge is required. A Discovery manager explained that their innovative role stemmed from applying clinical knowledge to early stage development work through the development of a Discovery Medicine department:

"Discovery medicine is a concept not an actual reality. It's all about bringing the lab closer to the clinics, physicians and vice versa - both directions are important. We bring a lot of clinical disease knowledge into the process of target identification, how patients manage and cope with the disease, the clinical need, disease knowledge...so it's mainly about bringing this aspect to the hardcore, vernacular geneticists and molecular biologists with more disease background."

In effect, this type of work, where R&D laboratory data is reinforced with Clinical knowledge, requires collaboration and was hailed as a potential Knowledge Management arena. Other employees working in this area noted, however, just how difficult this area was to bridge successfully. Even though promising data could be generated, the further stages of actually using this data to drive innovation were often held back:

"I finally found some of the data and the individuals behind the data. It was obvious that it hadn't been analysed properly, sometimes properly but not thoroughly enough. On the clinical side I think they had been analysed properly but they [the results from the data] hadn't been used."

Therefore, acting upon the data derived from collaboration is imperative. Yet, as previously discussed, it appears that the favoured mediums of face-to-face meeting, the telephone and the videoconference (VC) are given preference by almost all of the innovators interviewed, even though the majority of innovators felt these were poor channels with which to publicise innovation in relation to "knowledge and information discussion and capture". Yet it is the employees, who at times strive to hold meetings with limited time, who are undoubtedly essential for the day-to-day workings of AstraZeneca innovators:

"There are good people, mainly we communicate through face-to-face, email or telephone... but again it's difficult to get the key players in place."

They continued to note that a lack of the "right" people meant that people's skills were not utilised effectively, with one of the key skills recognised by the interviewees being the ability to network effectively in order to drive innovation:

"In key positions there is a shortage of people, so having the director working on a project is probably not the most convenient thing...but he's the guy who's meant to be pressing the flesh and meeting the key people."

Yet the face-to-face meeting consistently rated highly as the preferable means of sharing knowledge and information, over the available Knowledge Management tools in most cases:

"One of the best ways information gets passed around is when we have meetings. Something that's happened a few times is when we discuss our current views and knowledge, then out of that come suggestions for new ideas and the suggestion that could be done to meet everybody's requirements."

The reasons behind this stemmed from the fact that interviewees often found it is easier to explain vocally than to attempt to write down a complex idea for dissemination within a Knowledge Management system:

"Maybe it's me but I don't write as well as I speak and that's why [I prefer meetings]"

Other interviewees mentioned that attending a meeting or looking over a meeting presentation was often the easiest way to quickly get the "gist" of a project:

"Well I'm extremely lazy. I always try and do things in the easiest way possible. If I get a new project and I'm taking it over, then I hope that someone would send me a slide set and then I'd go into Google and get some more papers and some review articles."

During the researcher's time within the organisation a discussion forum was used within Clinical as a primer for meetings, this met with widespread success and an exponent explained that a variety of techniques are generally required to ensure clarity and consensus. Many stem from a Knowledge Management perspective, but others stem from the field of psychology:

"The discussion forum, I'm keen on online mind mapping, two things which I think are really valuable - these are using online mind mapping within meetings, the other is talking about problems. If you want to find a solution to the problem you must spend two thirds of your time talking about the problem."

The interviewee continued to explain that there are practical means available to facilitate complex discussions:

"At my last place a psychologist got everyone to write what the people thought the problem was on a card - he then found that no two people had the same understanding of the problem. So how can you even begin to solve a problem when the people haven't got a common understanding of the problem?"

What is evident from interviewees' comments is that no one solution can fit all. Such is the range of sources and scenarios encountered within pharmaceutical R&D that a diverse range of tools are needed to ensure that employees are fully aware of the information and knowledge available to them. Further care is also needed to ensure that each person has a good understanding of what innovative problem is being attempted to be solved, as misunderstanding rarely allows innovative ideas to progress, let alone when outside the scope of an employee's role:

"If you want to collaborate you need to communicate the message then you must make sure it doesn't step on anyone's feet. Let's say I'm in Clinical and I do something regularly that's innovative for Discovery, it won't matter because I'm sitting in the wrong place."

Hence strong social ties certainly drive innovation, with the idea of "water cooler innovation" being mentioned a number of times:

"The time when you come up with good ideas is when you're sitting down with two other people over a pint of beer or a coffee and you just brainstorm."

The move to an open plan environment within Clinical to increase "water cooler" interactions, had met with mixed views, primarily due to the lack of privacy associated with an open plan environment. When raising this point, the issue of discussing confidential project material in an open plan office was raised. A curious scenario is thus raised between allowing enough information and knowledge transfer to innovate, and restricting access to only allow certain people.

During the researcher's time a similar observation regarding confidentiality was made surrounding the introduction of a Knowledge Management system named eRoom[1]. This system was introduced to encourage collaboration and lessen duplication of project documents. Even though the tool is not designed to replace all the information tools available to employees, it is designed to link the ad hoc departmental and drug project websites that previously dominated the R&D intranet. The strategy of AstraZeneca appears to view eRoom as an informal collaborative environment, where discussion across project work could occur prior to making a "stop/ go decision" on a drug project. However, again interviewees complained of the closed project mentality existing within this virtual world:

"We do have eRooms for some of projects which have been quite useful, but in a sense it's duplicating them [the physical closed project environment], I think it's the wrong way of addressing the problem."

The interviewee continued to comment that eRooms appeared as the proposed solution to address the usability issues associated with tools such as GEL, in particular:

"The reason why we have eRooms is that the other things are difficult to use and that's not really the right way of addressing the problem - we end up duplicating and then don't know where to look for something."

[1] http://software.emc.com/microsites/eRoom/index.jsp

Others commented that although the tools that were available to them had changed, their ways of producing documents to populate these tools had essentially remained the same:

"No I'm producing documents, but I don't know if I'm doing it right...but I'm circulating bits I've done just by email to my collaborators and various teams but I'm not sure if that's right. I'm showing it to them and [saying] if you're the wrong person then please show it to the right person."

Overall the reliance upon emailing documents to fellow employees followed by a physical meeting was still very apparent, a situation eRoom in particular is meant to stop to an extent:

"I'd liaise with the Discovery people and get them to send [email] me the relevant stuff...I'd ring up the guy in Discovery who would cut and paste the bit of the MS3 document, but you know there's no logical way of doing it!."

The utilisation of virtual eRooms also possesses a tangible cost benefit. As one interviewee noted, the costs associated with not using a Knowledge Management system and holding a meeting instead, are high:

"I can sit in a 2 hour VC with half a dozen people this end and half a dozen at the other end, with a couple in the States and Sweden - so if you actually cost out how much these meeting cost, then it's a ridiculous process - probably costing about 20,000 dollars or something per meeting, a ridiculous waste!"

Another interviewee indicated that the cultural differences associated with Sweden and the UK, was demonstrated by the preference for meetings over email:

"Again, our Swedish colleagues, you often find they've put a meeting in my calendar and you ask them "why are they having it?" And they say they just needed the information, so we're thinking well why didn't you just email and I could send it to you? But they like talking about it!"

Other interviewees noted that a Knowledge Management system could be used to cut down upon the time taken to reach a decision:

"I find a lot of the meetings are just about information...you'd have a 3-4 hour meeting scheduled and a lot of it was just going over the ground of the previous meetings and the actual decision time was about half an hour."

Others commented that although holding a meeting such as this was often the easiest way, but sometimes it was not the most innovative way. Instead, possessing the ability to search across a drug information or knowledge domain with a Knowledge Management system, could offer a different viewpoint other than the "acknowledged AstraZeneca expert":

"I'm involved in a side effect project and I spoke to X who said, "Well, why don't you just ring up all these people in Sweden who have been doing this for years and they would give you all that straight off the back?" And, in a way, I know exactly what he's saying, it would save me time, but its back to never thinking about it yourself and just taking on board what people have done."

Hence interviewees noted that the danger of not using a Knowledge Management system could lessen the extent of free innovative thinking. However, a number of innovators mentioned the importance of capturing innovative ideas generated across the company in order to enhance the existing Knowledge Management systems available within AstraZeneca. Many interviewees particularly noted that innovative ideas, usually in a verbal form, stem from a wide variety of environments:

"Sometimes it's just conferences, meetings, and literature, speaking to people- that always lead to good ideas, speeches and stuff like that."

Again the notion of effectively capturing what was said was mentioned, in addition to the need to capture innovative thoughts that attending events generated. An interviewee had developed a PowerPoint template to aid the capture of information while at events, yet when user-led solutions such as these, are suggested they often fall upon deaf ears:

"I'll give you an example, when I started working on X - I went around to all the IS groups asking for help because I wanted some kind of input, but there was no help for two years and then they somehow get feedback from users who started saying that this thing is important."

Evidently, if there is sufficient demand for Knowledge Management systems to become common place within the processes mentioned within this section it will have to be led by the end users to an extent. However, without sufficient management backing, this again will fail, which is a situation akin to the findings on innovation throughout this chapter. Unfortunately there are difficulties associated with developing a Knowledge Management system that details the thoughts and decision processes involved in producing a drug. Recording such events not only provides the means for employees to visualise what has occurred but also the regulatory authorities, a factor that many interviewees acknowledge has a significant impact on what can and should be recorded:

"I think to be fair, the whole process has got much more complicated mainly due to the regulatory environment, so there are a lot of things we have to do, keep now, and file and do things, but I think there's no reason why we should make it more complicated than it has to be."

Hence, even though the process of managing information and knowledge is complex, the interviewees noted that the provided systems are also overly complex, with the regulatory information system, GEL, in particular being mentioned.

Throughout this section the emphasis has been upon capturing the discussion and ideas that stem from collaboration that are driving innovation. Yet the research data suggests that due to their complexity, Knowledge Management systems play a relatively minor role within the collaborative processes. These observations and comments captured within this section are represented in the following themes and conceptual matrix.

Innovation Theme 25: Innovation is reliant upon discovering diverse knowledge and information sources and generating an idea, but the collaborative culture within AstraZeneca sometimes fails to provide the opportunity to grasp the understanding and as such, a great deal of time is wasted within meetings.

Knowledge Management Theme 25: Collaboration occurs primarily via meetings, yet collaborative Knowledge Management tools exist throughout AstraZeneca. There is a greater need to either exploit or develop these tools to provide the collaborative medium required by innovation.

Table 8.2: Conceptually Clustered Matrix: The role of Knowledge Management as an aid to collaboration and innovation

Area Studied	Findings across Discovery & Clinical
Innovative Aspect	Knowledge Management tools and collaboration
Drivers	• Knowledge Management/ IS Strategy to provide collaborative environments • An acute need for information and knowledge • The need to discuss complex topics • The need to cut down on the *"meetings culture"* within AstraZeneca
Required Criteria	• A medium to invoke collaboration and discussion i.e. a meeting, TC, VC, discussion forum or an eRoom • The time and resource to conduct meetings on a regular basis in an environment that is conducive to innovation • Employees who have the ability to understand diverse information and knowledge and reach a consensus • Commitment to act upon information/ knowledge derived from collaboration • Usable Knowledge Management tools that fit the requirements of the innovators
Outputs	• Innovation from collaboration • The potential capture and dissemination of information and knowledge within a Knowledge Management tool • Potential saved time with a greater reliance upon Knowledge Management tools instead of meetings
Underlying themes	• Knowledge Management could play a greater role in stopping wasted time within meetings • Knowledge Management systems are not utilised to their full potential and end-user driven development could lead the way

8.3 CONCLUSION

This chapter has explored the relationship between innovation and Knowledge Management within AstraZeneca Discovery and Clinical. A number of key areas relating to the acceptance of innovation have been examined along with the associated knowledge and information drivers required to conduct innovation within pharmaceutical drug development.

The observations and findings within this chapter form a powerful and compelling argument to introduce Knowledge Management tools that link disparate information and knowledge sources and provide the means to promote discussion and collaboration. Furthermore, the aspect of information overload has been apparent as an undercurrent throughout this chapter.

The key findings of this study largely relate to a sense of disappointment with the Knowledge Management systems on offer. While many of the systems were relatively new and rolled out while the researcher was within the organisation, there remains scope for introducing a tool kit that specifically addresses all the observations of this research. It is also highly apparent that innovations stem from a large number of disparate external and internal sources. So any Knowledge Management system should bridge and refine these information and knowledge sources into a manageable environment.

The following chapter concentrates upon results of a case study conducted within AstraZeneca relating to a Knowledge Management based decision mapping exercise carried out within AstraZeneca, and provides an 'employees eye view' of innovation and its place within the organisation.

This chapter concludes with the innovation and Knowledge Management themes elicited from the data of chapters 6, 7 and 8, presented in Tables 8.3 & 8.4.

Table 8.3: Innovation Themes

Innovation Themes
Innovation Theme 1: Technological advances in drug development is not one of the main drivers of early stage drug innovation. On the whole it quickens the current "weight in numbers" approach but does not give rise to new compounds.
Innovation Theme 2: Technology can drive innovation within the right environment, an environment that is open to change and welcomes innovative ideas which do not have a specific application.
Innovation Theme 3: Pharmaceutical innovation is reliant upon collaboration and teamwork. An individual may have the initial idea but without co-operation it will ultimately fail.
Innovation Theme 4: Collaboration both internally and externally are expected to play an important role within AstraZeneca future strategy and portfolio. However, there are difficulties carrying out collaboration across the organisation, let alone externally.
Innovation Theme 5: Innovation relies upon an unpublicised and unseen grid of "innovation champions" who hold the influence to drive innovation forward.
Innovation Theme 6: External regulatory bodies (i.e. the FDA) have a powerful and controlling influence on how innovative drug companies may be throughout the development processes.
Innovation Theme 7: Creativity and innovation arise as a result of negotiating the rules and regulations implied both externally and internally. Without this foundation of external regulation, some innovative practice would not occur.
Innovation Theme 8: Innovation can arise as a direct result of the need to circumvent existing AstraZeneca processes in order to fulfil their role yet this carries the potential of blame.
Innovation Theme 9: Innovative ideas that could be of use within AstraZeneca's drug development portfolio are poorly received. It appears difficult for the majority of innovative employees to suggest potential innovative ideas and, therefore, influence the early development work.
Innovation Theme 10: Successful innovative practice requires the right information, organisational structure and team commitment at the very earliest of stages to gain momentum.
Innovation Theme 11: AstraZeneca have taken positive steps to embrace innovations that occur outside of their traditional therapeutic areas, but further steps need to be taken to ensure this resource meets the needs of the employees and is as receptive as it proclaims.
Innovation Theme 12: Innovation is hampered by the interchange between Discovery and Clinical resulting in the potential loss of valuable ideas.
Innovation Theme 13: Pharmaceutical innovation relies upon a plentiful supply of innovation stemming from external organisations. This effectively reduces the risk associated with innovation by the costs of the innovation being absorbed lower down the chain.

Innovation Theme 14: The process of acquiring innovation was perceived to be AstraZeneca's preferential means of driving innovative drug development. However, the benefits from acquiring this research rather than developing it in-house are not always clear.
Innovation Theme 15: Biomarkers represent a highly innovative and time sensitive area that requires innovative work to both stop and drive further R&D. It is also an area that has the potential to divert resources to other more promising projects earlier within the processes.
Innovation Theme 16: Hypothesis driven research restricts the extent of innovative activity possible by narrowing the viewpoint of the employees involved. As a result, innovative research and data is poorly shared across AstraZeneca.
Innovation Theme 17: Innovation typically arises as a result of a defined need by a project. Innovation that lacks specific and immediate application outside a project is highly likely to be disregarded.
Innovation Theme 18: Luck plays an essential role throughout the early stages of drug innovation, yet may be guided and created through effective management practices.
Innovation Theme 19: Innovation is required to allow employees to overcome traditional working practices, yet the conservatism of AstraZeneca can prevent innovative work from succeeding.
Innovation Theme 20: In many cases innovation occurs outside of the individual's traditional role, yet attempting to progress these innovations is particularly difficult as it relies upon both management and the end user (i.e. project team or software user) accepting the innovation.
Innovation Theme 21: Organisational restructuring is intended to increase productivity and drive innovation. However, in certain cases, the increased responsibility and realignment of the employee's roles leads to a decrease in potential innovative ability.
Innovation Theme 22: Innovation and productivity are markedly different in the scope of drug development. The current measures and KPIs employed within AstraZeneca often fail to take account of the breadth of innovation occurring throughout a project and focus upon reducing the time required to complete a task.
Innovation Theme 23: Patents are a tangible means of measuring pharmaceutical R&D but may not recognise the amount of innovation required to reach that stage. Furthermore, the process of patenting research may constrain innovation.
Innovation Theme 24: Knowledge Management can play an important role in driving innovation by providing the means to access cutting edge research, both internally and externally to AstraZeneca.
Innovation Theme 25: Innovation is reliant upon discovering diverse knowledge and information sources and generating an idea, but the collaborative culture within AstraZeneca sometimes fails to provide the opportunity to grasp the understanding and as such, a great deal of time is wasted within meetings.

Table 8.4: Knowledge Management Themes

Knowledge Management Themes
Knowledge Management Theme 1: Pharmaceutical innovation is heavily reliant upon applying technology and knowledge to develop a refined approach to discovering a viable compound at the early stages.
Knowledge Management Theme 2: AstraZeneca possesses sufficient knowledge and intellectual capital to adapt and exploit innovative technologies that have no specific need when purchased, although this is difficult to achieve, as the financial risks are increased by taking this approach.
Knowledge Management Theme 3: Pharmaceutical innovation relies upon assimilating the complimentary knowledge of the individuals. Specialist knowledge workers must act in synergy in order to innovate.
Knowledge Management Theme 4: AstraZeneca are seeking to drive their future strategy through collaboration and extended external Communities of Practice, yet in order to progress beyond simple information exchange, a knowledge centred strategy that reduces the bias that exists within scientific research is also required.
Knowledge Management Theme 5: The unseen "innovation grid" implied by the employees is not publicly known and relies upon personal networks of collaboration to achieve results. The knowledge and information generated from this grid is rarely captured and shared.
Knowledge Management Theme 6: The provision of external regulatory information is poorly handled; employees are unaware of where to find and how to interpret information that is applicable to their roles.
Knowledge Management Theme 7: External regulations govern the degree of additional knowledge that may be applied and acquired from conducting supplementary drug development processes, and in many cases the knowledge surrounding this process is poorly captured.
Knowledge Management Theme 8: Knowledge Management may play an important role in addressing the issue of reluctance associated with trying an innovative approach by ensuring that employees are aware of how their innovation could fit in within the regulatory framework.
Knowledge Management Theme 9: Early drug development innovation requires an entrepreneurial approach to develop interest from limited resource and organisational support, and is reliant upon sufficient knowledge to generate interest.
Knowledge Management Theme 10: Supporting innovation at an early stage can be aided by ensuring that sufficient information is available, presenting a strong business case and having access to the "right" influential strategy groups.
Knowledge Management Theme 11: Knowledge Management may play an important role in publicising and defining the innovations that AstraZeneca will specifically fund and manage. As the concept of innovation is perceived to differ according to who is proposing an idea, a common understanding to develop a symbiotic relationship would be beneficial.
Knowledge Management Theme 12: Information and knowledge exchange and reuse between Clinical and Discovery are felt to be poor and can lead to a sense of frustration. Knowledge Management techniques could help to improve this area.

Knowledge Management Theme 13: The degree of knowledge and information disregarded within these early stages is prolific, as only research that can be published will be shared publicly.
Knowledge Management Theme 14: Acquiring innovation does not always mean that the knowledge and information is also acquired. In certain cases the desire to acquire cutting edge molecules may mean this supporting information/ knowledge is scarce.
Knowledge Management Theme 15: Innovation at the biomarker stage relies upon sufficient knowledge and information to understand the mechanism of action of the drug. Without this, the risk of attrition further down the development pathway increases substantially.
Knowledge Management Theme 16: The hypothesis driven approach results in duplication that may or may not be uncovered. Adopting a "systems engineering" approach may avoid duplication of effort and wasted resource.
Knowledge Management Theme 17: There is a lack of appreciation of the knowledge capabilities of the employees and this is manifest in the levels of discontentment felt by innovators who may struggle to progress their innovative work.
Knowledge Management Theme 18: The community-of-practice model plays an integral part in bringing potential innovations to the forefront. However, this process may still be reliant upon an element of luck to make these initial connections.
Knowledge Management Theme 19: The knowledge and information generated from the discussion of potential alternatives and innovative work is rarely captured and rarely disseminated organisation wide.
Knowledge Management Theme 20: Innovation requires an exchange of knowledge where the innovator feels valued and rewarded for knowledge outside of their job remit. Sadly, in AstraZeneca, this sometimes is not the case.
Knowledge Management Theme 21: Organisational change causes a distinct change in the relative information and knowledge needs of the employees as they learn new skills and take on a different role.
Knowledge Management Theme 22: There is a need to employ intellectual capital assessment to measure the innovative activity occurring within AstraZeneca; yet also a need to develop a framework that accurately supports innovation within the organisation so as to encourage further innovative behaviour.
Knowledge Management Theme 23: Conducting patentable R&D results in additional knowledge and information than is not required to submit a patent and consequently may not be captured effectively. Measuring and using the information and knowledge generated outside of the patent may be more valuable than the patent itself in some cases.

Knowledge Management Theme 24: Innovation requires multiple and disparate sources of information and knowledge. Many are available within AstraZeneca but keeping abreast of the important sources is paramount to promote innovation and avoid reinvention.
Knowledge Management Theme 25: Collaboration occurs primarily via meetings, yet collaborative Knowledge Management tools exist throughout AstraZeneca. There is a greater need to either exploit or develop these tools to provide the collaborative medium for innovation.

CHAPTER 9

AN INNOVATION CASE STUDY

9.0 INTRODUCTION

While the researcher was in AstraZeneca, an opportunity to conduct a detailed case-based study of an innovative project arose. The case study concerned the use of a promising compound that had application across two diseases within the Clinical wing of the company. The decision making processes were examined and captured with the help of a novel Knowledge Management based tool (Adelmann & Jashapara, 2003). This chapter presents elements of the decisions captured and the results of a series of extensive interviews.

9.1 CASE STUDY: MANAGING RISK – A CAUTIONARY TALE

This particular drug project was investigated by the researcher over a period of six months and was highlighted by a number of interviewees across AstraZeneca Discovery and Clinical as an interesting example of AstraZeneca's policy on innovative behaviour. The family of compounds in question, showed a potentially useful indication in both Rheumatoid Arthritis (RA) and Chronic Obstructive Pulmonary Disease COPD. A compound that can act on two types of diseases is rare and it is possible to run the initial series of clinical trials in parallel. This is an innovative way of conducting drug trials and holds the potential to save a considerable amount of financial resource. This study demonstrates that while the initial idea was innovative and scientifically sound, the project was hindered in a number of areas. The reasons behind this are discussed within this section, but overall the findings graphically illustrate the observations and themes stated within this chapter as a whole. Namely that driving innovation (even a scientifically viable one) is a decidedly risky and complex process, requiring the support from a diverse range of areas from organisational structure, to Knowledge Management systems, to regulation.

As this section discusses an example of innovative practice within AstraZeneca, no themes or conceptual matrix will be generated. Its purpose is merely to illustrate the drivers for and the requirements of, innovation within AstraZeneca at present. The compound in question was recognised by senior management to be potentially effective in two disease areas:

"That [the idea for the project] came about as a result of a joint [across disease areas] TA [Therapeutic Area] discussion as they were thinking how they could best optimise the current portfolio and it wasn't a bad idea."

In this case the interviewees agreed that although the project was innovative and it appeared outwardly acceptable to all, the employees who worked upon this project were unsure who ultimately gave permission to proceed. One senior research scientist commented:

"I really don't know where the idea came from, but the Portfolio Management Committee and the heads of the TAs all agreed. Certainly it's nothing new under the sun but it was something that was worth trying at the time."

This indicates that responsibility for the project rested loosely with senior management. Yet those involved with the day to day physical co-ordination and interaction between the two Therapeutic Areas (TAs), were poorly informed and knew little of who would provide them with the managerial backing needed to drive the project forward. Another research scientist from the COPD side commented:

"Unfortunately the decision makers never got down to my level and consulted with us...When you're working on the shop floor it's very difficult to get an idea recognised - you'll hear something fantastic like the guys in logistics who came up with a recycling idea - you get those examples and that is an innovative idea that has come from the shop floor, but it's much harder in this part of the world."

Hence, interviewees felt that innovation was certainly possible within other functions of AstraZeneca, yet within their own department they were disappointed by the difficulties associated with obtaining support for a scientifically and financially sound schema. In an attitude typical of innovators consulted across AstraZeneca this lack of support rarely discouraged employees. One interviewee, who was the Project Manager for the RA side, commented:

"I was happy to take it [the drug project] on but there was a lot of pushback [resistance to change] and it was this pushback that won in the end."

Such was the extent of the resistance to change, that the end result was that the drug was forced through a rigid set of defined procedures and processes within the scope of the disease area that had showed the least promise. The term "pushback" indicated that although there was support to proceed with the innovative piggybacking study, the end result was that procedures designed to support running a single clinical trial had to be employed. The project manager continued:

"The main pitfall was that several of the processes that were in place are huge hurdles, investigators' brochures being one - but one of the big things that tripped us up was looking at compounds going into XX [disease 1]. For the XY [disease 2] aspect to work we would have needed to go into XY patients before XX patients and that was just too much for people to get their head around."

Therefore, there were clear procedural and *cultural* hurdles to overcome, yet both were surmountable in the opinion of the project employees. Particularly if the senior managerial backing that remained "hands off", had stepped forward and approved the work required to ensure the project ran successfully. A senior research scientist commented that, although the project failed to run concurrently and could have shared resource and knowledge at many stages across TAs, it was now being run as two distinct projects that required greater resources:

"It would have saved the company an absolute fortune - in fact the study we should have started in 2003 is going to start in 2006. So this has now been taken on by process and started by process and we're now at the point where the study we wanted to do - is actually starting in 2006!"

From these comments the interviewee went on to explain that *'process'* simply meant that the study had been allocated a budget and was being project managed. However, a high ranking senior manager within this project was also interviewed and they expressed dismay at how the innovative aspect of the project was sidelined and effectively shunned. Another managerial employee summed up the linear and enclosed attitude to drug development work that, due to strict project structures, could essentially mean ignoring a compound that had application outside of the project's immediate remit:

"So now they've gone through XX and now they're thinking let's try XY and it's the same with one of the other key compounds I've been working on - there was a total unwillingness to take the risk and put this drug into a XY patient on a variety of levels from safety to political."

They continued to say this went against the compelling scientific evidence that was available:

"Yet probably, from a clinical and a scientific perspective, it is the most likely drug to succeed in the arena, but one of its sisters will eventually get into patients, but again the study could have been done in 2005 but won't get done until 2007. I mean, losing 2 years of marketing to the competition, it beggars belief."

The majority of employees explained that once a compound has exhausted its promise in one disease area it is either disregarded or applied to another disease area. However, this is very much dependent on who was working on it and their influence, and as previously mentioned (see 7.5), the knowledge and information captured rarely leaves the immediate drug project environment.

From a scientific rationale this is clearly at odds with AstraZeneca's mission statement and does little to create an environment conducive to innovation and knowledge sharing. The ground-level and senior employees involved within this project expressed considerable dismay that the reasons behind the cessation of the project and their work falling behind by 2 years, was not aired within the company. A research scientist noted:

"We have no appreciation of the pressure higher up the chain, and what structures are forced higher up, but I really don't think it would be too difficult to send some clearer messages. It's sad when you see documents and statements that are cobblers. I mean, its not lies by any means but it is cobblers!"

Therefore, poor communication and a tendency to enclave the decision making processes are a key characteristic of this project. However, similar innovative projects also suffer from a similar ethos. As part of the case study approach, the researcher targeted a number of other innovative projects outside of the drug development arena. Although not directly involved in producing innovative drugs they centred upon the development of innovative software or business processes to aid drug development in the long term. Amongst those employees interviewed, was a physician who worked on an innovative IT software tool. They expressed similar concern that although their idea had been taken on by senior management, the end result was a diluted version of the prototype software:

"When something gets into IS you initially have control, but as it gets deeper then you don't have any control on what gets delivered - but it still gets delivered, but concealed in all the mumbo jumbo of announcements and newsletters, hiding the real work [of coming up with the software and the idea]."

The sense that AstraZeneca's innovation strategy is designed to encompass innovation and outwardly encourages innovation is widespread. However, when the process of introducing innovation is examined in greater detail, there is an undeniable consensus that support for innovative work is lacking across diverse environments from AstraZeneca IS to Discovery to Clinical.

Furthermore, a prototype innovative project may become changed and diluted by the time it is instigated. What is more apparent is that the classical principles of Knowledge Management, explored in Chapter 3, that may be used to support innovation are also noticeably absent or lacking in functionality. Providing the employees the opportunity to reuse, capture and exploit knowledge is fundamental to innovation within AstraZeneca, yet the *practice* is rather different. The following section concludes this chapter and briefly discusses the key findings in relation to the overall research aim.

9.2 CONCLUSION

This chapter has examined a highly innovative project within AstraZeneca from the perspective of the employee. By taking this stance a number of interesting observations and findings have been made, not least the notion that projects are driven by the need to avoid risk. In this case taking the safer option and trialling the drug within X disease did not yield a successful outcome. Throughout the process the employees tasked with trialling the compounds, expressed dismay that the compound was not also trialled in disease Y simultaneously. This point appears to be down to simply not knowing, who could provide support to the project. As the interviewees noted, to have achieved the project would have saved a considerable amount of time and resource. The data suggests a number of factors caused this, but the principle factor appears to be the difficulty in presenting a strong business case to try an innovative approach first. As noted in 7.1, managerial support is required to gain initial support to progress from an innovative concept, yet in this case the groundwork appears to have succeeded. It is the subsequent and continued support that appears to have been withdrawn at some point, most likely due to the resource demands from other, existing and less risky projects. Undoubtedly Knowledge Management can play a role in this area by providing the knowledge and information required to support all phases of innovation.

The following chapter utilises the findings of chapters 5, 6, 7, 8 and 9 to develop a Knowledge Management tool set that can aid the innovator overcome these and other difficulties faced by innovators within the pharmaceutical industry.

CHAPTER 10

DEFINING A KNOWLEDGE MANAGEMENT & INNOVATION FRAMEWORK

10.0 INTRODUCTION

This chapter marks the start of the discussion phase of the thesis. Throughout the chapters so far there has been a strong emphasis upon the interplay between knowledge and innovation. Innovation cannot proceed without adequate knowledge and information and it is undeniably a crucial factor within pharmaceutical drug development. Chapter 6 expanded upon the results of Chapter 5 and provided a valuable insight into the generic factors that affects innovation within AstraZeneca. While Chapter 7 examined those factors that were specific to AstraZeneca, Chapter 8 continued to explore the current Knowledge Management strategy employed by AstraZeneca and finally Chapter 9 provided details of a case study that utilised a Knowledge Management tool for analysis of the key decision making points. This chapter examines the link between innovation and knowledge management in greater detail, concluding with a novel Innovation/ Knowledge Management framework based upon the results of this research and subsequent work by the author (Parsons et al. 2005a).

10.1 DEVELOPING A KNOWLEDGE MANAGEMENT & INNOVATION FRAMEWORK

Throughout the previous chapters, innovation and Knowledge Management was analysed within the processes of AstraZeneca, specifically with regard to the knowledge and information required to drive those processes. To recap the definition of innovation chosen as the basis for this research was:

"A process of creating and developing new products or services through collaborative team processes and mechanisms that utilise and empower the skills and knowledge of the people" (Terziovski & Morgan, 2004)

The definition of Knowledge Management chosen was:

"A discipline that seeks to improve the performance of individuals and organizations by maintaining and leveraging the present and future value of knowledge assets" (Newman & Conrad, 1999)

These definitions are markedly similar as each suggests that the output, i.e. innovation or knowledge, derives from improving the relationships between employees within an organisation. The following discussion seeks to ground the results from this research within the pharmaceutical environment of AstraZeneca and shed light upon future developments for innovation and Knowledge Management.

To an extent the results of the previous chapters were to a degree expected from the literature review of Chapter 3, yet surprising in the insight that they give into the complex field of pharmaceutical innovation. Throughout the results, the notion that the organisational structure plays as important a role in driving innovation as the access to knowledge and information, counters the idea that providing an employee with sufficient knowledge and information will drive innovation. Nonaka & Takeuchi (1995) emphasise this finding in their archetypal work upon knowledge management by stating that simply providing an individual with a search capability across a knowledge repository is not the answer. The results of Section 8.1 imply that innovators will *assume* that repositories of this type within AstraZeneca, such as the R&D Portal will not contain the correct information required. Instead they appear to prefer to find their information and knowledge elsewhere, principally via collaboration or external sources.

The majority of technology focused Knowledge Management research espouses the use of a repository system, and in many ways, this reflects the strategy of AstraZeneca with the R&D portal and eRooms.

Yet the user still has the difficult task of converting this knowledge (or, in many cases, information) into a usable form that can then be applied to a problem, a process Nonaka & Takeuchi (1995) refer to as combination. The results of Chapter 7 demonstrated that the act of interpreting and then applying this information to generate knowledge and then to perform innovative work is the stumbling block. An employee may have a potentially lucrative idea, yet gathering in the necessary information, knowledge, political support and avenue for exploitation of the innovative concept remains an area that requires facilitating.

10.1.1 INNOVATION, KNOWLEDGE AND COLLABORATION

During this research a Discovery director proclaimed that effective innovative practice is dependent upon mitigating the risks involved within pharmaceutical development and making the connections between disparate *"bits of information and people"*. This finding supports the work of Dodgson (1993) who also observes that effective management style is an essential part of managing collaborative work. Unfortunately this research found that, although the management style could be effective, in terms of innovative work this was often followed by a lack of time and resource in terms of budget and manpower to follow up an innovative concept, a finding also in line with earlier research by Davenport & Prusak (1998).

This research also covered the role of biotechnology firms and university research as the precursor to innovation. On the whole many of the innovative concepts within AstraZeneca have their roots within an external organisation or contact and this may be considered as the archetypal notion of Customer Capital. The acceptance of externally derived innovation over internal innovation was also an interesting finding. This is a finding that bodes well for the future of the biotech industry, but perhaps less well for in-house pharmaceutical R&D. Hence there is considerable opportunity for external innovative ideas to progress within AstraZeneca. Yet, in order for an idea to stand out, Terziovski & Morgan (2004) suggest that the managers of these firms must be more aggressive in marketing their firm's potential for collaborative work.

Particularly as the majority of biotech firms rely upon pharmaceutical companies taking on their ideas and investing resource at some stage (Canongia 2007).

It is fitting that since the results gathering stage was conducted in 2005, the collaboration between Cambridge Antibody Technology and AstraZeneca, mentioned in Section 7.3, resulted in AstraZeneca purchasing the company outright (BBC News, 2006b). Therefore to have the highest chance of an innovation succeeding, the results and Dornblaser et al. (2003) found that optimistic and advanced research stands a higher chance of being taken into a company. Hence, it would appear that if an external innovative concept is sufficiently well advanced, then AstraZeneca will certainly take interest in it. This is largely because the financial risks associated with the early stages of compound development have been minimised.

Relying upon acquiring established research lessens the danger associated with innovation but can mean that compounds become a "me too" as Section 7.5 demonstrated. Conversely the level of risk must be balanced against the competition. If a competitor decides that the risk to progress an innovation is acceptable then they could gain a competitive advantage, particularly if the drug is a "first in class" and outperforms the available "me too" drugs.

This research emphasises that although the majority of innovation is externally derived, it is the individual who usually finds the source of the concept of innovation by assimilating multiple knowledge and information sources. In this case, these concepts are external ideas provided by a biotech, these are then required to be acknowledged and "bought in" to the company at a strategic level in order to have sufficient momentum. The results of Section 7.1 indicate this aspect from the point of early phase drug development, while the results of Section 7.2 acknowledge that "broadcasting" or "advertising" an innovative idea to the organisation can encourage innovation through the use of groups such as the Science Group and the New Opportunities Group. These findings are represented in Figure 10.1 and show two important aspects:

1. Creating the initial concept of innovation lies with the individual. The results of Chapter 7 indicate that while innovation can be acquired, the responsibility to develop and highlight an innovative concept essentially lies with the individual.

2. An innovative concept can only be progressed to a prototype once it has received the employee support (a critical mass) and backing of the organisation. Progression from a concept to an innovation rarely occurs without substantial organisational backing, e.g. managerial support, project management backing and project team backing. This aspect is indicated by the transition over the boundary between the *"Individual Level"* and the *"Organisation & Project Team Level"* (indicated by the dashed line).

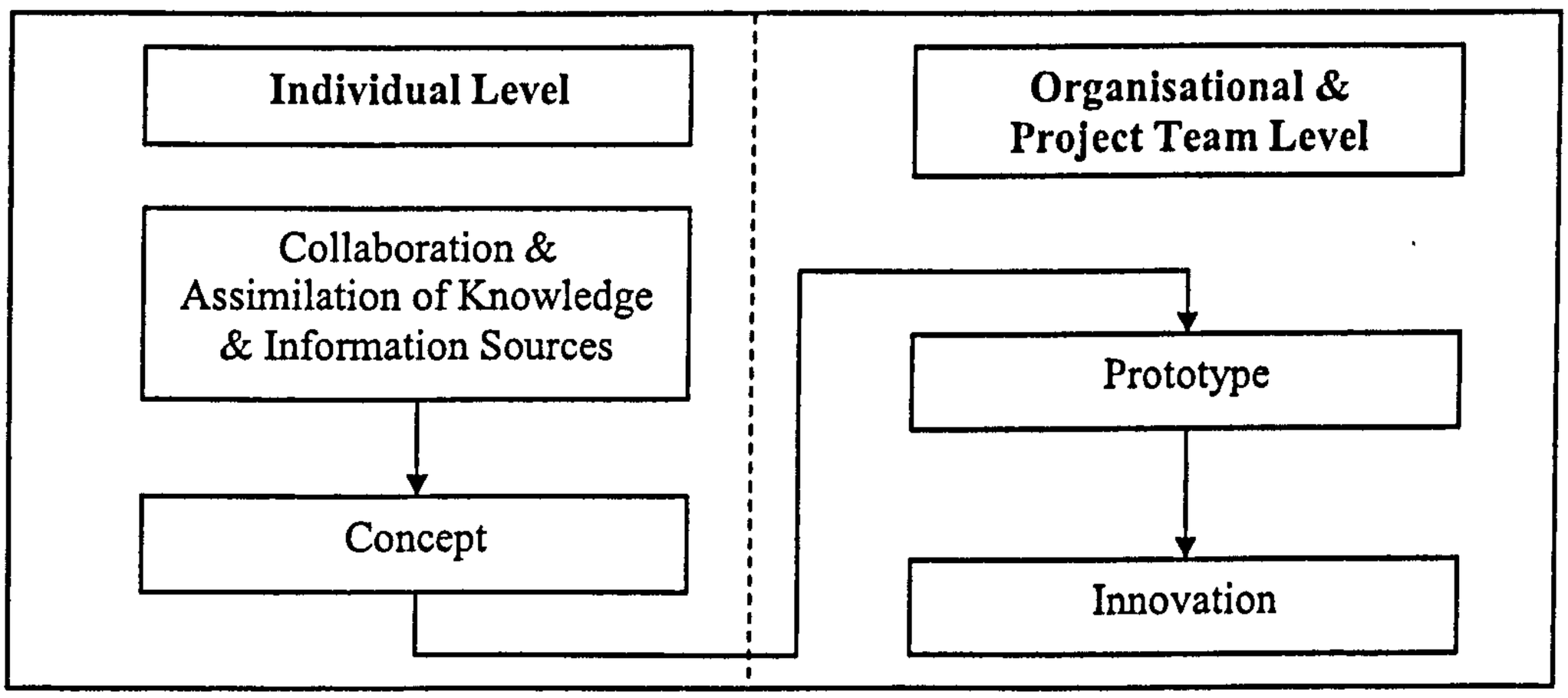

Figure 10.1: Modelling the employee as the initial driver of the concept of innovation and the organisation as the means to achieve innovation.

This research acknowledges that collaboration and networks of innovators primarily drive the assimilation of relevant ideas and innovative concepts. Of the innovations studied within this research almost all relied upon an external idea, whether this was derived from a colleague, a conference or a journal paper. Therefore this research dismisses the idea that the individual can be the sole creator and implementer of innovation.

This finding dismisses the idea of the 'skunk works' model associated with software organisations, where creative individuals are allowed the time and resource to progress innovations themselves (Kohn, 1995). This appears to be due to the extent that regulation and the regulatory bodies (e.g. the FDA) curtail and shape innovation within the pharmaceutical industry as shown by Section 6.4. Therefore, although the individual was responsible for the majority of the innovations studied, collaboration played a key role in gaining the knowledge and information required to develop the innovation. This is represented in Figure 10.1 by the reliance upon collaboration by the individual and the notion of teams supporting the development of a prototype. These findings that the individual cannot largely drive innovation alone are in stark contrast to the majority of the Knowledge Management literature. The literature frequently proposes that innovation is derived from free (and creative) individual thought and the application of the tacit knowledge of the individual (e.g. Lemon & Sahota, 2004; Mascitelli, 2000). Although the initial idea may be derived from the individual the act of progressing it clearly falls outside of one person within the pharmaceutical industry.

Hence, if Knowledge Management is to play a part, the main focus of the Knowledge Management toolset should be upon the creation and mimicking of social networks to drive innovation, thereby reflecting the current situation within AstraZeneca. Although AstraZeneca possesses an active Knowledge Management strategy the results of Section 8.2, has demonstrated that the emphasis remains firmly upon face-to-face communication. The literature also confirms that this is still regarded as the key communications channel in terms of innovation, in the majority of organisations (Rogers 2003).

The foundation of external social networks is an interesting area, as in some cases the external relationship was viewed as short term and transient, such as the case of innovation stemming from a small university grant for a novel dosing method. Hence, little physical knowledge capture occurred at the early stages due to the expected short term nature of the project.

Yet, if as in that case, the working relationship developed further and showed greater potential then it makes strong business sense to capture the knowledge exchanged. Interviewees noted that this would have made the case of the CAT collaboration easier and could potentially have helped to make this relationship more productive. Pittaway et al. (2004) imply that these relationships are dependent upon the type of innovation occurring, namely either incremental or radical. This research also confirms this finding, yet stresses that what may begin as radical innovation may quickly progress to incremental innovation once an innovative concept has been taken into the organisation. The acquisition and the development of the dosing hardware discussed in Section 6.2.2 is an example of this type of evolution of an innovation from relatively radical to evolutionary.

It is interesting that a number of the innovations studied, like the dosing technology, started off as solutions for a problem that did not exist or was ill defined. Developing radical innovation is the realm of the creative scientist and AstraZeneca possesses many of these types of people. Sometimes it appears that these ideas are ahead of their time, as in the case of a novel Knowledge Management system, yet other times they are applicable to current processes. Hence it is important to store these ideas for future use, as what may be dismissed today by their peers, may be highly applicable in the future. Above all, this research has demonstrated that there is a focus upon "knowledge networks" and collaboration as a driver for innovation, whether this is a positive or a negative influence.

The results of Section 7.3 suggest that the link between the type of innovation and the success of the innovation are important, and hence emphasises the importance of capturing innovative practice however radical it may be. The following section examines this in greater detail and seeks to develop the model denoted in Figure 10.1.

10.1.2 CHANGE, INNOVATION, SCIENTIFIC BIAS AND MANAGEMENT

Section 7.3 noted that regardless of how promising or exciting innovative research appears, it must possess a practical place within AstraZeneca's overall strategy. There is evidently an innovative culture within AstraZeneca that drives this initial conceptual innovative research. Yet to an extent it is the act of *presenting* the results, which appears to be hampering the introduction of new ways of thinking, practice and innovation. Newman & Conrad's (1999) definition of Knowledge Management emphasises that Knowledge Management is concerned with leveraging the knowledge and information of the organisation. In many respects it is the aspect of leveraging the knowledge of the organisation that appears to be extremely difficult within pharmaceutical innovation.

As Chapter 7 illustrated, the key factor behind the difficulties in levering existing knowledge is that innovation on the whole creates change, whether to AstraZeneca's existing processes or to the role of the employee. This change can tangibly affect or reduce the amount of resource available to the employee to conduct their project based role. Hence an employee must make their own time to be innovative or simply try to be innovative within what interviewees regarded as inhibitive management structures or *"process" (*see Section 9.1 with respect to the "piggybacking" drug innovation). Findings by Hotek & White (1999) also surmise that when introducing change such as this, employees must be made aware of what resources will be offered and how such a change can help them. In the case of innovation within AstraZeneca, the benefits to the employee are unclear, particularly when their innovative idea may or may not be progressed beyond a concept or prototype (e.g. a novel Clinical Trial methodology). Hence the "piggybacking" example illustrates that the more radical the innovation is, then the greater the resistance to change is, regardless of the potential benefits.

The results of Section 6.3 illustrated that the reasons behind this resistance stem from scientific bias which will effectively act against novel ideas that lie outside of the accepted methodologies and structures of AstraZeneca.

So tackling this bias against innovation felt by employees is an important aspect of any potential Knowledge Management toolset. However, many authors state that bias will always exist within scientific research (Starbuck 1992) and this research suggests that a blinkered *"world view"* along with self belief in the idea, is sometimes necessary to initially drive an innovation. This aspect requires further research to clarify this point and may, in many respects, be countered by the creation of the New Opportunities Group who will try to reduce scientific bias through collaboration and the exploitation of Customer Capital. This research has shown that this group has chosen to drive innovation by establishing networks of innovators and collaborators in a classical Community of Practice (see Wenger & Snyder, 2000) and is an ideal team to be supported by Knowledge Management systems.

However, there is evidently a fine line between excessive management of innovation, which Section 6.4.3 noted can stifle innovation and supportive management. While Section 7.6 suggests that from an innovation perspective managerial direction should equate to a 'guiding hand', whereby innovation is not forced but helped. In addition, the overall research data suggests that innovators can be placed in the right place at the right time through the structure of the organisation and the actions of management (e.g. the purchase of the FTIM dosing technology). In essence an exploitation of the existing employee based Human Capital. However, Section 7.6 also demonstrated how difficult it is to exploit the various skills of the employees already within AstraZeneca, with the preferred model being the acquisition of external innovation and knowledge. The ability of an organisation to draw in innovation, knowledge and skills as it requires, is well documented (see Thomke et al. 1998) and more recently has been named absorptive capacity (see Fosfuri & Tribo 2006). Yet this absorptive model relies upon the location of the necessary resource and skills to overcome a problem as it is posed. Relying upon this type of *reactive* model to drive innovation in this fashion, introduces risk into the equation and hence financial consequences if an innovation fails to solve the problem. This is particularly potent when viewed within the concept of long term compound development time scales and high attrition rates as revealed by Section 3.1.4.

Hence this also explains AstraZeneca's reliance upon external organisations such as biotechnology firms and universities to fund this early stage development work. The early literature findings of this research found that compound attrition is incredibly high within the pharmaceutical industry and higher still when new disease areas are being considered (Alanine, 2003). However, AstraZeneca has an enviable record in later phase compound attrition and this is due to caution, a strategy of risk aversion and an organisational culture that promotes collaboration. This results, in part, through achieving a consensus before work is progressed, albeit primarily at a managerial level. This, in turn, reduces attrition but also makes *"shop floor"* drug related innovation difficult as Section 6.2.3 illustrated. Hence, many interviewees stressed that driving innovation relies upon *"who you know"* and how good your influencing skills are in convincing management and the associated stakeholders to back an innovative project. This finding is also confirmed by Bovey & Hede (2001) and is conceptually indicative of the supportive Structural Capital of AstraZeneca. Overall this research and the Knowledge Management literature suggest an employee's innovative ability is governed by their environment and the direct management associated with their role, a finding confirmed by Probst et al. (2000).

The findings over the last sections have made a number of important points that aid the development of the model in Figure 10.1. Primarily they introduce the role that Intellectual Capital plays in relation to innovation, the individual and the organisation. Therefore, in terms of Intellectual Capital at an *organisational level*, the influence on innovation, based upon the findings from this research, can be described in a number of ways:

- The Human Capital (employees) of the organisation can drive innovation and help to lessen the reliance upon absorptive capacity.

- Customer Capital relates to the formation of collaborative networks with external and internal customers. In particular, this should exploit the relationship with external research organisations, such as biotechnology companies and universities, that effectively drive compound innovation within AstraZeneca at present.

- Structural capital (e.g. the organisation's knowledge, processes, and organisational structure) can only support innovation once the concept has been approved at the organisational level.

These findings are represented in Figure 10.2 and illustrate how the levels of Intellectual Capital within AstraZeneca influence innovation.

Of particular interest is that although the individual, whether this is an employee (i.e. Human Capital} or external contact (e.g. Customer Capital} provides the innovative concept, it is only when the concept can be progressed to a prototype will the Structural Capital of the organisation play a role in supporting the innovation:

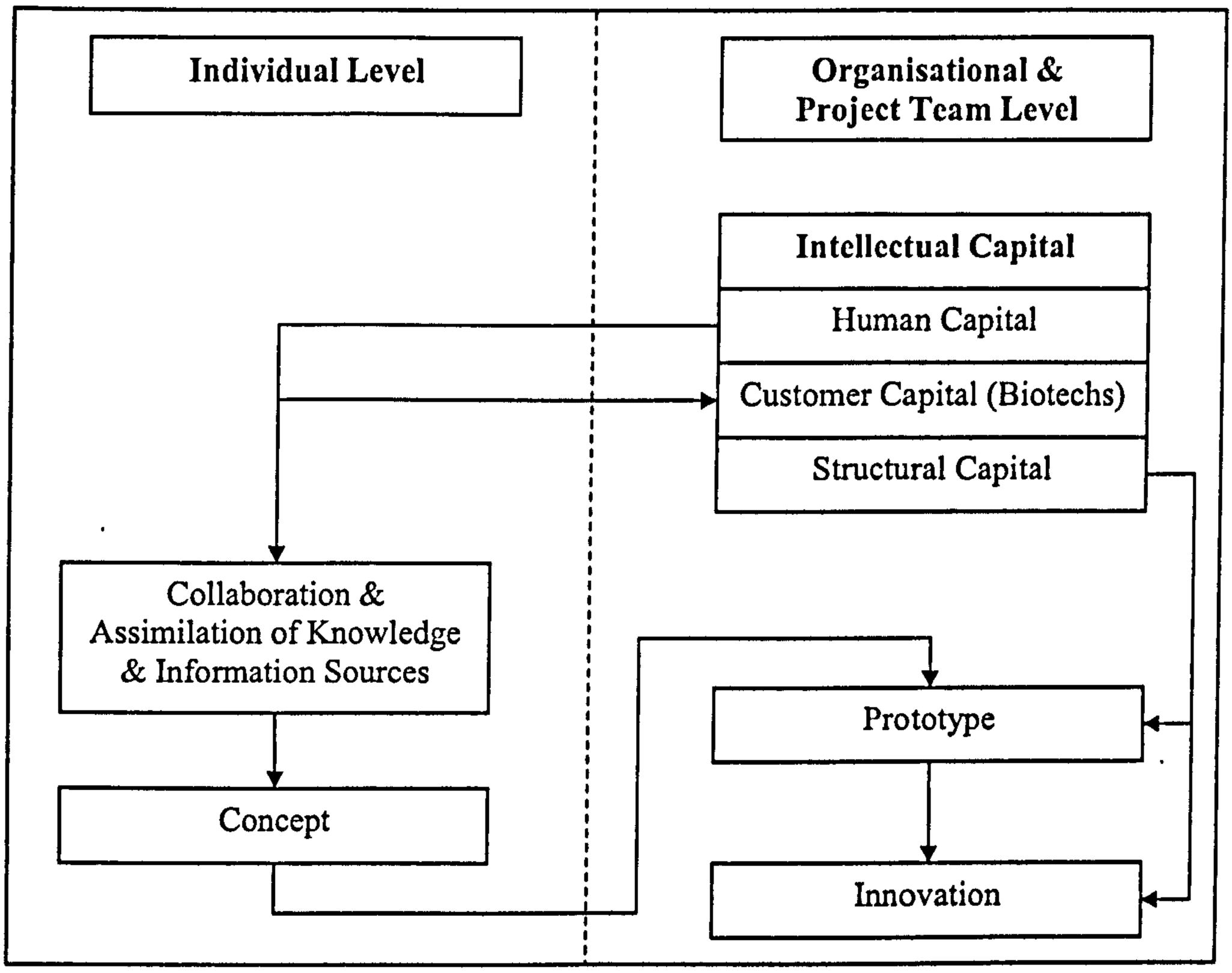

Figure 10.2: Modelling the drivers of innovation and the Intellectual Capital of the organisation as the means to achieve innovation.

The arrow linking the individual and the Customer Capital is two way. This indicates a collaborative and strategic relationship, in that knowledge & information exchange is a two-way process in order to drive innovation. Section 8.2 indicates that this relationship may be transient and under exploited from a Knowledge Management point of view (e.g. little information and knowledge capture), but having a strong external collaborator (e.g. a respected biotech or renowned university) does appear to lessen the risk associated with innovation.

The collaborative aspect appears to protect the innovative employee from risk, and the potential to be blamed for failure as it can encourage sponsorship at a project level, thus taking the onus off the individual.

Yet the data in Section 6.4.3 indicates that employees perceived that a "blame culture" does exist within AstraZeneca, which can affect the ability of the employees to be innovative.

Prior findings by Sundgren & Styhre (2003) within AstraZeneca R&D, Lund, also concluded that there is disaffection with regards to innovation and the management culture. Yet this is a finding that appears typical within large organisations in general and typically arises within project focused teams (Argote et al. 2003). Section 7.4 found that *"discrete groupings"* within R&D project teams causes a distinction of innovative behaviour between employees. In that certain groups of employees are more likely to accept responsibility for any failure and hence would be more likely to adopt innovative practice. This factor was shown by this research to be a key driver of innovative drug development work and this view is supported by literature from Mahesh & Suresh (2004) and Gunnlaugsdottir (2003).

This dichotomy between employees, and in certain cases, project teams, appears to largely arise from the difficulties in effectively balancing the need to innovate and the need to generate a profit. Interviewees commented that creativity and their innovations often arose from the *need* to circumvent an AstraZeneca management process. Interestingly, Knowledge Management literature is particularly emphatic that a "blame culture" can do nothing but hinder innovation (e.g. Corso et al. 2001). Yet this work and a study by Waring (2005) suggest that a "blame culture" is thought of by physicians as a natural part of a medical culture. Many of the interviewees have a medical background and it is interesting to perceive similar perceptions with regards to innovation, risk and blame.

A further important point is that the support of AstraZeneca processes and Structural Capital is dependent upon an innovative concept meeting the needs of the organisation. Section 7.5.3 revealed that innovation which lies outside of the defined strategy may be disregarded, regardless of its potential. This is largely due to the use of measures and metrics that measure efficiency and productivity, not innovation.

Furthermore teams such as the Science Group and the various Therapeutic Areas Global Product Teams will assess a potential innovation on these measures. This inevitably leads to the lack of support unless there is a specific business need. Hence an innovation must:

1. "Get on the radar" of these teams
2. Overcome scientific bias
3. Meet a defined business need
4. Overcome resistance to change
5. Create sponsorship
6. Meet the existing metrics

The first point is interesting as currently these teams meet at most on a monthly basis and interviewees noted that making time to discuss ideas outside of existing projects could be sidelined. In addition to this, many different groups at each stage must approve the process. Examples of these groups include the Commercial Review Board (CRB), Product Review Board (PRB), Senior Executive Team (SET) and Therapy Area Portfolio Team (TAPT). This obviously takes time and for some groups a meeting may only occur annually, hence the focus and resource is firmly upon compounds that are currently in the development pipeline and not innovation. Therefore, it is not hard to see the affect that process can have upon innovation, particularly if it is unclear which of these controlling groups can help to sustain an innovative concept. It is clear that these tollgates will favour external work and not the in-house individual, as external work will generally have progressed beyond the concept phase. These observations are represented in Figure 10.3 by the addition of tollgates, which are based upon productivity metrics, within the organisational supportive processes:

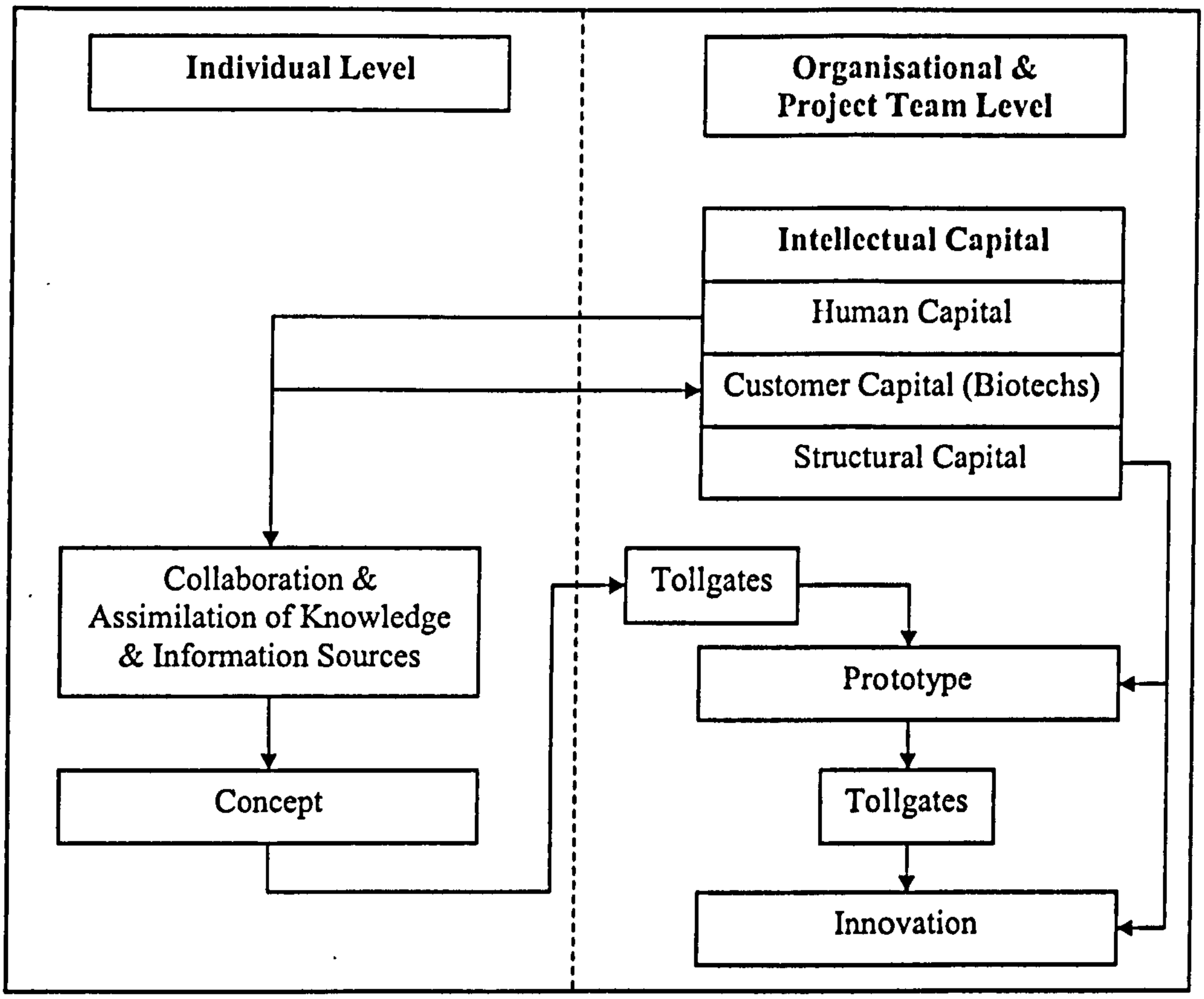

Figure 10.3: Modelling the drivers of innovation and the Intellectual Capital of the organisation as the means to achieve innovation.

10.1.3 THE ROLE OF REGULATION, SAFETY AND LUCK

This research found that patient safety and regulatory compliance is the topmost priority with regards to AstraZeneca's overall role in innovative drug development. The research data also noted that due to the stringent regulations and the exemplary standards set by the employees, it was highly unlikely that a dangerous drug would ever make it to Phase I clinical trials. Yet, as the ill fated trial run by Parexel (BBC News, 2006c) demonstrated, due to the degree of unknowns involved in innovative drug development, relying upon the regulatory process alone is not enough. AstraZeneca possesses an exemplary safety record and this is largely due to the scientific expertise and peer review culture within AstraZeneca.

The recent release of the lung cancer drug Iressa was highlighted by a number of interviewees as an example of how the efficacy of a drug is hard to predict. During the clinical trials the number of patients that positively responded to the Iressa treatment was statistically significant, yet on release of the drug it became apparent that only 10% of patients responded to the drug and this was later found out to be due to a mutation in a patient's EGFR gene (Ruder, 2004). Interviewees stressed that their early opinion was that the drug was a potential blockbuster product, but went on to say that you can only be fully certain of a drugs chemistry and efficacy when a drug is released after Phase III clinical trials. The following quote concerning Iressa, taken from an article by Ruder (2004), explains that even though Iressa may never be a blockbuster product, AstraZeneca and its employees are still fundamentally driven to save lives and release promising compounds as quickly as possible:

"Iressa came from the lab to the clinic before the mechanism of the drug was truly understood because it so dramatically extended some patients' lives, which is a positive thing."

Hence the drive to release promising drugs and balance the risk is a contentious area and one that Knowledge Management could undoubtedly aid, primarily by linking like-minded innovative employees together. This research found that an unusual, and welcome, side effect of gathering innovative people together was the generation of luck. Indeed the results of Chapter 7 suggested that luck plays an important role in initial innovative work. Research by Schmid & Smith (2004) also suggests that luck has an important role in pharmaceutical innovation and this largely stems from collaboration with other employees (e.g. the Human Capital of the organisation).

Yet it is the extent of luck's involvement which is startling, particularly when the slow and "incremental" pace of pharmaceutical innovation is taken into account. These findings relating to luck and the slow innovative pace also emphasise the amount of risk involved within these processes, mirroring findings of research by Schmid & Smith (2004). These findings are represented in the model of Figure 10.4:

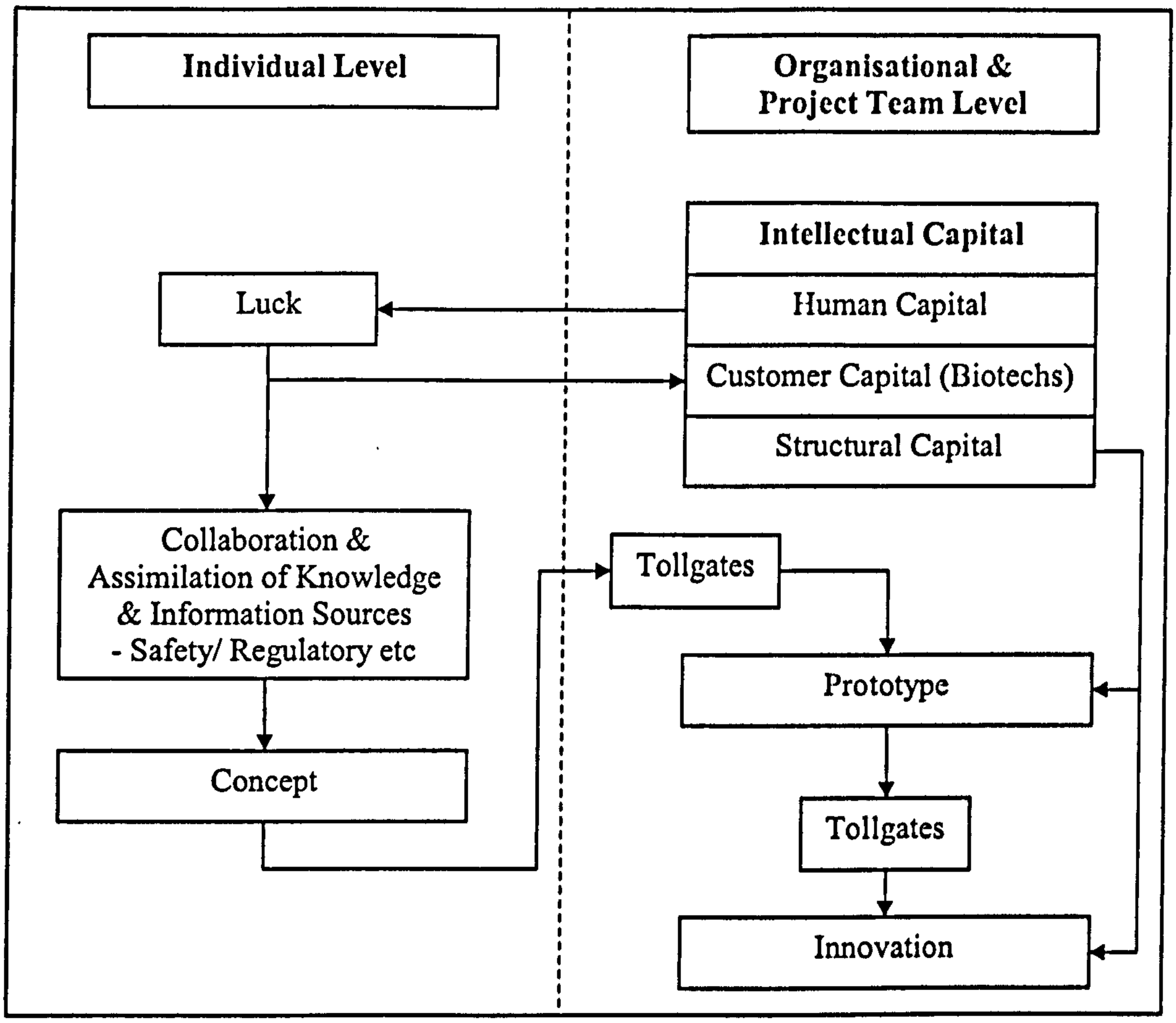

Figure 10.4: Modelling the drivers of innovation and the role of luck and safety as a means to achieve innovation.

The acknowledgement by the majority of interviewees, that luck plays an important role emphasises the role that Knowledge Management could play in reducing this reliance. The following section utilises the previous discussion and expands the model within Figure 10.4, to develop a theoretical Innovation and Knowledge Management centred framework. This framework illustrates the scope of a potential Knowledge Management toolset within AstraZeneca as a means to drive innovation.

10.2 DEFINING THE KNOWLEDGE MANAGEMENT & INNOVATION FRAMEWORK

Innovation has been shown to rely primarily upon assimilating information and knowledge at the individual level. Although luck plays an important role it is the individual who locates the necessary sources of knowledge and information. However, Chapter 8 implies that Knowledge Management must offer more than the act of retaining information and knowledge, a finding also implied by Wickramasinghe's (2003) research. The view resulting from this research is that the goal of information and knowledge exchange and capture is not enough of a driver to ensure a system's use in terms of innovation.

The results of Chapter 8 indicate that from a technology perspective, information is primarily acquired rather than contributed. However, at a social level both acquisition and contribution occur through collaboration and social networking (see Section 8.2). This is largely because employees stated that in order to contribute to a KM system they must have specialist knowledge of *both* the system and their scientific domain, a finding also implied by Grant (2002). It would appear that this also holds true if the employee is to adequately contribute knowledge or information, to a Knowledge Management system. Effectively the employee must be able to capture their specialised domain knowledge in a form that represents the tacit knowledge within their role. A feat that Chapter 3 noted has been the 'bug bear' of the majority of Knowledge Management systems to date and appears to be independent of the training received.

As the results of Section 8.1 demonstrated the broad range of Knowledge Management and IS systems within, and external to AstraZeneca, also means that users become accustomed to finding information in a particular system, be this internal (Product Knowledge Transfer) or external (Scrip).

The results show that users prefer to utilise Knowledge Management systems passively and therefore not contribute information or knowledge, such as using the R&D portal search functionality. Therefore the results of Section 8.1 indicate that from a technology perspective, the information is acquired rather than contributed.

Providing a system that allows the employee to capture their knowledge and then allows another employee to understand and apply this information is tricky, particularly when the diverse range of information and knowledge sources that an innovator must take into account whenever they attempt pharmaceutical based innovation, is recognised. Hence, this research recognises that within AstraZeneca, the renowned knowledge push/ pull model suggested by Williams & Gibson (1990), firmly rests with the "pull" of information & knowledge at present. While the results imply that providing a Knowledge Management based system for innovators to "push" their ideas and knowledge across AstraZeneca should, if the employee can master the system, theoretically enhance innovation.

Therefore, a major finding of this research is that Knowledge Management's apparent obsession with explicitly capturing the information and knowledge of the employees, may not offer the greatest return in terms of pharmaceutical innovation. Instead it would appear that this aspect should be tertiary to the primary role of facilitating social networks and the secondary role of disseminating external and internal information. This research suggests that only once the primary and secondary considerations have been addressed, can an employee hope to be able to capture knowledge in sufficient depth to be worthwhile to the organisation. In essence, an employee must have sufficient "worldview" of their domain before capture can take place, an analogy that is reminiscent of the German word "Weltanschauung".

The main aim of this research as detailed in Chapter 1 was to develop a Knowledge Management tool set that could drive innovation. So far, the discussion suggests that a tool set should possess varying levels so as to drive innovation in line with the findings of Section 10.1.

The reluctance to embrace change implies that it would be wise to mimic the existing innovative drivers within AstraZeneca at present and seek to aid, rather than induce change. To take account of these factors the proposed toolset features three levels:

1. A Primary Level based upon social networking and collaboration both internally and externally, which is driving innovation within AstraZeneca at present

2. A Secondary Level of internal and external information sources that are largely used to "pull" information from sources such as the R&D portal, internal AstraZeneca websites, GEL and PKT, and external sources such as MedLine, SCRIP etc

3. A Tertiary Level Knowledge Management system that can be used to store innovative knowledge with the correct support e.g. Case Based Reasoning/ Decision Capture system. This "push/ pull" level is becoming more widespread within AstraZeneca with innovations such as Knowledge Objects (Adelmann & Jashapara 2003) and other Knowledge Management based systems.

Therefore, a set of Knowledge Management systems should be able to play the important role of providing accurate current knowledge that allows an employee to collaborate and assimilate information and knowledge rapidly. The toolset is designed to be used by the individual and as such, sits with the individual as conceptually represented in Figure 10.5:

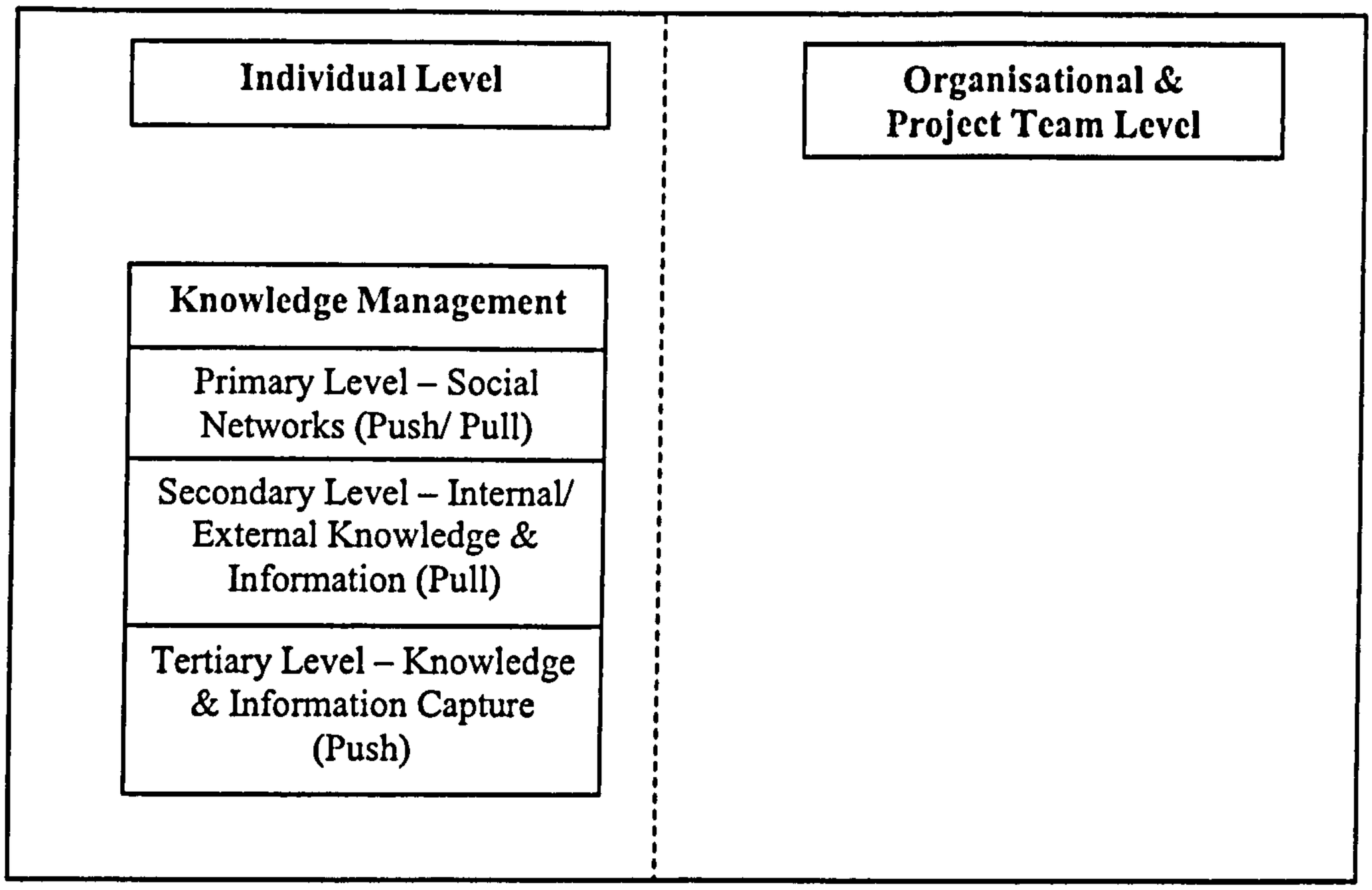

Figure 10.5: Modelling the levels of Knowledge Management tools required for innovation.

Central to this idea is the notion that a set of Knowledge Management systems can perform three distinct roles, namely:

1. The foundation and facilitation of social/ knowledge networks
2. The assimilation and dissemination of relevant up to date information and knowledge – both from within the organisation and from external sources
3. The satisfactory capture of information and knowledge

These roles are quite separate in character and require a different set of tools, yet must be introduced to meet the requirements of AstraZeneca's innovative employees. In reality the proposed Knowledge Management toolset is essentially a *descriptive* framework that can be used to suggest components to *support* and *sustain* innovation. Chapter 3, Section 3.3, illustrates the difference between a prescriptive framework and a descriptive framework in greater detail.

Primarily a prescriptive framework defines a set methodology that must be followed to provide benefit, while a descriptive framework merely suggests a structure and components (Rubenstein-Montano et al. 2001).

Prior to carrying out this research the research aim was to develop a tool set, yet it has become clearer that upon observing the relationship between Knowledge Management and innovation this stage of the tool set development is in reality a framework. Simply because this stage of the research provides an *indication* of what is required and not *how* to specifically carry out a task Above all the framework's key role is to, channel information and knowledge to the individual in order for the individual to assimilate these sources and ultimately drive innovation. Figure 10.6 demonstrates how the previous models of innovation have been aligned with the Knowledge Management framework:

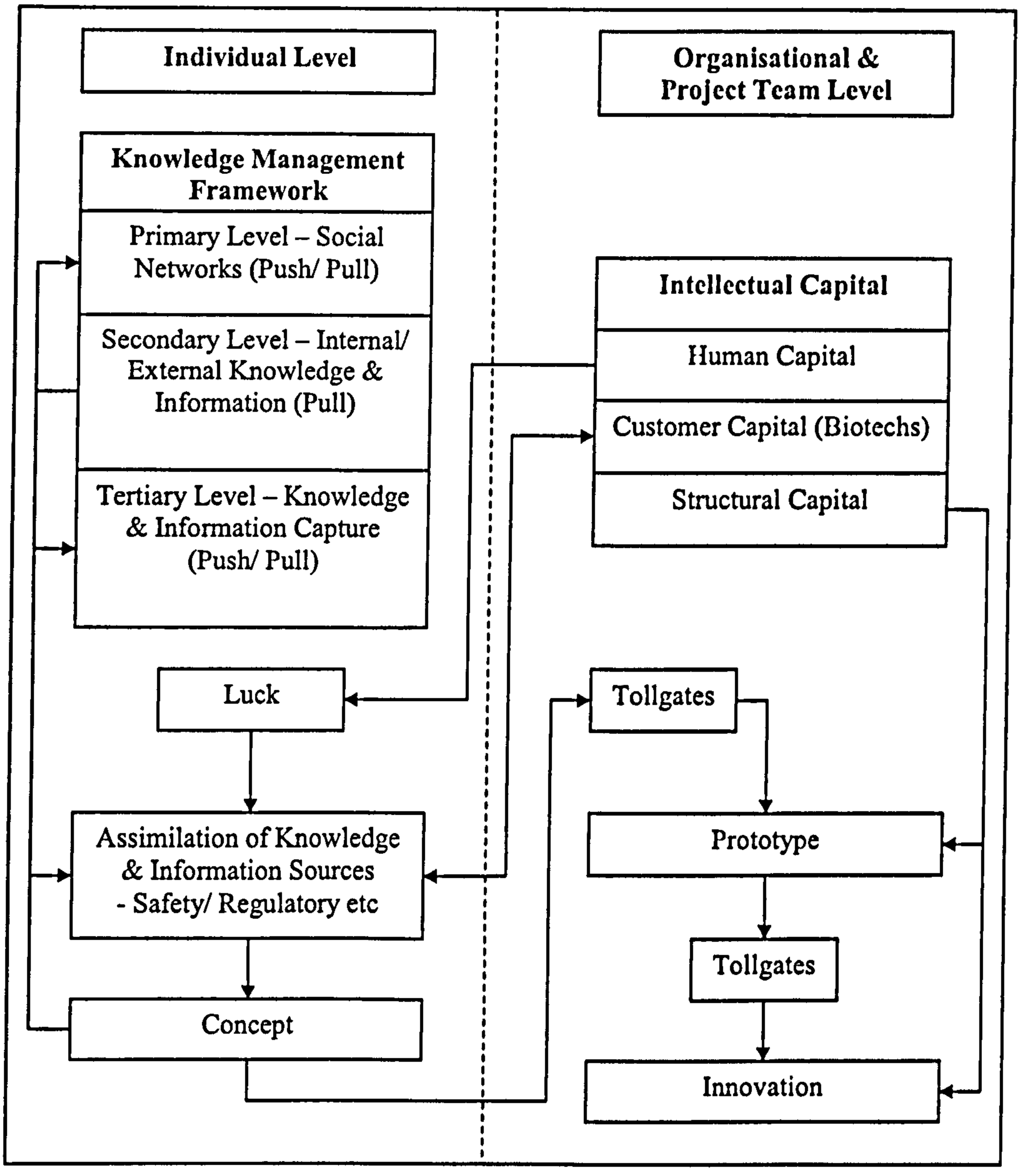

Figure 10.6: Modelling the Knowledge Management Framework with regards to innovation.

Figure 10.6 provides an insight into how the Knowledge Management toolset may be deployed within AstraZeneca. While illustrating the means for the employee to view as wide a range of information, knowledge and collaborative sources as possible.

While the two way relationship between the concept and the Knowledge Management toolset, indicates the means to channel a supported and peer-reviewed innovative concept back into the organisation, either through the social networks within the Knowledge Management system or through the capture of relevant knowledge. In this manner the Knowledge Management framework will allow the employee to access a wide range of potential sources and have the ability to publicise their work to their peers and potential strategic sponsors.

However, Figure 10.6 does not demonstrate the link between the intellectual capital of the organisation and Knowledge Management. In order to fully develop the model it is important to model the role of Intellectual Capital within the system. In order to support the current activities, the role of Intellectual Capital is restricted to providing employees (e.g. Human Capital) and external contacts (e.g. Customer Capital) access to the Knowledge Management toolset. The role of Structural Capital is to support the Knowledge Management framework and sustain the innovation. It is important to note that Structural Capital does not contribute to innovation; it is only used to *support* the Knowledge Management technology and sustain an innovation once an individual has developed a prototype. Figure 10.7 illustrates the interaction between the Knowledge Management toolset and the Intellectual Capital of the organisation:

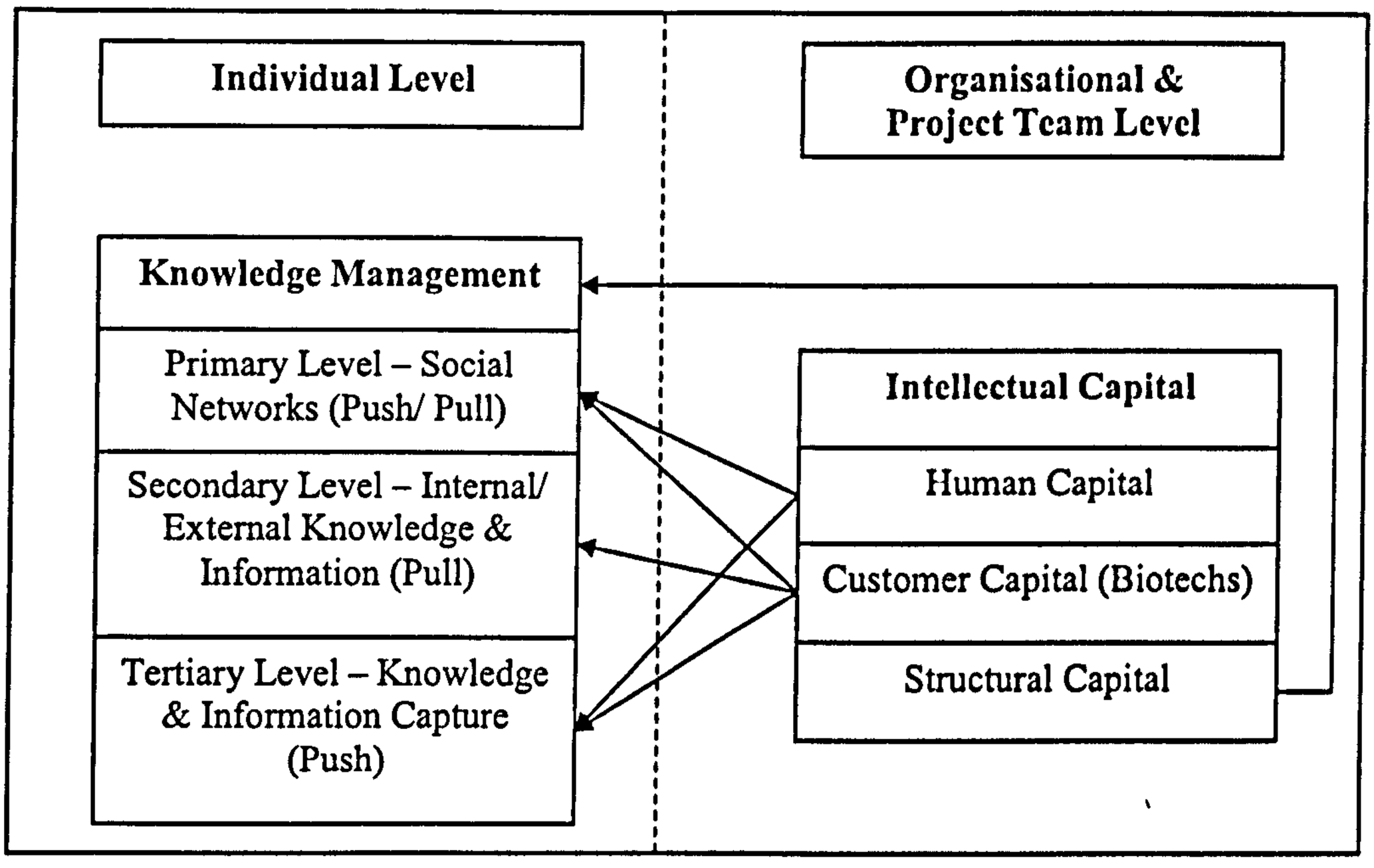

Figure 10.7: Modelling the interactions between the Knowledge Management framework and Intellectual Capital

Throughout this discussion the development of the framework's varying levels was driven by the results of the previous chapters. In this manner the framework or toolset attempts to support innovation by mimicking the existing innovative environment. Figure 10.8 brings together the entire models of this chapter to provide a *descriptive* framework of Innovation and Knowledge Management.

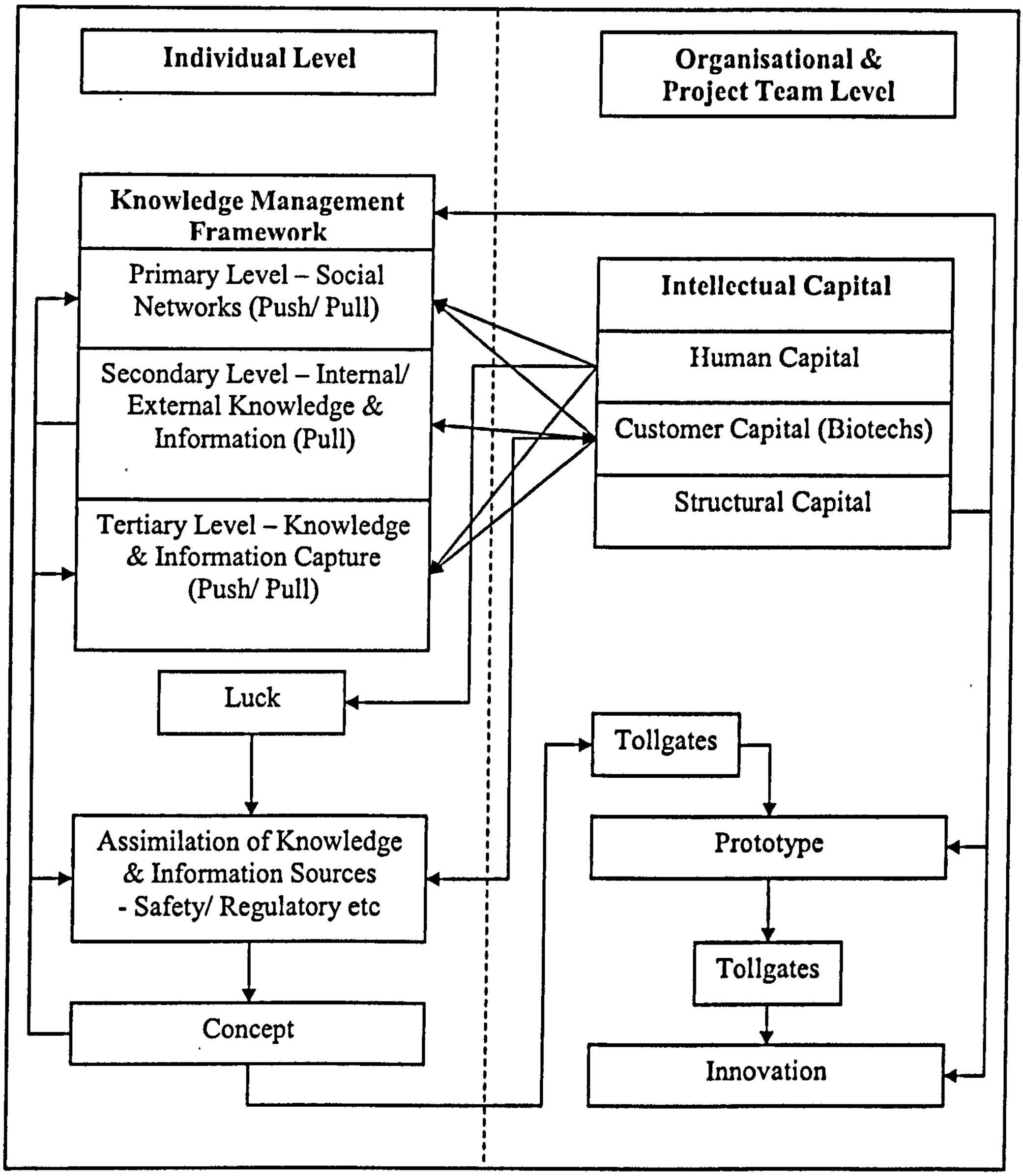

Figure 10.8: An Innovation and Knowledge Management Framework for driving pharmaceutical innovation

The framework in Figure 10.8 is a summation of this discussion and earlier research within a conference paper, written by the author on Collaboration and Organisational Learning (Parsons et al. 2005a).

It is intended that the framework's role is to graphically illustrate how Knowledge Management may be used to drive innovation within AstraZeneca. For example it is the author's view that concentrating upon offering collaborative tools to the employees will offer the greatest benefit. This facet is represented by the two way arrow between the Primary Knowledge Management toolset and the assimilation of ideas stage. It is envisaged that the framework could form a central role to support innovation within AstraZeneca. In essence it suggests the means to drive innovation at the individual level to an organisational level. The framework also describes how innovation may be sustained and suggests the starting point for developing a process that ties in all the elements that are required for innovation to firstly occur and secondly be sustainable.

The elucidation of the various innovation models and the development of a Knowledge Management framework is a novel contribution to Knowledge Management research in the field of pharmaceutical innovation. The researcher acknowledges that there are many alternative models of innovation available (e.g. Jashapara (2004); Edvinsson et al. (2004); Tidd et al. (2001)) yet none consider the importance of Knowledge Management, Intellectual Capital and pharmaceutical innovation as a whole. For example Jashapara's (2004) model acknowledges that tacit knowledge is of greatest importance for the initial aspect of knowledge creation. This research confirms this with regards to the social networks within pharmaceutical innovation. Yet in all cases this research suggest that social networks are only fruitful if the scientific bias that stops an innovation being accepted is overcome. This is a process which takes considerable time and effort from the employee and can result in an innovative concept but little, if any, management backing or practical help.

Evidently there are many viewpoints that may be considered as viable, particularly when conducting interpretivist research. However, from the perspective of technology it has been noticeable that current models of innovation rarely provide practical advice. They only provide an insight into what is currently perceived to be occurring within an organisation.

The following chapter addresses this gap in the research and discusses the Knowledge Management technology that is required to use the Knowledge Management/ Innovation framework and implement a Knowledge Management toolset.

10.3 CONCLUSIONS

This chapter has demonstrated the development of a series of models of pharmaceutical innovation and a descriptive framework for Innovation and Knowledge Management. The framework in Figure 10.8 forms a sound basis on which to develop the final Knowledge Management toolset and, as such, makes a novel contribution to Knowledge Management research. The research discussed in this chapter expands peer-reviewed work by the author (see Parsons et al. 2005a) and is intended to promote discussion with Knowledge Management practitioners and academics alike.

A key finding of this research is that collaborative tools potentially offer the greatest impact and gain to an organisation. Furthermore this "social" level of Knowledge Management systems can be supported by a 2nd Level that allows effective knowledge and information retrieval across disparate domains, both internally and externally. A 3rd Level of decision support and capture complements these two levels and ensures that information and knowledge can be captured as required. The models developed within this chapter illustrate the role of the individual within innovation and counter established Knowledge Management literature that places value primarily upon capturing the knowledge of the organisation.

The discussion within this chapter also raises a number of valid points that shed light upon the use of Knowledge Management within an organisation, while raising areas for further discussion and research as to how Knowledge Management can aid innovation, with regards to an organisation's overall strategy.

The Knowledge Management toolset and its implementation are discussed in greater detail in the following chapter.

CHAPTER 11

DEVELOPMENT OF THE

KNOWLEDGE MANAGEMENT TOOLSET

11.0 INTRODUCTION

The interviews raised a number of points with regard to the Knowledge Management requirements of the employees. Such is the diversity of information and knowledge sources available to the innovator that an attempt to provide a "one system fits all" approach and corral the many sources within a single Knowledge Management system may be futile. Instead this chapter discusses the findings of the research and explores the notion that a modular approach to support the organisation's use of knowledge may be more beneficial. Hence this chapter aims to define how Knowledge Management can support innovation within the pharmaceutical industry and provide practical guidance to the Knowledge Management practitioner. This chapter is based upon the Framework (Figure 10.8), the discussion of the previous chapter, three conference papers presented by the researcher (Parsons et al. 2005c, 2006a & 2006b) and a book chapter which is currently in print (Parsons et al. 2007).

11.1 DEVELOPING A SOCIO-TECHNICAL FRAMEWORK TO SUPPORT ASTRAZENECA'S INNOVATION STRATEGY

The development of the framework in Figure 10.8 stems from the belief that it is essential to pass ownership of an innovation from the creative individual to the organisation. Only once this has occurred will an innovation succeed. Hence the role of a Knowledge Management system or toolset differs in this case from the established norm of a simple knowledge repository. There is a plethora of academic research and practitioner's guides advocating the value Knowledge Management systems of this type can provide (see Gunnlaugsdottir's (2003) review of current Knowledge Management technology).

Yet Walczak (2005) noted that few papers are actually linked to what is currently occurring within an organisation and fewer still seek to support an organisation's intellectual capital in order to specifically drive innovation.

The work of the previous chapters have provided a detailed analysis of AstraZeneca's innovative work from a *social* employee perspective and so the researcher is well positioned to provide comment upon what *technical* Knowledge Management methods and tools could be used. Amalgamating the two areas of the social aspect and the technological aspect will yield a socio-technical solution that will support innovation within the company and this socio-technical approach is in line with recommendations penned by Earl (1996).

Hence, this chapter will elaborate upon the Innovation and Knowledge Management framework from Chapter 10 and suggest "best fit" technical systems to carry out innovation. Table 11.1 details a number of critical innovation factors for each component of the proposed socio-technical system and these are deemed the socially derived factors of the system. These high level factors are derived from the analysis of the research data to date and stem from the conceptual matrices of Chapters 6, 7 and 8. These factors provide a description of what the overall Knowledge Management toolset should provide and this can be mapped to the Knowledge Management Framework of Figure 10.8.

Table 11.1: The Critical Innovative Factors

Area of Framework	Critical Innovative Factors
Innovation to concept to prototype	• Knowledge • Information • Data • Resource • Collaboration and social networks • Expert knowledge • Perseverance • Perceived risks/ benefits • Autonomy • Guidance with regards to "strategic" innovation • Tollgates, milestones & metrics
Knowledge Management	• Access to relevant knowledge, information and data • Collation of knowledge • Capture of knowledge • Resources of external and internal information and data • Communities of Practice • Identification of internal and external experts • Resource
Knowledge and Information Sources	• Literature • Colleagues • Access to internal/ external consultants • Biotechs, universities, etc. • Internet access – RSS (Really Simple Syndication) 2.0 feeds • AstraZeneca Intranet – R&D Portal, GEL, PKT, etc. • Clear guidelines & explicit boundaries with regards to regulation • Reception to change • Security and access rights

As the table demonstrates, these factors are diverse in nature. At present no one system could deliver all of these aspects. It is essential for the toolset to focus primarily upon the collaborative aspect as this currently reflects the means by which employees are currently working.

Furthermore, captured information and knowledge can quickly become outdated within pharmaceutical R&D; hence the reliance upon collaboration rather than capture becomes more apparent. Yet it is still vitally important to capture work that is occurring within AstraZeneca in order to avoid rehashing existing work. As an example, a decision capture system would be valuable to capture and disseminate the decisions of the Global Product Team in each Therapeutic Area. Section 10.1.3 suggests that the Knowledge Management toolset should also play an important role in attempting to mitigate the risk associated with drug development, particularly concerning early work for Phase I Clinical Trials. A recent article in Eye for Pharmaceutical (Hardy et al. 2005) demonstrates how Knowledge Management can be used for drug safety and provides a potential model for implementation within AstraZeneca.

The results of Chapters 6, 7 and 8 detail many areas where such tools may potentially be useful, but this chapter is primarily concerned with developing the technical aspect of the Knowledge Management Framework of Figure 10.8. The following sections develop a "state of the art" toolset that reflects the findings of the research and will support the framework of Figure 10.8 Where possible, examples of the technology being proposed are provided through links to commercial or open sources projects and software. However, before a Knowledge Management system can be implemented, it is wise to address the underlying technical framework that should be used to support the tool set. Rather than choose a proprietary information and knowledge storage format, the research of Chapter 3 revealed that the semantic web and XML based technology appears to offer the greatest benefit.

11.2 CREATING A SEMANTIC FRAMEWORK – USING METADATA, ONTOLOGIES AND SEARCH ENGINES TO DRIVE INNOVATION

In order to successfully implement a knowledge management toolset, it would be wise to introduce an underlying architecture and framework that supports knowledge capture, searching, and collaboration.

While the researcher was in AstraZeneca, work by Adelmann (2006) was actively examining the use of ontologies to "dynamically categorise" information and knowledge as it was presented to the user and this work offers great potential for overcoming the problems associated with disparate information sources. It is important to acknowledge that the semantic framework mentioned in this part of the research stems from, and builds upon the result of the author's collaboration with AstraZeneca's Dr Holger Adelmann and Andy Gaughan.

The need to define the underlying architecture is clear. Currently several hundred different software systems exist within AstraZeneca and most of these will utilise a proprietary schema to store information and data. Attempting to integrate these is almost impossible, so in order to avoid this scenario and add another proprietary system schema to the mix, it is wise to adopt a data schema that is platform independent such as XML (Yu et al. 2003).

Currently a wide variety of commercial knowledge management systems and existing AstraZeneca information systems such as GEL and eRooms have support for XML. XML access takes the form of a Simple Object Access Protocol (SOAP) request that includes user level security protocol as standard within eRooms (Connolly, 2002) while the proposed GEL architecture was unknown at this point. However, AstraZeneca possesses a large resource of talented software developers who are familiar with XML technologies and schemas so implementing a suitable schema should not prove overly difficult. Furthermore AstraZeneca's choice suppliers Microsoft (Microsoft, 2007a), Oracle (Oracle, 2007), and other major software suppliers are championing XML within their latest releases. Hence the functionality to use XML may exist within AstraZeneca due to the process of software upgrades alone. This would allow a variety of information to be captured and be in line with recommendations for information capture by Anagnostakis et al. (2005).

The Semantic Web on the other hand, is a concept that creates a framework around information and knowledge stores and is rapidly gaining acceptance as a credible knowledge and information retrieval approach (McGuiness, 2002).

The interest in this area is particularly apparent within the biotech field, as pharmaceutical based R&D is known to require more than simple web based information (Goble et al. 2005). It is also evident within Section 8.1 that the simple provision of information alone is insufficient to drive innovation.

This research discovered that the sheer magnitude of sources meant innovators were unable to discover relevant information without taking considerable time out of their normal work. The Semantic Web attempts to bypass these problems by utilising a domain specific ontology to physically map interrelated concepts within the domain. The Semantic Web is reliant upon the use of ontologies to create this logical framework and this process can provide a backbone to a knowledge management system. Gardner (2005) provides an excellent illustration of the use of ontologies within Pfizer utilising the Spotfire DecisionSite software (Spotfire, 2007) to promote areas such as *"biomarker discovery, alternate indications discovery, in-licensing opportunities, market differentiation and predictive toxicology"*.

Hence, the use of domain ontologies infers cognitive reasoning and structure between domain specific terminology and the elucidation of the relationships between these concepts. Ontologies may be tailored to capture the domain specific terminology within the various arenas of drug development across the company. The early results suggested that a degree of personalisation of information sources was preferable when attempting to aid innovative employees. This implies that the ontology should be tailored to the individual. Rather than conduct this time consuming task it may be possible to utilise an existing ontology such as MeSH (MeSH, 2007) and allow the user to modify this as they uncover relevant information. In effect, providing a system that allows the user to create links between knowledge and information sources for themselves, rather than rely upon specialist ontology developers or automated systems.

During the researcher's time within AstraZeneca, the researcher was involved in a project utilising a domain ontology created using KAON (Adelmann, 2006). KAON (KAON, 2007) is an interactive and intuitive tool that creates ontologies with a proprietary data model.

However, other open source tools such as Protégé (Protégé, 2007) offer export in OWL, XML or RDF schemas. OWL is now widely acknowledged as the current ontology standard by the W3C, so it makes commercial sense to develop the ontology in the format with greatest potential long-term support (Olavsrud, 2003).

Alternatives to developing an in-house ontology include commercially developed ontologies and other accompanying tools that aim to specifically target a particular drug development domain. The BioWisdom software, Sofia (BioWisdom, 2007), is currently being trialled within AstraZeneca and it is this type of tool that employees believe could offer great benefit.

Systems that can recognise synonyms, drug related terminology, company specific terms, and generic drug terms via a mapped ontology could solve the problem faced by innovators of attempting to amalgamate disparate information sources. With the ultimate aim of allowing the representation, retrieval, processing, and indexing of information and knowledge contained within AstraZeneca's systems and external systems.

Further work by Lee & Sohn (2003) examines embedding rules within information sources using a rule based language that would automatically aid in ontology development. During this research innovators noted that the ideal system would be very much in the background and utilising rules to classify and derive ontologies automatically would offer this functionality. Furthermore it may be possible to explicitly model the rules that the innovators are utilising with further research. For example the research identified that external sources such as SCRIP and PubMed were highly important to innovators. Hard coding rules that exploit the ontology to filter and then present information sources, would enable this information to be automatically presented to other employee's researching the same area. Hence the RuleML language would offer AstraZeneca the functionality to be *reactive* to received information *depending upon the information content*, rather than simply pull information (see Boley et al. 2001). A factor that this research suggests, would be invaluable to the overloaded innovators and could be perceived as capturing the tacit social networking side of the innovator's work into a hard coded form or *"intelligent networking agent"*.

Patel et al. (2005) also note that this concept has shown promise when used for collaborative tasks within the engineering domain. Furthermore, the use of rules to filter information has been explored by Eberhart (2003) in greater detail and it would appear possible that with the correct rules, information could be flagged up to areas of the organisation that effectively control innovation.

For instance this research found that the therapeutic Global Product Teams are a controlling influence for innovative activity through the use of milestones and tollgates. Therefore, if relevant information and knowledge on innovative work was highlighted to them automatically with regards to these tollgates, then the chance of obtaining funding could be greater. In many respects a rule based system could be used to automatically "market" and highlight innovation that met AstraZeneca's strategy either automatically or as the individual uncovered it. Specialist Business Intelligence functions already exist within AstraZeneca to carry out this task, yet there is still a large disconnect between their work and the work of the innovative employee. Hence, providing the functionality for the individual to further their innovation from concept to prototype would aid these processes overall.

From a search and retrieval perspective, AstraZeneca already possesses a powerful search engine called Autonomy which also possesses the ability to act as a form of intelligent agent. This is a document retrieval system that attempts to *"intelligently"* create inferences between documents (Autonomy, 2007a). At present employees commented that although the system holds promise, the information that was currently indexed and searched was not conducive to innovation. Yet such a system would be a powerful information and knowledge resource if it could be interlinked with domain ontologies to search both internal and external information and knowledge stores as suggested by the software suppliers (Autonomy 2007b). This would be similar to Bristol-Myers Squibb, who utilises the Autonomy IDOL K2 system to search internal information and collate newsfeeds form external sources to good effect:

"When a scientist looks for the latest clinical trial findings on a treatment for schizophrenia known to researchers as "Aripiprazole," IDOL K2 expands the term to include synonyms like "BMS-337039" and "Abilitat" and returns all documents relevant to this compound." Bristol-Myers Squibb Autonomy Case Study (Autonomy, 2007c)

As the previous chapters indicated, AstraZeneca employees rely upon external sources such as SCRIP to obtain the latest relevant information. Hence employing an automated system to index this would automatically link relevant internal research to relevant external research. Although this may heighten the element of scientific bias and therefore encourage "me too" drugs, it would also make employees aware of other relevant information and provide the knowledge and information base to make the mental leap to develop an innovative concept. From a visualisation perspective Autonomy provides a powerful means to visualise clusters of results according to the content of the information. This process utilises an underlying technology labelled "KeyView", which can extract content information from over 300 file types, such as Word, PDF, XML, Excel etc (Autonomy, 2007d). As AstraZeneca already possesses this functionality, it would appear that utilising the KeyView system to extract a summary of relevant information in an XML form from documents would be a worthy premise. However, Autonomy is a proprietary system so developing and altering the code requires the purchase of licences, which would require capital resource. Lucene (Lucene 2007) is an open source Java search engine which offers the ability to extract content from many file types across platforms and has been used with good results by Adelmann (2006).

A further notion to consider is that, at present, the structure of AstraZeneca's data, information and knowledge varies according to the author, the template used and the project. Attempting to standardise this process would appear be almost impossible, yet efforts by other companies with similar information requirements, such as BAE Systems, show considerable promise when linking structured information sources with Autonomy's search capability (Autonomy 2007e). Additional work by Eldridge (2006) examines visualisation tools currently used within AstraZeneca for the display of patent and chemical data sets.

Although these tools are based upon data, the article does illustrate the visualisation methods that could offer a means of linking in the higher levels of knowledge and information to low level data sets. This would be very helpful if the employee required further investigation or verification of the data that had generated the information and knowledge (e.g. Phase I Clinical Trials ECG data), as raised by the notion of scientific bias in Section 6.3.

Utilising a semantic framework such as the one described, with the addition of metadata tags in line with Claus & Underwood (2002) or the Dublin Core (Dublin Core, 2007), maximises the chance of relevant knowledge and information retrieval, which the research suggests *could* lead to innovation. However few validation studies exist with regard to semantic technology and the pharmaceutical domain. Earlier work by Feldman et al. (2003) supports this notion that the only means of tackling pharmaceutical information is to pre-process the source text to extract relevant information and then search across this simplified domain to make inferences. Employees in this research also noted that if they were to search across free text sources with a drug related keyword, then this would retrieve many thousands of results.

A typical drug project report or regulatory submission document would contain numerous mentions of numerous drug related terminology, hence a mechanism to summarise and simplify this within the context of a drug would be required. Software tools are available for extracting key points from text such as Copernic (Copernic, 2007) or Extractor (Extractor, 2007), but even after pre-processing this would still be reliant upon the semantic framework to make the links between relevant summarised documents accurately.

This observation also raises the point that the sources searched should differ according to the task in hand. As the research data in Section 8.1 revealed, innovators already search for knowledge, information and data across multiple domains and then use their experience to assimilate these sources. Yet an employee tasked with producing a project management report may *only* require internal sources, which are very different to an innovative research scientist.

Hence it would be wise for a Knowledge Management system to include the element of context with regard to what type of *innovative* work is being undertaken. Context may be addressed by a number of means, from the technological based strategy of text mining or the use of ontologies (see Lin & Harding, 2007), to the social aspects of Communities of Practice and expert systems for example. The aspect of utilising the semantic framework and the Knowledge Management tool set will be examined further in greater detail in the following section with regards to driving pharmaceutical innovation.

11.3 DEVELOPING THE KNOWLEDGE MANAGEMENT TOOL SET

So far this chapter has confirmed that the use of semantic web technologies could be used to theoretically support a Knowledge Management toolset. Yet the framework of Figure 10.8 requires that three levels of Knowledge Management systems are put in place to perform these tasks, namely:

1. The foundation and facilitation of social/ knowledge networks
2. The assimilation and dissemination of relevant up to date information and knowledge – both from within the organisation and from external sources
3. The satisfactory capture of information and knowledge

Collaborative tools within the Knowledge Management tool set, could take many guises such as forum-based Communities of Practice, expert location systems, and knowledge mapping software. Section 10.2 notes that they would offer a high return on innovative performance above that of information/ retrieval and capture tools according to the literature review of Chapter 3 and the results of Chapters 6,7 & 8. Furthermore the results of Chapters 6, 7 & 8 indicate that no one tool can fit the needs of pharmaceutical innovators. Instead an array of tools must be used depending upon the situation. If these tools use the functionality of a semantic framework and provide the means to visualise and link knowledge, whether this knowledge is a tangible asset such as a Knowledge Object or an example of human capital in the form of a knowledgeable employee, then this research indicates that innovation *can be driven.*

The literature review of Chapter 3 suggested that Knowledge Management within the pharmaceutical industry primarily focused upon social networking. However, Section 6.3 of this research has demonstrated that innovative networking is far from simple. Organisational structure, the need to negate bias, the impact of regulation and a host of other factors affect the ability of a Knowledge Management tool to drive innovation.

Yet what tools should the Knowledge Management tool set comprise of? There are hundreds, if not thousands, of potential systems available and many would be suitable. To help this task, Chapter 3 (Section 3.3.3) named and classified a variety of Knowledge Management tools within Tables 3.2, 3.3 & 3.4. This section of the research discusses their value to pharmaceutical innovation and their proposed role within the Knowledge Management framework of Figure 10.8.

11.3.1 DEFINING THE KNOWLEDGE MANAGEMENT TOOL SET

Tables 3.2, 3.3 & 3.4 within Chapter 3 provided many potential tools that could be of use in developing the tool set. To reduce the tool set to a manageable level, each tool was assessed in line with its potential to fit the needs of the Knowledge Management framework of Figure 10.8. Each tool was awarded a theoretical value of "High", "Medium" or "Low" depending upon its potential value to innovation. The reasons for this are briefly denoted in Tables A.2.1, A.2.2 and A.2.3 within Appendix 2.

In short, each tool was assigned a *subjective* value based upon the potential of the tool to support the Knowledge Management Framework and hence innovation. This was either "Low", "Medium" or "High" and was assigned based upon how closely the tool could support a "Representative Theme". For example Innovation Theme 25 states:

"Innovation is reliant upon discovering diverse knowledge and information sources and generating an idea, the collaborative culture within AstraZeneca sometimes fails to provide the opportunity to grasp the understanding and as such, a great deal of time is wasted within meetings."

Therefore this theme is representative of the need to store accurate information, and hence this theme is directly associated with the need for information storage and hence a Knowledge Management "Storage" type tool.

Of the "Storage" tools detailed in Table A.2.1, the database is essential for accurate information storage and would support the needs detailed in this theme and hence is rated "High".

Similarly collaborative files systems such as eRooms and potentially GEL, meet the needs of this theme, hence are rated "High". However, shared folders were highlighted in Section 8.1, as prone to errors and inaccurately classifying documents, hence their use within the tool set is limited and hence are rated "Medium". Therefore this stage produces a "best fit" type tool set that utilises both the Innovation and Knowledge Management Themes to support the tool's selection.

As this stage is subjective, it will require further validation, but as a starting point it serves to identify what tools are categorically required and which are surplus to requirements. Due to the diverse issues identified within each theme, it is simply beyond the scope of this research to attempt to assign a tool to each theme in turn. Each theme covers quite a diverse range of findings and it is unlikely that each theme could be met by a specific tool in any case. Instead the "best fit" approach has been taken in order to make this stage feasible, while keeping the requirements of the innovators in mind.

Validation of the choice of tool can unfortunately only occur once the tools are rolled out in practice. However, Chapter 12 details a potential means of evaluating the success of these tools in relation to an existing project. Chapter 12 also examines the likelihood that a Knowledge Management tool will be successful and hence provides theoretical support for these choices.

Finally after each tool was chosen and assigned a "Representative Theme", the tools that scored a theoretical "High" value were collated and then assigned to either:

- The Semantic Framework: tools to support the Knowledge Management Framework

- Level 1 of the Knowledge Management & Innovative Framework: tools to found and facilitate social/ knowledge networks

- Level 2 of the Knowledge Management & Innovative Framework: tools to assimilate and disseminate relevant up to date information and knowledge – both from within the organisation and from external sources

- Level 3 of the Knowledge Management & Innovative Framework: tools to capture information and knowledge

Table 11.2 illustrates the conceptual Knowledge Management semantic framework required to drive pharmaceutical innovation based upon the evaluation of the known Knowledge Management tools:

Table 11.2: A conceptual underlying Semantic Framework to drive innovation

Knowledge Management Semantic Framework Component	Name of Tool	Value and applicability to driving innovation
Organisational	Ontology/ Taxonomy development	**High**
	Ontology/ Taxonomy acquisition	**High**
	Glossaries	**High**
	Thesauri	**High**
Search	Search engines	**High**
	Indexing	**High**
	The Semantic Web	**High**
Storage	Databases – XML	**High**
Workflow	Process modelling	**High**
Text mining	Semantic analysis	**High**
Web mining	Collaborative profiling	**High**
Visualization	2D and 3D navigation	**High**
	Knowledge/ geographic mapping	**High**

Table 11.2 illustrates the toolset and various components that could be theoretically used to implement a Semantic Framework within AstraZeneca.

Employing these tools as a framework within AstraZeneca, would provide a basis for innovation that would then allow the additional levels of the Knowledge Management toolset to function effectively as denoted in Table 11.3.

Table 11.3: A conceptual Knowledge Management Toolset to drive innovation

Level of Knowledge Management System	Type of Knowledge Management Tool	Name of Tool	Value and applicability to driving innovation
Primary Level	**Social Networks (Push/ Pull)**		
	Community	Communities of Practice/ Forums inc facilitation and management	**High**
		Knowledge Mapping Social Network/ Analysis (SNA)	**High**
		Idea generation	**High**
	Collaboration	Calendaring	**High**
		Meeting support – Decision capture	**High**
		Application sharing – Office Communicator	**High**
		Expert location systems	**High**
Secondary Level	**Internal/ External Information/ Knowledge (Pull)**		
	Distribution	Web/ Internet/ Extranets	**High**
		Personalisation	**High**
	Connectivity	File sharing - eRoom	**High**
		Wireless networking/ mobile computing	**High**
		Peer-to-peer (P2P)	**High**
		Personalization	**High**
		Audio/video streaming	**High**

Table 11.3: A conceptual Knowledge Management Toolset to drive innovation continued

Tertiary Level	**Knowledge & Information (Push)**		
	Authoring	Knowledge Objects/ Knowledge-bases	**High**
		Office suites	**High**
		Desktop Publishing	**High**
		Graphic suites & multimedia tools	**High**
		Groupware & decision support technology	**High**

The reasons behind the deployment and selection of the various tools are denoted in Appendix 2 and are based upon prior findings of this research. The prior discussion within this thesis suggests that deploying the framework and toolset would meet the needs of AstraZeneca's innovators and allow the process of concept development and innovation to occur more readily than at present. Each level of the toolset is designed to leverage different aspects of AstraZeneca's intellectual capital, such as structural, human and customer capital by founding links between the organisation and innovative employees.

Evidently this toolset could be expanded, but at a bare minimum it is theorised that the deployment of these tools, in line with the framework of Figure 10.8, would answer the problems currently felt by AstraZeneca's employees. The key is identifying and allowing people to collaborate across AstraZeneca by utilising the toolset. Unfortunately it is beyond the scope of this research to investigate in detail the potential application of each tool. However, the researcher analysed the use of a Community of Practice while in AstraZeneca (see Parsons et al. 2005b) and the following section examines this in greater detail.

11.3.2 COLLABORATION, THE COMMUNITY OF PRACTICE AND NETWORKS– A MODEL FOR INNOVATION

Collaborative tools within the Knowledge Management tool set, could take many guises such as forum-based Communities of Practice, expert location systems, and knowledge mapping software. Section 10.2 notes that they would offer a high return on innovative performance above that of information/ retrieval tools according to the literature review of Chapter 3 and the results of Chapters 6,7 & 8.

The model of the Community of Practice (CoP) was initially studied by the researcher within AstraZeneca and gave many promising results, within the closely knit Clinical Medical Science department (see Parsons et al. (2005b) presented by the researcher at IRMA 2005, San Diego). However the successful departmental CoP was disbanded when the intranet websites were replaced with the R&D portal, a step that eradicated the information and discussion that took place within the forum, but could be simply reinstated if needed.

The research paper showed that the forum was a highly valued means of achieving valuable collaboration and formed a viable Community of Practice (CoP) of approximately 20 employees. This is an example of a CoP in its simplest guise and was based upon the provision of a proprietary software discussion forum or bulletin board. Topics and questions relating to drug project work were posted to a forum and fellow employees posted replies to discuss the questions posed. This approach is widely adopted (Wenger & Snyder, 2000) and basic forum software is freely available (e.g. PhPBB, 2007).

Empirical research by the researcher in 2003, published as an in-house report for the specification of a new discussion forum (see Experimental Medicine Discussion Forum Specification, Appendix 3). Demonstrated that the community had a positive affect in terms of supporting project work, yet its use for driving innovation was unclear. However, what was apparent was that employees were beginning to utilise the forum as a media to promote and discuss innovative clinical trials work, rather than as a media to discuss existing techniques. This aspect suggests a network of forums across AstraZeneca that focus specifically upon innovation would be worthwhile.

AstraZeneca's R&D portal currently uses a software tool called eRoom (eRoom, 2007) to replace the older defunct forums. This software is principally used to capture and display the documents and information surrounding drug projects. However, eRooms could be used to provide the organisation with Communities of Practice and a collaborative discussion environment.

Employees may search for knowledge and information across all eRooms within the organisation and collaboration is encouraged through the interaction of employees over common topics. However, due to security constraints, the eRoom system is provided on a restricted access basis. The process of gaining access is complex and dependent upon a business need. This is made worse by the fact that an employee can still search across all eRooms within the company, and retrieve the titles of relevant files or discussions. However, due to file security constraints they may be unable to access the contents of these files or discussions. Therefore, the research data of Chapter 6 showed that innovators are more likely to turn to colleagues.

However, eRooms could be specifically used to drive innovation by allowing open access to all employees who could discuss and contribute to issues outside of their immediate project teams. As one employee noted, this type of open access is largely against the culture of AstraZeneca, when they tried to access relevant data from a Global Product Team within the oncology therapeutic area they met with resistance:

"It was a sort of "it's ours, it proprietary". You know, I don't have to sign a confidentiality agreement I've already done that and that was very bizarre. To be fair, it was right in the middle of the Iressa problem so they were very protective, but that held us back a lot."

Hence, an innovative eRoom based CoP *must* have management backing and *must* provide an area that is separate from the specifics of project, in effect, a sanctuary from the process orientated culture that dominates AstraZeneca at present. However, interviewees noted that although such an area would be welcome they must still be careful not to divulge sensitive project information.

The act of committing information to an online media essentially provides a permanent audit trail for regulatory authorities, hence this may explain AstraZeneca's reluctance to allow free form discussions across many topics. Yet if the balance between regulatory and innovation can be achieved, then employees could be directed to this resource for innovative work across AstraZeneca.

The idea of using the domain ontology to support a discussion forum was discussed with Holger Adelmann of AstraZeneca, as a way around the security constraints imposed by eRoom. This led to the development of an in-house paper that described the benefits of linking the semantic framework to a discussion forum. This paper is included in Appendix 4 and makes a case for running multiple discussion forums. The majority of forums would be based within an eRoom for project support, while others would act on a global level and use a semantic framework to support innovation, link discussions and allow "dynamic categorisation" of discussion threads. The paper in Appendix 4 elaborates upon these concepts and is based upon the work and ideas of Dr Holger Adelmann.

The semantic framework and search technology previously discussed would play a key role in driving innovation, principally, by exposing the forum to employees across the organisation through visualisation and the ontology backed search engines. eRooms currently does not offer the functionality to utilise an ontology-based search, instead they offer a simple Boolean-based search across multiple communities. Evidently this type of search is limited to correctly using keywords to return relevant results, but a semantic search utilising a domain-ontology would return all related concepts. However, it may be technically possible to invoke this type of system across the many eRooms. This advance would prove a powerful means of sharing information through discussion and collaboration. Another key tool that is worthy of further attention is an expert system which again would rely upon the semantic framework for its use.

11.3.3 COLLABORATIVE NETWORKS THROUGH EXPERT LOCATION

An expert location system is deemed a "High" value component as they allow staff to discover colleagues across the organisation regardless of location. An expert location system or People Pages exists within AstraZeneca and consists of a simple web-based interface that records employee's contact details, skills, interests, role, and areas of interest. Evidently this system requires users to input their skills and expertise on a regular basis but the research data revealed that few innovators made use of the current system.

Innovators noted that it is easy to forget to update the system and there is no mandatory requirement for them to update their skills. In order to exploit this technology it may be necessary to record the skills of personnel as they undertake and end a project. In this manner they would record that their activities are focused upon a particular compound and then record the relevant skills and knowledge they have acquired from the project. This would potentially allow collaboration to occur in near real time as each employee published the area they are working upon. This research found the information and knowledge requirements for innovation are immediate and an out of date system can not be used to drive cutting edge innovation. Chapter 6 notes that innovation requires scientific debate in order to gain credibility, reduce bias and obtain organisational backing. One way to encourage this would be to allow innovators to easily locate each other via this type of system, particularly if the employees who effectively drive innovation, such as project managers, were included. It is envisaged that the expertise locator system would also utilise the semantic framework to promote project based collaboration and ensure that staff that who are working on similar areas or have expert knowledge are identified and informed.

An alternative to manually inputting skills would be to use an automated system that derives the relevant expertise data from e-mail and documents (AGiLiENCE Expertise Locator, 2007). However, the use of an automated system raises questions concerning privacy and trust and innovators voiced that this should be approached with caution.

During the interviews staff responded that an automatic system would be a useful addition, although some expressed an interest in remaining anonymous through fear of an increase in demand for their expertise and resources. Above all, if social networking tools are to be effective, the employees will require time to conduct these activities and answer queries.

The researcher was present within many HR meetings and it is the goal of AstraZeneca for collaborative working to be built into a mandatory HR requirement, by assigning time into the processes surrounding implementation of a drug development project. However, how much of this time will actually be available is unclear. Nevertheless, if the system simply functions as a networking tool, on the level of software such as FaceBook (FaceBook, 2007) then it may help to strengthen existing networks and retain the critical mass of people required for innovation.

The means to identify relevant personnel and visualise the results has also received significant academic and practitioner research. The following section discusses these developments in line with the Knowledge Management tool set and AstraZeneca's requirements.

11.3.4 KNOWLEDGE MAPS

A knowledge map is the means by which an organisation's knowledge and information may be visualised. It graphically illustrates the knowledge contained within the knowledge and information archives of an organisation and allows users to quickly track like minded colleagues and knowledge across the organisation (Dong & Li, 2004; Kang, et al. 2004). A system to provide Knowledge Mapping functionality to the R&D portal would be a welcome innovation, particularly when tied in with the semantic framework, Autonomy and an expert locator system. In essence, a user searching for a particular phrase or drug could invoke a system that returns the knowledge entities as visual references within the R&D portal. Employees would be able to search across all the information sources, discussion forums, and expert location systems within the R&D domain.

The results would then be retrieved in accordance with the ontology of the semantic framework and visualisation could be provided by a system akin to the Kartoo search engine (see Kartoo (2007) & Figure 11.1) and Spotfire (Spotfire, 2007).

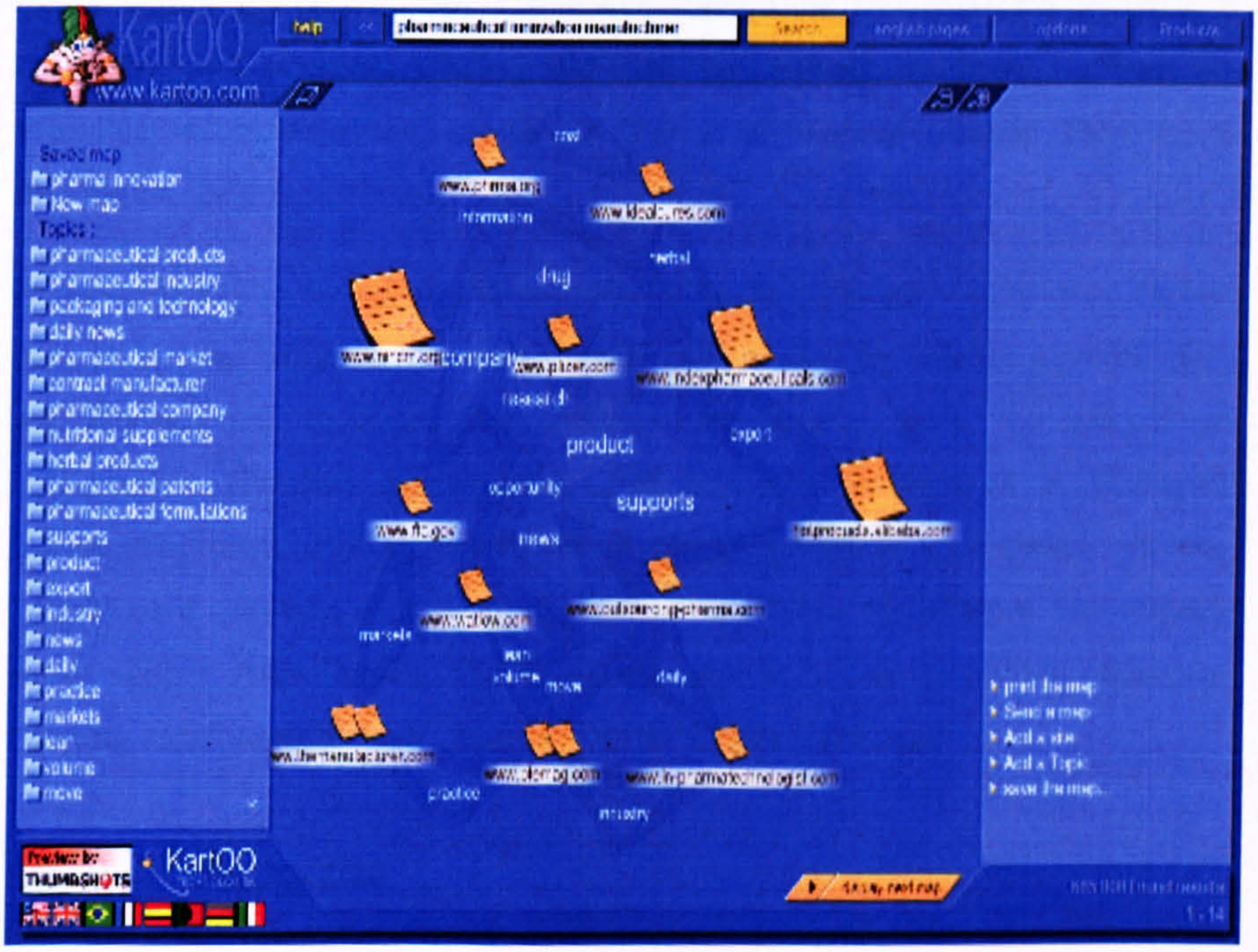

Figure 11.1: The Kartoo Search Engine showing results from a search for "pharmaceutical innovation"

AstraZeneca currently utilises Spotfire for data display and the researcher demonstrated the Kartoo software within AstraZeneca to positive interest. In-depth research by Hellstrom & Husted (2004) also suggests that providing a visual interactive map of the knowledge retrieved by a search engine is a powerful medium and would allow staff to rapidly locate valuable information and knowledge and forge collaborations within the organisation.

Kartoo software is noted to be effective at linking poorly categorised documents and any proposed search system would require this ability.

Chapter 8 noted that project documents are archived at a project level and not at a global level which would be more conducive to searching.

Efforts being made to make GEL easier to search and locate documents would benefit from the inclusion of a visual element such as Kartoo. A similar system exists within Pfizer who use a semantic framework and metadata to provide clustering and retrieval, thereby allowing the user to navigate through the available information and knowledge in a clear manner (Goble, Stevens, & Bechhofer, 2005).

In short the key to the collaborative aspect of the Knowledge Management toolset is to found and mimic the existing internal and external knowledge networks that are fundamental to innovation within AstraZeneca. With the advent of collaborative elements appearing in commonplace software such as Microsoft Office (Microsoft, 2007a), the choice of potential tools is widespread. It may simply be a question of highlighting the potential use of software that already exists within AstraZeneca. The following section briefly examines additional "cutting edge" tools that may be added to the toolset if required.

11.3.5 SOCIAL MEDIA

While this research was carried out, collaborative and social tools such as the blog or Weblog and Wiki became more prominent. Karger & Quan (2006) advocate the use of the blog as a powerful knowledge creation and capture tool when used in conjunction with a semantic framework. Blogging software such as WordPress (WordPress, 2007) is common place and theoretically allows the rapid creation and communication of semantically rich information, which *may* aid the retrieval and capture of organisational knowledge. While the use of Wikis within industry is poorly understood at present, the growth of internet based Wikis such as Wikipedia (Wikipedia, 2007) is undeniable. In short a Wiki allows web based text to be edited and altered by other users, while the blog allows comments and suggestions to be posted regarding a piece of text or an article, see Ramos & Piper (2006) for further information.

It would appear that the blog is certainly a popular and established medium for the communication of news over the Internet, but to date little research has been conducted into their use within the pharmaceutical industry.

Todoroki et al. (2006) have conducted a promising study into the use of a blog to capture the information regarding laboratory experiments that would usually be captured within notebooks. An example of another pharmaceutical related blog is *"In the Pipeline"* (Lowe, 2007). This is an established public access blog that focuses on drug development within the pharmaceutical industry and illustrates the potential of the medium as a Knowledge Management tool set component.

"In the Pipeline" is run by one man, David Lowe and illustrates how articles and comments on drug development promote discussion within an online Community of Practice. These discussions attract responses from a wide range of people who are primarily employed within the pharmaceutical industry and the use of a blog to generate discussion surrounding innovative concepts could prove worthwhile within AstraZeneca.

The researcher presented a paper at the OLKC, 2006 conference in Warwick, UK (see Parsons et al. 2006b) and this generated discussion suggesting that the blog could prove worthwhile if used to drive innovation. In particular, the audience agreed with the researcher's observations that a blog could provide a worthwhile record of a drug project as it was carried out. In this way the blog would capture an overview of the information that was generated by the project as it occurred and, to some extent, form a "ready made" network of semantically rich information if each innovative drug project captured key decisions as they occurred using a blog. Unfortunately whether the idea of open access information that can be edited and discussed online, such as that provided by blogs and wikis, would be welcomed by all is debateable. As Section 6.3 and 6.4 suggest, the issues of security, regulation and Intellectual Property make publishing emerging project information a risky venture, as essentially all the thoughts and debate *could* potentially be audited by regulatory authorities. Furthermore the web based use of social media tools such as blogs and wikis, are founded upon the principle of freedom of information and if such issues constrained the discussion, then their value in an internal site would require further research.

However, what a social tool would achieve is to link employees principally within project teams but also externally to that team through the semantic network, a notion that forms the basis of the expert locator type software. This would tackle many of the issues that currently impede innovation within AstraZeneca and the toolset could be expanded to include the newer branch of social and collaborative tools. These could include tools provided by Microsoft within the Office Communicator suite (Microsoft, 2007b) and the web based Groove (Groove, 2007), which could offer secure instant messaging and document collaboration between colleagues within a UK/ Sweden project group for example.

11.4 CONCLUSION

At present Tables 11.2 and 11.3 provide a high level overview of what specific tools the Knowledge Management toolset should comprise. Allowing fellow employees to collaborate and communicate across AstraZeneca's R&D domains and externally, with research organisations and universities is the key to driving pharmaceutical innovation. The collaborative element of the toolset is designed to support innovation and provide the facilities for existing groups of innovators. Rather than focusing upon developing new groups, the results indicate that AstraZeneca has a large number of different innovative networks (e.g. Medical Science, New Opportunities Group, etc.) which at present lack a focus or hub.

The toolset is designed to lever the intellectual capital of the organisation and provide the focus or hub for these groups or Communities of Practice, while additionally providing a supporting framework of collaboration, information/ knowledge retrieval and capture to be used as required, in line with Figure 10.8.

The following chapter finalises the discussion and suggests ways by which the effectiveness of a Knowledge Management tool may be assessed.

CHAPTER 12

EVALUATING KNOWLEDGE MANAGEMENT

12.0 INTRODUCTION

Many authors suggest Knowledge Management is a relatively simple technique with which to improve an organisation's innovation capability (e.g. Alavi & Leidner, 2001; Zack, 2000). However, many Knowledge Management papers are based upon the deployment of technology and to the experienced Knowledge Management practitioner, who may have experienced the initial hype of Knowledge Management, it asks the question:

"Will this system really work? And will it deliver the promised benefits?"

Davenport & Glaser's (2002) study of Knowledge Management systems, maintains that few will deliver upon their promise because they do not connect with the organisation and require considerable effort on the part of the knowledge worker to maintain. In many cases a Knowledge Management system will fulfil a niche need by providing information and knowledge to a specialist sub-set of the organisation. Yet, if a Knowledge Management system does instigate, or at least promote a valuable innovation, as in the case of AstraZeneca's ontology backed discussion forums (Adelmann & Jashapara, 2003), it will ultimately be worthwhile. However, measuring the benefit of a Knowledge Management system is notoriously difficult.

The finding in Chapter 7 is that pharmaceutical innovation is a long-term and evolutionary web of interlinked processes. The evaluation requires a detailed, qualitative examination and accompanying interpretive philosophical examination of the factors that permitted innovation to occur. Without this level of detail, as attained by this research, a Knowledge Management system could appear to possess very little value.

Such is the complexity of pharmaceutical innovation that the single ideal Knowledge Management tool may simply not exist. Instead, the tool set of Chapter 11 could form a series of interlinked systems that together form a modular approach. Utilising this approach would embrace the social and technological aspects of the organisation, but in many respects it counters the established view of the "one system fits all" approach.

When instigating this work within AstraZeneca, the initial emphasis was upon developing the ideal Knowledge Management system to allow pharmaceutical innovation, primarily by developing and embracing a variety of Knowledge Management tools that could meet the needs of the employee and thus allow innovation. However, the results of Chapter 7 and the Framework of Figure 10.8 now make it clear that these tools must also fit the organisational processes. Hence, this in turn complicates the issue of a simple Knowledge Management/ Innovation system, by introducing aspects that are rarely considered within Knowledge Management tools at present - such as the organisational structure, the allied processes that support the organisation, and the intangible assets that help to support the employee.

The tool set of Section 11.3 is specifically designed to overcome these problems, yet the discussion within this chapter is relevant to other Knowledge Management practitioners who are charged with implementing Knowledge Management within an organisation.

12.1 MEASURING THE EFFECTIVENESS OF KNOWLEDGE MANAGEMENT

Chapters 6, 7 & 8 emphasise that the processes and organisational structure are important factors, yet few interviewees were aware of the role intellectual capital and particularly intangible assets play within the organisation. The literature review of Chapter 3 briefly examined intangible assets but since conducting the data analysis, it is clear that they play a greater role than previously envisaged within a Knowledge Management system. Kaplan & Norton (2001) & Andriessen (2005) denote intangible assets as:

- The skills, competencies and motivation of the employees
- Database and information technologies

- Efficient and responsive operating processes
- Innovation in products and services
- Customer loyalty and relationships
- Political, regulatory and societal approval

It is clear that many of the results and findings within the conceptual matrices and themes of Chapters 6, 7 and 8 could be construed as intangible assets. This finding suggests that there is a strong link between Knowledge Management, intangible assets and innovation. For example, Table 12.1 briefly denotes a selection of results from this study and displays the intangible assets of pharmaceutical innovation:

Table 12.1: Examining a selection of intangible assets within AstraZeneca

Intangible Assets	Example within AstraZeneca
The skills, competencies and motivation of the employees	Expert knowledge of Clinical & Discovery scientists; specialist physicians' clinical knowledge; molecular geneticists' knowledge, etc.
Database and information technologies	PKT; GEL; R&D Portal, etc.
Efficient and responsive operating processes	New Opportunities Group; Global Product Team, etc.
Innovation in products and services	Diverging the current portfolio by developing innovative drugs; acquiring innovative research, etc.
Customer loyalty and relationships	Networking & collaboration between biotechnology companies; patient safety websites to build customer confidence, etc.
Political, regulatory and societal approval	Close liaison with the FDA; internal politics that can drive favourable innovation; internal society of innovative employees, etc.

Constructing a framework of intangible assets is therefore a relatively easy process from the themes and matrices of this study within AstraZeneca.

These assets could be used as the basis for a balanced scorecard. That in turn, can be used to formulate a strategy for the organisation that acknowledges the intellectual capital of the organisation. The balanced scorecard can aid the identification of factors which will affect the overall strategy of the organisation and help to bring these to the attention of the managers (Spender & Marr, 2005). Yet rarely within the Knowledge Management literature will a Knowledge Management tool specifically set out to support the strategic objectives of the organisation. This observation is striking, as, on the whole, the research showed that Knowledge Management tools and systems commonly support information and knowledge sharing only within a defined domain within the organisation (e.g. the R&D portal, PKT and departmental discussion forums).

It is only upon analysing this research, did the researcher witness the apparent disconnect between Knowledge Management, innovation and an organisation's strategy – particularly on the level of the key performance indicators (KPIs) used by AstraZeneca to assess any potential gains from innovation or a Knowledge Management system (see Section 7.8). For example, if the definition of intangible assets is refined into three further categories (Andriessen, 2005) then the link between knowledge, Knowledge Management and strategy is clear:

1. Strategic competencies - the strategic skills and knowledge required to support the organisational strategy

2. Strategic technologies - the information systems, databases, tools and network required to support the strategy

3. Climate for action - the cultural shifts needed to motivate, empower, and align the workforce behind the strategy

The results of the study of the Knowledge Management tools in Chapter 8 clearly demonstrate that elements of these aspects are missing from the existing Knowledge Management systems and processes within AstraZeneca.

For example, employees persistently broached the opinion that their innovative ideas were difficult to progress without sufficient managerial backing.

While many of the innovative ideas are closely aligned with AstraZeneca's strategy, the support to progress their idea from concept to prototype was limited. Hence, it appears that the technology and climate to support these innovations through Knowledge Management is lacking. A similar observation was also made by Zack (1999) and this still appears to be a common finding throughout large organisations in general.

Knowledge Management within the pharmaceutical industry appears to be driven by supporting employees in their daily work and not in supporting the company's innovative strategy. Evidently, a fine balance is required whereby the system supports the daily activities of the employee in order to generate revenue, yet also allows future revenue to be acquired by exploiting the intangible assets and Human Capital of the organisation. Therefore, this research suggests that there is a clear distinction between the types of Knowledge Management that are needed within an organisation, one to support and one to innovate. Innovators frequently complained of having to overcome "process", which they determined to be the organisation's management processes and regulations which they felt inhibited innovation. This is a factor that could simply be related to trying to use tools and systems that are designed to support daily project work rather than support innovation, for example GEL, eRooms, etc. This in turn, appears to be due to the fact that the measures of success of a system or process are tied to metrics that primarily measure financial success. Hence, unless a system or innovation can support an AstraZeneca process that has a financial measure, it appears of little value. Furthermore this research suggests that the majority of innovative work is largely intangible until it reaches a prototype stage. Only then may it be measured by the existing metrics, a factor that explains why innovation is primarily acquired externally rather than developed.

The results of Chapter 8 make it is clear that AstraZeneca's "process" can adversely affect Knowledge Management systems, particularly when the system exists only to serve localised innovative activity. Unless the outputs of a system explicitly aid drug-project focused "process" then organisational backing and the "fabled climate for action" will be lacking.

From a financial perspective it is perfectly rational to invest only in technology that directly supports the drug development processes. However, the results of Chapter 6 imply that a well thought out and reasoned innovation can bypass months of laborious work and *"process"*.

Therefore, solely supporting existing processes certainly appears financially sound, yet in terms of the time taken to reach a viable drug compound, the innovative route may be quicker and hence substantially cheaper. One such example of the focus upon "process" is the expensive conversion of the GEL (Global Electronic Library) document management database to an XML schema for enhanced information retrieval. The redesign of this information repository will make it easier to share regulatory and commercial documents both internally and externally with regulatory bodies. Ensuring this system is as simple to use as possible is essential for AstraZeneca to comply with regulatory bodies, yet it is unclear to what extent achieving this will drive innovation. It will certainly aid information retrieval by enhancing the search capability and allowing the standalone GEL database to be incorporated into the AstraZeneca global search capability. However, it is a large undertaking with little guarantee that the regulatory and project documents (mainly Word and PDF) within the database will be of use to the innovator. Granted that interviewees commented that there is a need for an overview of prior work within AstraZeneca, but interviewees noted that the files within the GEL database are simply too complex and detailed to be of use.

Unless information sources are concise and accurate, this research suggests that an innovator will simply contact a colleague through an informal social network instead. One employee commented that it would be wonderful to have a global shared folder containing presentations of the various disease areas that are researched within AstraZeneca. This concise yet effective solution would have saved half a day of a senior research scientist's valuable time when they had to give a briefing at an external conference. Whether such a folder could be construed as a "Knowledge Management system" is a matter of discussion, but the end goal is exactly the same as a complex Knowledge Management system – it saves the time of the specialist knowledge worker and allows them to focus upon the innovative aspect of their role.

Hence, a supportive Knowledge Management system will ultimately allow the worker to carry out their job more effectively; however an innovative Knowledge Management system should specifically identify and provide the knowledge and information that is required to innovate.

12.2 SUPPORTIVE AND INNOVATIVE KNOWLEDGE MANAGEMENT

This research suggests the notion that Knowledge Management itself has a distinction, between supportive systems and innovative systems. During the researcher's time within AstraZeneca the implementation of a supportive software system was analysed. Although this was not strictly a Knowledge Management system, the system was innovative in that it formed collaborative relationships across the organisation and was linked to the current strategy. The novel clinical system named Early Efficacy Enterprise or E3 simplifies the process of conducting clinical trials and provides a faster and more efficient means of predicting the efficacy of new cancer drugs. While the researcher was discussing the implementation of the project with the project manager, it was apparent that this type of innovative system fell firmly within the role of a supportive system.

The efficiency was predicted to rise by 35% and as this type of system directly supported the core strategy of the company, resources that had not been available before, were made available. The manager acknowledged that gaining initial funding had been difficult, but the promised gain in efficiency was tangible and directly supported the progression of compounds from Phase II to Phase III clinical trials, thereby attracting senior sponsorship. Another major factor was that the project had defined customers who signed internal contracts for the service, namely Phase III investigators who, because of the project, could manage their budget more accurately and thus record a tangible benefit.

When the project was analysed, 11 trials had signed up and more were expected; with a progression of the system from the oncology TA (Therapeutic Area), to the respiratory and inflammation TA (RITA) was expected within the future.

Essentially the project acted as an internal consultancy providing a service to internal customers and negating the need for expensive external collaborations with Contract Research Organisations (CROs). The success of this project led the researcher to attempt to discover why exactly this project was so successful over other innovative work.

If this project is conceptualised within Kaplan & Norton's (2001) framework of intangible assets, then it is clear that each intangible can be matched to the software system. At this point a leap of faith was required to apply these values to software, but essentially an intangible asset typically signifies a concept that has value that cannot be measured in financial terms. In this case it is not the tangible value of the software that is being assessed, but the intangible value it provides to the organisation as an innovation. Table 12.2 illustrates the project in relation to the definitions of an intangible asset, as defined by Kaplan & Norton (2001) and Andriessen (2005):

Table 12.2: Examining the intangible assets of the E^3 project

Intangible Assets Definitions	Example of intangible asset	Satisfied the definition?
Utilises the skills, competencies and motivation of the employees	Utilises the skills of AstraZeneca's employees (10 at present)	Yes
Database and information technologies	Provides a template and database for analysing and sharing clinical trials data quickly	Yes
Efficient and responsive operating processes	Increases the efficiency of the current Phase II to Phase III business processes by 35%	Yes
Innovation in products and services	Provides an innovative product and a innovative customer based service	Yes
Customer loyalty and relationships	Creates strong relationships for its customers by saving them resource	Yes
Political, regulatory and societal approval	Has strong senior and regulatory sponsorship as it clarifies and hastens a complex area	Yes

Hence, the parallels between a successful innovation and the definition of an intangible asset are clear. The tangible measure of the 35% increase in efficiency is being driven through the development of strong customer loyalty and the utilisation of in-house skills.

Hence, in terms of innovation, this project has generated value in excess of its original remit by exploiting the organisation's intangible assets and by specifically supporting a set of crucial business processes that generate future revenue. It would be naïve to suggest that a Knowledge Management system can only support the specific business processes that generate revenue, as the majority of innovative work, by its very definition, is outside the existing processes. Yet it suggests that a Knowledge Management system will gain more managerial backing if it directly supports a specific process that supports an objective of the organisation's strategy.

Hence it is important to tailor a Knowledge Management system to directly support the existing business processes and support the organisation's strategy. The need to support existing work patterns appears to be linked to the fact that the introduction of a Knowledge Management system generally calls for change and improvement, rather than support. Mertin et al. (2001) demonstrate this point by listing the proposed benefits of a Knowledge Management system as:

1. Cost/ time reduction, increase in productivity
2. Process improvement
3. Improvement in the exchange of information
4. Customer orientation & satisfaction
5. Transparent organisational structure/ processes
6. Better decision making and prediction
7. Quality improvement
8. Staff satisfaction

9. Competitive advantage and increased market share

These nine factors are exclusively based upon changing the existing processes through utilising a Knowledge Management system and indicate how disruptive Knowledge Management can appear to the management of an organisation. When viewed from this perspective, what incentives are there to introduce a system that potentially could interfere with the existing revenue processes of the organisation? In order to be used for innovation, a Knowledge Management system must induce a change in working patterns over time, change which may or may not support the existing processes. In a highly risk averse environment such as pharmaceutical R&D, the introduction of yet more risk and change, will obviously raise eyebrows and require significant effort to prove the benefits that may arise through a change in working patterns.

For example, a novel Knowledge Management system was studied within AstraZeneca and assessed against these factors and the definition of an intangible asset as defined by Kaplan & Norton (2001) and Andriessen (2005) (Table 12.3). The Knowledge Management system was designed to capture the literature and documents that are required for early stage drug trials. Essentially, the system acted as a central repository for information that was deemed useful for the employees. The unique aspect was that it bypassed the use of private shared drive folders and therefore, all information in the system was accessible to others. The system also employed a domain ontology-driven searching functionality so as to aid the user in locating relevant information and the work of other employees.

Table 12.3: Examining the intangible assets of the a novel Knowledge Management system

Intangible Assets Definitions	Example of intangible asset	Satisfied the definition?
Utilises the skills, competencies and motivation of the employees	Utilises the skills of AstraZeneca's employees (1-10 at present)	Yes
Database and information technologies	Provides a template and database for analysing and sharing information	Yes
Efficient and responsive operating processes	Is thought to increase the efficiency of an internal department	No
Innovation in products and services	It may provide innovation - although this is unproven	No
Customer loyalty and relationships	May creates strong relationships internally, yet not externally	No
Political, regulatory and societal approval	Has senior support but lacks regulatory and organisational support	No

The results revealed that the system supported an improvement in the exchange of information, better decision making and an increase in staff satisfaction for a sub section of Clinical scientists. These benefits only resulted through a change in the working patterns of the employees to include this system in their daily work. Yet it does not directly support one specific process as the E3 system does, instead it helps many. Therefore, it is difficult to see how the Knowledge Management system succeeded in relation to a number of the intangible assets criteria. On the other hand the E3 system and the outputs from the E3 system, satisfy the definition of an intangible asset. Therefore, this is a strong argument to ensure that before a system is implemented, there are tangible measures of success identified that show how the system will support a current business process, even if the system will cause change through innovation.

In many respects the research data supports the academic literature which suggests that given sufficient time, Knowledge Management systems will also deliver a benefit. Yet, as this process is driven by change and not support, it requires time to take affect, time that this research has shown, will not be provided unless a tangible benefit is perceived. The notion that Knowledge Management is strongly linked to change over a period of time, appears to be hampering Knowledge Management as a field. Recent research by Davenport & Peitsch (2005) also noted that pharmaceutical organisations seek to drive drug development by:

"Changing the way the scientists and technicians operate, in order to create, share and use knowledge more efficiently and more effectively".

Knowledge Management that is designed for innovation, it would appear, is not based upon support for current processes, but instead calls for change and that may explain some of the comments fielded by the interviewees:

"We've been harping on about Knowledge Management and how it can help and very little has been actually executed."

If employees are expected to change to utilise the existing Knowledge Management systems and this offers little benefit over collaboration between colleagues in face-to-face meetings, then it is clear that the uptake of these systems will be slow, particularly with regard to innovation. It is a fair assumption that an employee will change their working patterns to utilise a system that supports their current role, but only if the system offers them a benefit. The following section explores potential measures to capture the benefits of the proposed Knowledge Management tool set of Chapters 10 & 11.

12.3 MEASURING INNOVATION

One aspect of this research has been to assess and learn more on measuring the value of innovation to an organisation. While there is a wealth of intellectual capital research available that proclaims to measure innovation and the intangible assets of a company, the reality of applying these measures is rather different, particularly with regard to measuring the benefit of Knowledge Management.

Chapter 3 analysed relevant research concerning techniques such as the Balanced Scorecard, Intellectual Capital statements and so forth. However, what was striking was that very few papers actually suggest what these measures should be measuring. Instead the authors would acknowledge that it is important, yet entirely subjective and these measures are dependent upon the context of the intangibles to be measured. Evidently this is not overly helpful as it basically states that you must design your own measures. However, the results of the conceptual matrices within Chapters 6, 7 & 8, do provide measures in the form of the "Drivers" and "Required Criteria" for innovation. Overall the results provide the measures, listed in Tables 12.4 and 12.5, that could be used to indicate the effectiveness of innovative activities within AstraZeneca.

Table 12.4: Measuring pharmaceutical innovation

Area Assessed	Assessed Area	Metrics
Issues concerning the innovation	1. Link between existing AstraZeneca strategy and the innovation	Checklist of where the innovation "fits" within the organisation i.e. supports a particular Therapy Area (TA), meets the requirements of the GPT, supports a "First in class" compound etc
	2. Impact of innovation in terms of financial resource and revenue generated	Potential cost savings in terms of man hours/ FTE (Full Time Employee) saved by using the innovation and potential Return on Investment (ROI) and potential revenue from the innovation
	3. Conference presentations/ peer reviewed papers/ newsletters produced regarding the innovation	Number of papers/ conferences/ newsletters/ AstraZeneca Innovation Awards
	4. Value and "worth" felt by the employee(s) who developed the innovative concept – i.e. avoiding a "blame culture"	Questionnaire with Likert Scale to assess employee perspectives
	5. Number of patents developed from the innovation	Number of patents associated with the innovation – however this is a long term undertaking

Table 12.5: Measuring the value of information & knowledge for pharmaceutical innovation

Area Assessed	Assessed Area	Measures
Issues concerning the use of the information & knowledge (source)	1. What was the source of information/ knowledge? e.g. CoP/ decision support software/ R&D portal etc	Checklist of potential sources, for example Knowledge Objects, R&D Portal, PKT, GEL etc
	2. Did the source allow a project to progress?	Question – Yes or No with free text response to capture the reasons why
	3. How important was the source in terms of allowing innovation?	Question with free text response to identify the subjective value of the source
	4. Did the source help to "gel" teams?	Questionnaire relating to the collaborative aspect of the information and knowledge required (see Section 5.3.3.2 for examples)
	5. How many people contributed to the source and what were their roles?	Number of people and checklist to capture their role and title
	6. Did the source help people to work more effectively together?	Survey based upon a Likert Scale to gauge how the information/ knowledge helped to drive innovation
	7. Was the source easy to find?	Survey using a Likert Scale (1-5 scale from strongly disagree to strongly agree) to gauge how easy the information was to locate. For example, measure the level of agreement with a set of statements such as: *"I found the information source easily"*
	8. Was the source easy to use?	Survey using a Likert Scale to assess the ease of which the information/ knowledge could be used. For example, the level of agreement with a set of statements such as: *"The information I find is easy to understand"*

The examples provided in Table 12.5 illustrate that many of these measures could consist of a simple Likert Scale, survey or checklist. However, this would require retrospective assessment after an innovation had sufficiently progressed in the short term. At present very little follow up work is conducted concerning the value of an innovation, such as an Innovation Award within AstraZeneca, so this would be a beneficial exercise. The longer term benefits are rather more difficult to assess due to the long product life cycle of a compound. However, short term assessment would be feasible and worthwhile, possibly with the inclusion of these assessments at project review or milestones. The use of patent data was felt by the interviewees in Chapter 7 to be a poor representation of innovative activity. However, a recent article within Eureka (Palmer, 2006) explains how accurately mapping the development of patents can aid innovation by producing a roadmap of future trends within R&D. Similarly, the knowledge & information reused from software systems such as discussion forums, lessons learnt & decision systems and collaborative software could be theoretically tracked or mapped, to provide a measure of how effective the system is. However, carrying out this in practice would prove onerous, yet could be valuable in terms of the evaluation of a Knowledge Management/ IS system within an organisation.

Figure 12.1 illustrates the concept of how innovative information/ knowledge could be measured if the Knowledge Management toolset from Figure 10.8 was used as a means to innovate:

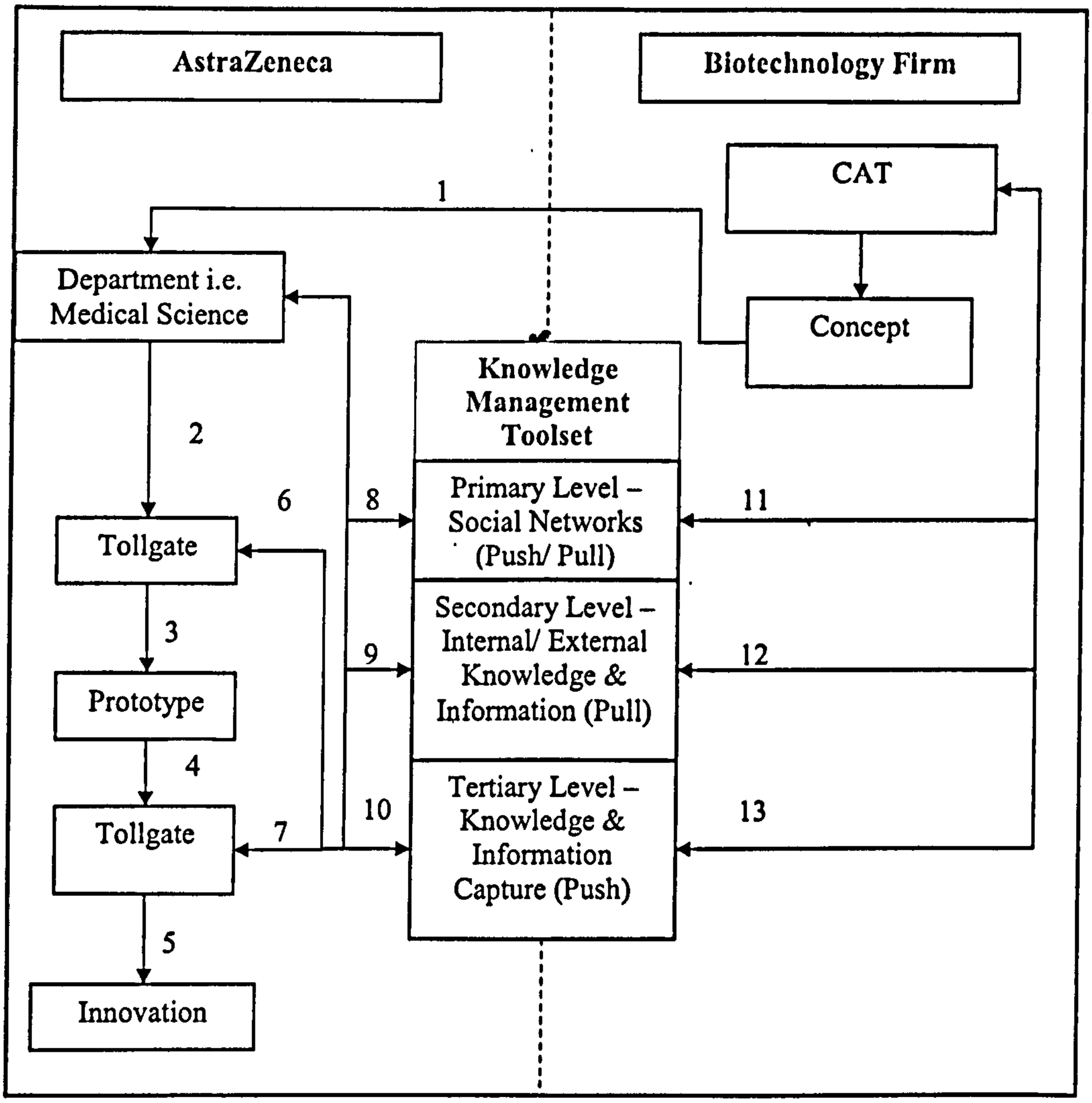

Figure 12.1: Assessing Information/ Knowledge Flow between organisations with regards to innovation

Measures similar to those identified in Table 12.4 & 12.5 could be used at each point denoted by a number within the diagram.

The number signifies the possible measure or measures to be employed. Potential innovative measures could include:

1. The number and details of innovative concepts derived from external sources, such as biotechnology firms and universities. It is also important to record where within AstraZeneca these innovations are introduced, for example Medical Science.
2. The number and details of the innovative concepts that are approved by the internal departmental employees or stakeholders and are then passed on to AstraZeneca departments or individuals, who are responsible for progressing the innovation further. For example, this may be the progression of a novel proteomics study from Medical Science to the GPT. This stage may also record if the innovation is passed on to other teams or individuals within a single department for further work. This metric seeks to establish the percentage of innovations that progress past initial scientific scrutiny once they are acquired from external sources.
3. The number & details of the innovative concepts that pass the tollgates and criteria set by internal AstraZeneca groups such as the New Opportunities Group. This will provide a percentage measure of how far an innovation has progressed and help to identify if the criteria for innovation used by departments and AstraZeneca's strategic groups differ.
4. The number & details of the innovative prototypes that pass initial departmental scrutiny and are taken under AstraZeneca's strategy. Again this measure will assess how, where and why innovation may either fail or succeed.
5. The number & details of the innovative prototypes that pass the final set of tollgates and make it to an innovation, whether this is a final compound, Knowledge Management system or novel FTIM study. Again this measure will assess how, where and why innovation may either fail or succeed.

Figure 12.1 also illustrates measures that could be used to assess the information and knowledge exchange occurring at each stage of the development process:

6. The source and details of the information and knowledge acquired from the Knowledge Management system which have directly contributed to the assessment of an innovative concept at a tollgate. It is envisaged that the majority of knowledge will stem from the primary level, yet the secondary and tertiary levels will provide supportive knowledge and information. The capture of where the information and knowledge is obtained from is crucial to demonstrate the value of a Knowledge Management system. This is particularly important and would help to generate interest in using Knowledge Management systems, such as the Knowledge Object system, to support the capture of decision knowledge concerning these areas.
7. The measures used at this stage would be similar to those used at stage 6. Aiming to capture where the information and knowledge is being derived from and how the decisions were being taken. At this stage of the process it is expected that additional information and data will be required to augment the scientific research. This would include marketing data to assess the potential of the innovation and financial data to support additional investment. Although the Knowledge Management system would not provide this, it would still be wise to capture how and why this additional data influenced the eventual "Stop/ Go" decision.
8. These measures would assess the use of the social aspects of the Knowledge Management system to provide scientific support for an innovation. Potential measures include:
    - The number of formal Communities of Practice
    - The total number of participants within the social system, particularly the discussion forums
    - The number of regular contributors (knowledge champions) and the number of contributors within each community

- The number of tools utilised to provide scientific evidence to support the innovative concept
- The number of contributions that directly contribute to supporting or disproving an innovation. It is also important to assess when and why an innovation may not progress as this can help prevent financial loss and compound attrition later on.
- The percentage of contributions provided by the social tools (Primary Level) in comparison to the Secondary and Tertiary levels of the Knowledge Management tool set.

9. These measures would assess the use of the external and internal information "Pull" aspects of the Knowledge Management system to provide scientific support for an innovation. Potential measures include:
    - The number of available sources
    - The relative use of these sources (e.g. server logs) and hence the relative importance of the various sources at the various stages
    - The number and details of supporting or disproving scientific evidence i.e. academic papers/ journals, in-house reports or external research
10. These measures would assess the use of the "push" aspects of the Knowledge Management system to provide scientific support for an innovation. Potential measures include:
    - The number of best practice/ lessons learnt captured
    - The number and location of the decisions captured along the innovative process
    - The number of Knowledge Objects created
    - The amount of times the captured information is accessed
    - The where, when and how the captured information and knowledge has been used, particularly when it supports an argument for or against innovation
    - The percentage of reviews that capture information/ knowledge at each stage of an innovative project

11. These measures would assess the use of the social aspects of the Knowledge Management system by the external collaborator. The measures would be the same as the measures in point 8, yet primarily identify where an external partner has contributed the expert knowledge or information.
12. These measures would assess the use of the information/ knowledge "push" aspects of the Knowledge Management system by the external collaborator. The measures would be the same as the measures in point 9, yet primarily identify where an external partner has contributed the expert knowledge or information.
13. These measures would be similar to measures in point 10, but would identify if an external partner had contributed to/ or used the knowledge or information stores within the Knowledge Management system.

It is hypothesised that building up the knowledge offered by these measures could help to identify where collaboration is succeeding and help to refine the toolset software. For example, if the majority of decisions are being taken when a concept is first bought into AstraZeneca, such as a "Stop/ Go" decision, then tailoring decision support software (Level Three) to support these decisions would obviously help. Similarly if sufficient data could be gathered to reveal trends then the toolset could be tailored depending upon whether the innovative work was a Phase I FTIM (first time in man) study or a proteomic study, for example. At present, data is not gathered regarding this aspect and it would be interesting to gauge whether different types of collaborative partner required different approaches with regards to information/ knowledge exchange. As effective collaboration with external organisations is essential for the longevity of AstraZeneca, it makes commercial sense to invest in this area and attempt to negate the effects of the mistrust and Intellectual Property retention that was evident in the findings of Chapters 6, 7 and 8. Employing measures to evaluate the impact of a Knowledge Management system would also help to gain support for the system and tangibly demonstrate that rather than requiring funds, it actually helps to generate revenue.

An alternative means to measure innovation that is lightly covered within existing pharmaceutical research, is via the visualisation of the information and knowledge within the organisation, a term commonly referred to as "knowledge mapping".

This technique was investigated by the researcher in collaboration with Dr Holger Adelmann and employees of the Medical Science department. This exercise led to the researcher capturing the outputs from the piggybacking project studied in Chapter 9, within a decision capture matrix. This is a novel means of displaying the decisions, assumptions and the outcomes relating to each decision, throughout a project. Figure 12.2 illustrates the capture of the decision, the assumptions that decision was based upon and the eventual outcome of the decision:

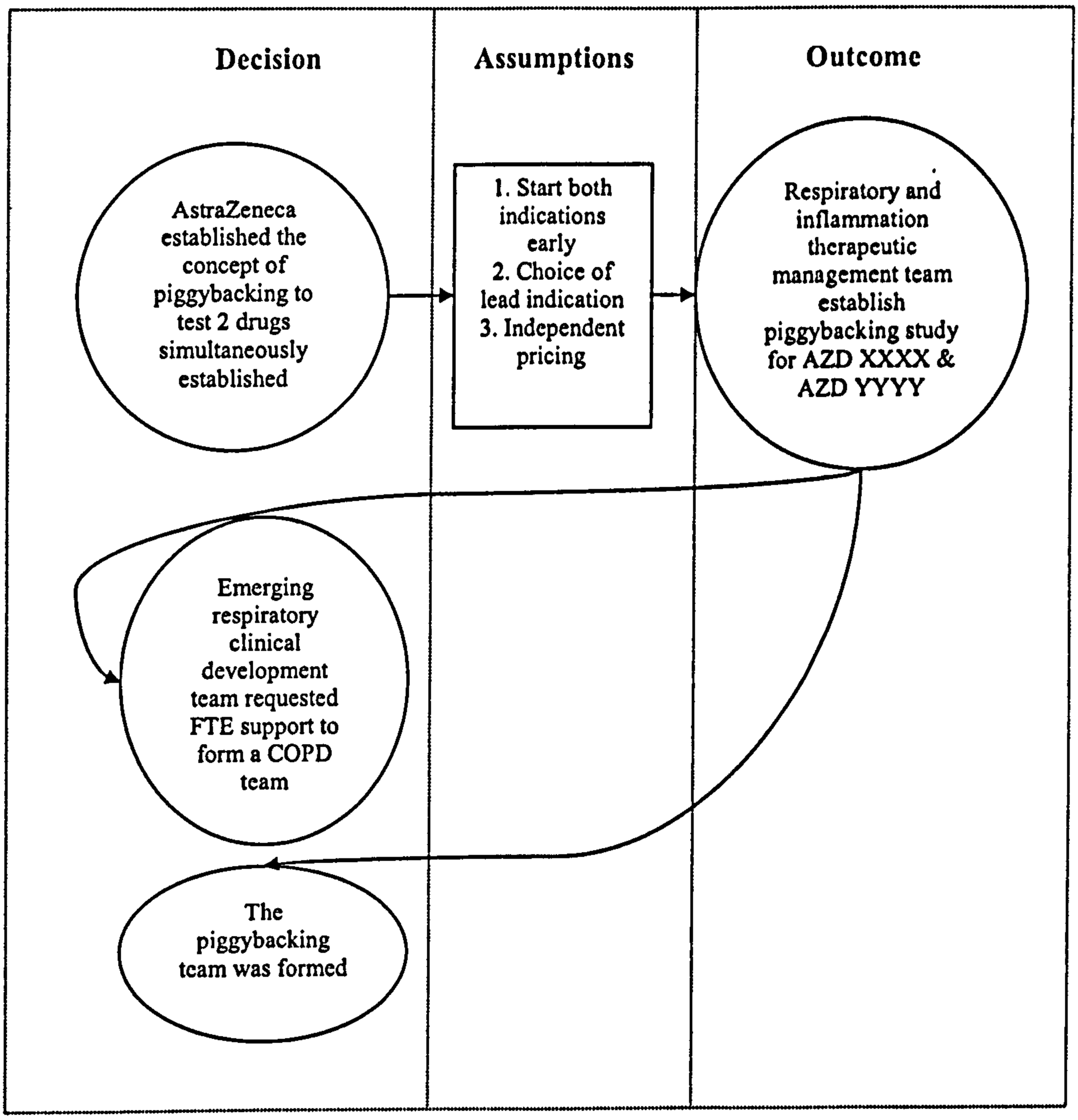

Figure 12.2: Example knowledge mapping of the piggybacking project

Figure 12.2 illustrates a cut down version of the original knowledge map, yet the technique visually demonstrates that the outcome of one decision can have an impact on the decisions taken further down the process. A decision's outcome can impact the subsequent decisions made and this method provides a visual means of identifying which decisions were key within the project. In the case of the piggybacking project this technique revealed that the key decision was the one to develop a separate clinical plan, which occurred approximately 6 months into the project.

Due to privacy issues, the full knowledge map is not available within this thesis, however, the full version illustrates that the decision to use two separate clinical plans was based upon the outcomes of two previous decisions, all of which were based upon assumptions. The decision to develop two separate clinical plans was based upon the assumption that the regulatory bodies required two plans, although the experience of the project team and the scientific evidence suggested that one plan would be sufficient. Hence, the use of the Knowledge Management tool set to clarify this assumption before the decision was made could have been beneficial and possibly led to the success of the project. Essentially a Knowledge Map in this sense helps to clarify the factors that are affecting a project and allow the employees to see where the main influences are stemming from. Once a key decision stage has been identified, similar decisions could be supported more effectively in the future by the Knowledge Management toolset. The decisions shown in this example are a limited version of the original information so as to preserve security. However, the original knowledge map possessed eight key decisions, 16 assumptions and 8 outcomes of those decisions throughout the project. The information was derived using the questions in Appendix 5 as a guide. In addition, the piggybacking project yielded a number of valuable indicators of the success of a project. These are also defined in Appendix 5 and provide a possible template for identifying issues across multiple studies. This work met with a positive response from employees within AstraZeneca and Bernard Marr of Cranfield University, and could potentially be used to augment the proposed tool set of Chapter 11. However, further research would be required before the full potential could be realised.

The following section now briefly outlines the key findings from this research before concluding this chapter.

12.4 CAN KNOWLEDGE MANAGEMENT TRULY DRIVE PHARMACEUTICAL INNOVATION?

At the minimum this thesis has provided the answer to the "Where? Why? & How?" questions as to how Knowledge Management can be used to drive innovation within AstraZeneca. From the discussion it is apparent that one simple Knowledge Management tool does not fit all situations. A post by the Information Management guru Tom Wilson on David Gurteen's website (2002) emphasised the challenges facing Knowledge Management:

"I'd guess that the majority of businesses are run in ways that actively prevent information sharing and KM in the information sharing sense is not something that can be grafted on to an organization - it's not a 'solution' to be bought and implemented, but a fundamental change in the ways CEO's [Chief Executive Officers] think about people - as knowing, thinking, innovative beings, rather than units in the production process. We've got a long way to go." (Wilson, 2002b)

This still holds true approximately four years after this statement was made. The qualitative results of this research, and particularly the literature review of Chapter 3, have shown that Knowledge Management currently revolves around information capture. As this chapter has demonstrated, the latest generation of semantic tools and social media offers the potential to change this situation for the better, yet whether these tools have the impact they proclaim, remains to be seen. However, it is clear that the chosen toolset supports the innovation framework defined in Figure 10.8 and it is theorised that, as a whole, the toolset can be used to drive pharmaceutical innovation both internally and externally.

It would appear that allowing fellow employees to collaborate and communicate across AstraZeneca's R&D domains and externally within research organisations and universities is the key to driving pharmaceutical innovation. Unfortunately, as the results of Chapter 6 showed, collaboration is rarely as straightforward as it seems.

Yet other pharmaceutical companies are using collaboration to good affect, particularly with regards to external research organisation. Eli Lilly is commonly cited as a champion of collaborative pharmaceutical R&D, and research by Stach (2006) provides a good overview of how they are achieving this success. Primarily, Eli Lilly employ an innovation model that actively sources external research that complements their existing internal research. This occurs through a specific and funded group labelled the Global External Research and Development group (GER&D). To all intents this group would sit in the framework of Figure 10.8 within the "Assimilation of Knowledge & Information Sources" concept. Although AstraZeneca possess these types of teams at a smaller level, it is perhaps necessary to expand this element in order to minimise the role of serendipity and ensure that innovative ideas and concepts are immediately tied with the aims of the organisation, rather than rely upon the efforts of internal employees to "force" their innovative work upon the organisation.

Eli Lilly then employ a further team labelled the Corporate Business Development group to lead negotiations and agree a beneficial contract after a potential innovation has been identified. After this has occurred a further group named the Alliance Management group take charge of the innovation and collaboration, and progress it through the company to create value. This model employs the mantra of "Find-it, Get-it and Create-value". A mantra that was also raised during the researcher's discussions with Rolls-Royce who proclaimed that their equivalent team had a "telephone to God", in order to ensure promising innovation is driven and not discarded. It is theorised that the toolset of Tables 11.2 & 11.3 would answer the problems currently felt by AstraZeneca's employees and essentially informally mimic the formal groups that exist within Eli Lilly at present.

In terms of the concept of strategic intangible assets, this research suggests that instead of capturing knowledge, a Knowledge Management system may simply have to make people aware of what research is taking place, an analogy to the task of Eli Lilly's Global External Research and Development group. However, there are many means of achieving this, from a simple People Pages/ Expert Locator system to a more in-depth system that can provide greater context to the innovation being proposed.

As Section 6.3 suggests, the greater the contextual element provided, the lesser the chance of scientific bias will unduly sway the argument one way. Hence setting the correct scientific context can in many ways reduce the bias present within scientific research.

Providing a greater understanding of related research undeniably helps to define an innovative idea, allowing comparison between existing research and the innovation and also allowing fellow employees to grasp where the innovative idea has application. Unfortunately while setting sufficient context may help, employees noted that bias is inescapable in pharmaceutical innovation and this research suggests it is essential for an innovation to progress beyond the idea of a concept. So, in many respects, scientific bias is a driver of innovation. If an employee can publicise and market an innovation that appears to directly support the organisation's strategy and hence is in line with the organisations strategic intangible assets, then there is a strong chance the innovation will succeed (e.g. the E3 system & the FTIM dosing technology) regardless of scientific bias. Hence bias that supports the organisational strategy can in many cases, be acceptable as long as the science behind the bias is sound.

In conclusion to the key findings of the discussion, it is worth noting that pharmaceutical innovation is essentially governed by physical rules that dictate the structure of a compound. Of these physical rules, Lipinski's "Rule of Five" (Lowe, 2006) set of chemical criteria was noted by the Discovery wing of the company to be an over riding factor in modern drug production.

These criteria essentially define the physical properties an orally dosed drug is perceived to require such as a being a small molecule (<500g/mol).

Even after identifying a valid biological target a suitable compound may not be found, or at the minimum a 'best fit' compound adopted. A Clinical Scientist described this as the "pinch point" and is worth noting as one of the key criteria that will certainly delay or even stop a valid biological target or compound being exploited fully.

The physical science is an inescapable part of drug development, as modern drug development is loaded to focus upon finding small molecules that can be dosed by mouth primarily. Yet all employees noted that finding a compound, let alone a small molecule, that acts in the right way upon an identified biological target is akin to the proverbial needle in the haystack.

It is in this area that the Knowledge Management toolset can potentially offer the greatest help by identifying and forming alliances with collaborators that possess these types of molecules. Once a suitable compound has been discovered Knowledge Management can also certainly help, particularly in the application of clinical knowledge. Hence, in conclusion, applying the toolset should offer a powerful benefit to AstraZeneca in terms of innovative ability and future revenue.

12.5 CONCLUSION

The discussion within this chapter raises an number of valid points that shed light upon the use of Knowledge Management within an organisation and discusses how Knowledge Management can help innovation to align with the organisation's overall strategy. Of particular interest is the observation that the successful implementation of the toolset relies upon the tools meeting the requirement of an intangible asset. As Chapter 3 noted, Knowledge Management tools often fail to take hold within a company and this is principally due the fact that they require change. This research indicates that Knowledge Management should integrate with the employees in their daily roles, whether this is in a supportive or innovative capacity.

Finally, if the outputs of the collaborative networks and accompanying Levels of the toolset, can be measured using the suggested metrics, then the true value of the toolset could be estimated with regard to innovation.

The following chapter concludes the research and revisits the research aims and objectives, before suggesting opportunities for further research.

CHAPTER 13

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS FOR FURTHER WORK

13.0 INTRODUCTION

The aim of this chapter is to summarise the findings of the thesis in line with the aims and objectives which were defined in Chapter 2. This chapter also provides recommendations for further work and draws conclusions from the research as a whole. Guidance for future research is also discussed, to be used by the stakeholders of this research and Knowledge Management practitioners.

13.1 RESEARCH OVERVIEW

The advent of Knowledge Management has bought with it, a considerable amount of hype and proclamation. The promise of Knowledge Management is considerable yet this thesis has demonstrated that the realities of using Knowledge Management are rather more complex. With this in mind, this research was commissioned to examine where Knowledge Management could have benefit and how it could be used to enhance pharmaceutical innovation within AstraZeneca. The research aim was:

"To create and evaluate a Knowledge Management tool set to enhance innovation within AstraZeneca."

In order to satisfy this aim and develop the tool set the research was split into a number of high level objectives:

1. Identify the general views associated with innovation and pharmaceutical innovation

2. Identify the drivers, the criteria for innovation, the outputs of the innovation and the themes associated with innovation, specifically within AstraZeneca

3. Examine and evaluate the Knowledge Management strategy and existing tools in use across AstraZeneca R&D

4. Examine potential Knowledge Management tools that could be used to support innovation in AstraZeneca and evaluate their potential use and impact to enhance innovation

5. Test the validity of the Knowledge Management tool set and research by publishing the results within AstraZeneca and producing peer-reviewed conference proceedings

6. Deliver the tool set to AstraZeneca R&D

The majority of these objectives were achieved and the details surrounding this are explored in the following section.

13.2 RESEARCH FINDINGS

13.2.1 OBJECTIVE 1

1. "Identify the general views associated with innovation and pharmaceutical innovation."

The objective consisted of three separate tasks. The first of which was:

- Conduct a review of the literature to identify and understand the general views on innovation and innovative processes within the literature. This stage will identify what constitutes innovation and what processes are thought to support innovation.

The review of the innovation literature was extensive and formed a substantial part of Chapter 3. The study revealed that innovation may be conceived of as an adoption of a new system, a product, a process, a service, a program or policy. The definition of pharmaceutical innovation would traditionally be the development of a new compound or drug.

Yet the literature review demonstrated that innovation goes beyond the development of a tangible product. The definition of innovation used by the research was "the embrace of a novel concept". This was a broad definition yet it provided the research with a basis on which to explore innovation within AstraZeneca. The notion of pharmaceutical innovation was studied and the processes, drivers and information and knowledge that are required were examined and identified. This section highlighted areas that the literature deemed important to examine. This included the move towards innovation acquisition rather than in-house R&D, and the reliance upon accurate knowledge and information at all stages of the drug development process. The second and third tasks of Objective 1 were:

- Conduct an exploratory case study on innovation within AstraZeneca to identify the departments and principle innovative employees across AstraZeneca R&D. This will take the form of a qualitative case study utilising semi-structured interviews
- Clarify and compare the innovative practices of these departments and innovators across AstraZeneca with the literature concerning pharmaceutical innovation

These tasks relied upon the development of a semi-structured questionnaire which was successfully derived from the literature review of Chapter 3. The results from this stage led to Chapter 5 which details the results of this survey within the Medical Science department of AstraZeneca, Charnwood. The Methodology Chapter 4 concluded that the use of a longitudinal case study, coupled with an interpretivist approach was a viable research methodology. One of the primary reasons for the exploratory study was to evaluate this methodology and decide whether it would support the overall research aim. In addition, the tasks within this objective led to the development of a research tool in the form of a detailed questionnaire. A research framework was also identified with which to assess the innovation and Knowledge Management processes within AstraZeneca.

Furthermore, Chapter 5 identified the basis of the critical factors associated with innovation and the use of Knowledge Management.

13.2.2 OBJECTIVE 2

2. "Identify the drivers, the criteria for innovation, the outputs of the innovation and the themes associated with innovation specifically within AstraZeneca."

This objective comprised three tasks, the first of which was:

- Conduct a series of detailed case studies to identify the knowledge and information needs of the innovative employees and departments within AstraZeneca. These will form a set of innovation and knowledge criteria, drivers, outputs and themes to be used to develop the Knowledge Management tool set.

Achieving this task formed the bulk of the results of Chapters 6, 7 and 8. Representative results of the case studies were published and analysed in accordance with the data analysis methodology chosen in Chapter 4 and Chapter 5. Meeting this objective provided a detailed account of the nature of innovation within AstraZeneca and identified many aspects where innovative practice was both aided and hindered. The criteria, drivers and outputs of innovation, provide a useful guide to supporting innovative activity within AstraZeneca. Furthermore, the information and knowledge needs of the employees were also analysed at length. The reliance upon luck, the role of regulation and the role of social networks in facilitating pharmaceutical innovation were notable contributions to public research. This task also helped to clarify the multitude of factors that affect pharmaceutical innovation and provided academics, Knowledge Management practitioners and AstraZeneca employees with a greater understanding of the problem domain.

- Produce a model of pharmaceutical innovation that reflects innovation occurring within AstraZeneca based upon: the identified themes, criteria, outputs and drivers of innovation

This task was achieved in Chapter 10, where a novel model illustrating the interdependence between innovation, knowledge and information was developed. The model illustrates the interactions and processes that should be considered when supporting pharmaceutical innovation. This model is unique in that it includes aspects external to the organisation, which reflect that the majority of pharmaceutical stems from external research. The model also highlights that Knowledge Management can function in a marketing role, whereby innovative concepts are essentially announced to the organisation. This aspect raises the profile of the innovative individual, thereby providing personal gratification, but also highlights novel research to the organisational strategists who can develop the concept to an innovation. Encouraging this degree of contact from the "grass roots" level employee to the managerial staff, is crucial for innovative activity and one that the tool set of Chapter 11 encourages.

- Clarify and compare the innovative practices of these departments and innovators across AstraZeneca with the literature concerning pharmaceutical innovation

This task was satisfied throughout Chapters 3, 10, 11 and 12. Where possible academic literature or practitioners' reports were referred to and compared to the research findings. This element will provide AstraZeneca with ideas and suggestions for future Knowledge Management related work. It is fair to say that the majority of the results grounded existing academic research, yet the innovation criteria and themes relating to the use of Knowledge Management tools within the pharmaceutical innovation arena certainly help academic research in this area.

13.2.3 OBJECTIVE 3

3. "Evaluate the existing Knowledge Management strategy and tools"

The third objective was to examine and evaluate the Knowledge Management strategy and existing tools in use across AstraZeneca R&D. The objective was composed of four distinct stages:

- Conduct a review of the academic and practitioners' literature to identify Knowledge Management methods, tools and strategies

This stage consisted of an extensive review of the existing Knowledge Management literature with regards to KM tools, systems and their use within pharmaceutical innovation. The review revealed that, although the use of KM was advocated within the pharmaceutical arena, few papers have directly studied driving innovation through Knowledge Management. This research collated and analysed a substantial amount of potentially viable academic and practitioners' reports, in order for the findings of this stage to be incorporated into the KM tool set of Chapter 11. This stage built upon the results of the prior tasks and focused primarily upon the social networking tools, while the importance of utilising ontologies and semantic technologies was also discussed.

- Define how the value of knowledge and Knowledge Management is assessed within the literature

This stage examined the use of intellectual capital techniques and summarised their use within Knowledge Management. This research provided a broad view of the measurement of intangibles and was invaluable in identifying how AstraZeneca could achieve their greatest return via Knowledge Management.

- Conduct a qualitative case study and consult with employees within AstraZeneca, to identify Knowledge Management tools that are being used to support innovation

This process was achieved through semi-structured interviews across AstraZeneca with end users, participant observation by the researcher with Knowledge Management staff and the use of workshops to discuss the Knowledge Management strategy of AstraZeneca. The results of this stage were qualitative in nature and formed a rich picture of the use and potential use of Knowledge Management within AstraZeneca. The data was again analysed using the representative themes of Innovation and Knowledge Management.

This stage identified where innovation could be supported by KM tools. These results formed the basis of Chapter 8 and led to the evolution of the KM framework of Chapter 10 and the definition of the KM tool set in Chapter 11.

- Examine how Knowledge Management is and could be evaluated within AstraZeneca

The research found that very little assessment of Knowledge Management currently occurs within AstraZeneca, with the assessment being limited to the use of the Balanced Scorecard. The methods and discussion presented in Chapter 12 represent a novel means of assessing a Knowledge Management system and generated interesting discussion concerning this area with Bernard Marr of Cranfield University.

13.2.4 OBJECTIVE 4

4. "Examine potential Knowledge Management tools that could be used to support innovation in AstraZeneca and evaluate their potential use and impact to enhance innovation."

- Produce a model of Knowledge Management that could be used to drive pharmaceutical innovation within AstraZeneca

The novel three level model of Knowledge Management was developed and refined within Chapter 10. In many respects this descriptive model is unique and offers the potential to be instigated in other knowledge intensive industries which are reliant upon external collaboration.

- Develop a Knowledge Management tool set from the previous review of the literature and the existing Knowledge Management tools within AstraZeneca.

This stage was successfully achieved in Chapter 11, with the descriptive Innovation and Knowledge Management model of Chapter 10 providing the framework and structure of the novel prescriptive tool set. The Knowledge Management tools were chosen dependent upon the results and themes of the results Chapters 6, 7 and 8.

This process ensured that the chosen tool sets would meet the needs of the employees, the organisational culture and above all, support the existing processes of innovation within AstraZeneca.

13.2.5 OBJECTIVE 5

5. "Test the validity of the Knowledge Management tool set and research by publishing the results within AstraZeneca and producing peer-reviewed conference proceedings."

- Evaluate the results of the research and the Knowledge Management recommendations by conducting a series of interviews to seek the opinions of the employees responsible for innovating within AstraZeneca.

This stage was achieved successfully towards the end of the researcher's time within AstraZeneca. Personnel involved in Knowledge Management were approached and the tool set refined in accordance with their views. Due to time constraints encountered at the end of the research phase, this stage does require further research. However, as a starting point, the identified tool set would augment existing AstraZeneca systems and was deemed to meet the majority of the employee's needs by AstraZeneca Knowledge Management employees.

- Publish peer reviewed conference papers and present the results to promote discussion

This stage was achieved through the publication and presentation of five conference papers relating to pharmaceutical innovation, collaboration and Knowledge Management. Valuable and occasionally contentious discussion was generated during each presentation, with the discussions validating the selection of the tool set and the research as a whole. An additional book chapter concerning the development of a Knowledge Management portal has also been reviewed and accepted, with the publication date set for late 2007.

13.2.6 OBJECTIVE 6

6. "Deliver the tool set to AstraZeneca R&D."

- Facilitate the implementation of the Knowledge Management tool set
- Evaluate the Knowledge Management tool set through a series of systematic surveys and further case studies.

The final objective required the implementation of the Knowledge Management toolset within AstraZeneca. It is with regret that this stage was simply beyond the scope of this research, primarily due to the time constraints associated with implementing such systems in a highly regulated environment. However, the researcher did support viable Communities of Practice during his time there and contributed to the development of novel Knowledge Management systems, which have been included within the tool set. Hence, overall, this research has contributed valuable and novel research and aided the uptake of Knowledge Management within AstraZeneca. Therefore, notable success was achieved in this area even though the objective was only partially achieved.

13.3 LIMITATIONS

Despite the novelty of this research in developing a viable Knowledge Management tool set and modelling pharmaceutical innovation, there remain limitations. The primary area is the implementation of the Knowledge Management tool set within AstraZeneca. The research aims were ambitious in this regard and with hindsight, would have focused upon establishing a series of pilot studies once the requirements were outlined. It is believed that this limitation would have been overcome with sufficient time. The employees of AstraZeneca will continue with the final objective and implement the tool set over the longer term.

In many respects the subjective nature of qualitative research could raise concern. However, as the methodology review within Chapter 4 discussed, the use of qualitative research provides a rich and detailed contextual element which can be lacking from quantitative research (Walsham, 1995). The subjective limitation was overcome through the use of qualitative data analysis techniques that played to the strengths of the interpretative approach. With further time, the findings of this research could have been accompanied by quantitative analysis, to balance the subjective nature of the research.

The number of participants interviewed, was also a limiting factor and was due to limiting the scope of the research to a manageable level and limited access to the innovative employees. Ideally a larger employee set, than the 60 employees sampled, would have been interviewed with greater access, sufficient time and greater resource. This would have enabled further validation of the findings and could also have highlighted differences in innovative and Knowledge Management practice across AstraZeneca with the potential to explore the use of the tool set on an international basis, between the UK and Sweden for instance.

In summary the subjective nature of the research and the eventual limited choice of tools, from the myriad of potential Knowledge Management tools, strategies, methodologies and techniques will always be contentious. When presenting a paper at IRMA (2005), the researcher remarked that the Community of Practice (CoP) may not be the panacea to all an organisation's troubles, while this comment was met with hostility from a CoP software consultant, the academics amongst the audience strongly agreed. It would appear that the only means to satisfy such differences is through a process of reasoned "trial and error" where Knowledge Management tools are implemented in an organisation and assessed in-situ.

As this research has shown, the success of a Knowledge Management system is largely dependent upon the system supporting existing processes, rather than requiring change.

An observation that appears to be largely ignored by the majority of Knowledge Management literature available, and hence leads to argument and discussion as to whether or not Knowledge Management can deliver a tangible benefit at all. Chapter 12 clarified this issue further and throws greater light upon the highly subjective nature of Knowledge Management and as such, is a novel contribution to the existing research on this area. However, it should be remembered that the tool set developed in this research should be taken as proposition rather than fact and further validation is required.

13.4 RECOMMENDATIONS FOR OTHER ORGANISATIONS

After presenting a paper at a Knowledge Management conference (OLCK 2006), the researcher was asked to contribute a chapter to a book upon the development of Knowledge Management portals. This chapter is due to be published in mid 2007 and focuses upon the physical tools and strategies that may be used to drive innovation (See Parsons et al. 2007). This event is a good validation of the research itself, yet it also highlights that this research has considerable applicability to other organisations.

Aside from the works application within other pharmaceutical companies, the commonalities with regards to innovative organisations are evident. Organisations such as BAE Systems and Rolls-Royce have already taken great interest in this work and it is envisaged that *any* organisation that relies upon collaboration and particularly external collaboration, for example managing supply chains or maintaining viable business relationships, would derive value from the tool set. Furthermore the models and Innovation/ Knowledge Management frameworks discussed in this thesis could be used as a guide to successful Knowledge Management implementation in other organisations. In particular the research tool of Chapter 5 would be valuable to other organisations as a benchmarking tool in its own right. The example metrics provided in Chapter 12 also highlight the need to measure intangibles and provide examples of how this can be achieved. These measures specifically measure a hitherto "grey area" and could potentially help employees gain recognition for work that falls outside of the traditional Balanced Scorecard metrics.

Finally the literature review of Chapter 3 is a valuable piece of research and reference material in its own right for other organisations and researchers interested in Knowledge Management and innovation.

13.5 RECOMMENDATIONS FOR FURTHER WORK

The author's research has been varied and detailed and has raised a number of interesting research avenues:

- The first would be to investigate the implementation of the tool set and evaluate its success in driving innovation. From a theoretical perspective and limited individual trials of the components, the tool set would appear viable, yet it is only upon instigating such systems can the success be measured. Although the tool set has been designed to complement the working patterns of the innovative employees, it remains to be seen whether the cultural issues highlighted in this work will hamper its use.

- The generic Knowledge Management tool set could be adapted to suit the needs of specific departments by the addition of role-specific software with a contextual or "personalisation" element. This factor arose from discussions with Knowledge Management experts within AstraZeneca and academia, which concluded that although the employees may require the same sources of information, the contextual element surrounding that information may be different.

- The research model and frameworks could be adapted to suit other organisations and establish whether these models hold true outside of AstraZeneca. It is expected that the majority of the concepts will remain constant, although the information and knowledge flows will change in accordance with the organisations. The concept of luck is also an area that requires further investigation both within AstraZeneca and other organisations.

A conversation with a Rolls-Royce employee hinted that luck plays an important a role in their innovative processes, yet the extent of this is unclear.

- This research raises concerns over the reliance of pharmaceutical companies on acquiring external research. As a means to bypass the early and risky innovative stages, acquiring innovation appears to be well founded, yet it would appear that once an innovation is acquired then this early confirmatory R&D work is repeated. This is a process that costs considerable resource to achieve and may lead to the innovative concept being disregarded due to the internal politics of the company. The early R&D stages have strong financial drivers to both save money (through early compound attrition) and generate future revenue (through a viable compound). Hence, identifying the factors that affect the balance between attrition and success would be a valuable exercise and one that the Knowledge Management tool set could potentially support.

- The final area for future research concerns the measurement of innovation throughout its life cycle. Example measures and means were suggested within this thesis yet the actual measurement of innovation, from innovative R&D concept to marketable drug, is a long term project which is worthy of further research.

13.6 OVERALL CONCLUSIONS

In conclusion, this research has been a fascinating journey through a highly complex area that has yielded novel and interesting research. The principle aims of the research have been successfully achieved and valuable contributions to academic research have been made through the publication of this research. Additionally, elements of the tool set are already in use and AstraZeneca now possess a strategy to further their Knowledge Management work.

This thesis has shown that innovative practice within AstraZeneca is a complex process, one where employees may have the individual incentive, but require the organisational resource to progress their ideas.

Without the backing of senior management, innovative ideas may fall foul at a number of milestones, with resource appearing as a critical success factor within the results chapters. If the issue of resource could be overcome, then there is also the area of the perceived risks and benefits of an innovative approach and its ability to comply with legislation, to be considered. Hence the innovative process is a careful balancing act of multiple factors. From the scientific perspective, to the organisational culture, to the financial perspective, to the information & knowledge angle amongst others, all the areas have a tangible affect upon the eventual success of the innovation. Attempting to categorise and manage all of these influences is beyond the scope of this work, yet this work has highlighted the factors which the employees are aware of, and must address on a daily basis.

In conclusion, providing employees with the ability to weigh up these factors and make a reasoned decision, through the use of the Knowledge Management tool set will undoubtedly help to drive innovation within AstraZeneca. Certainly, there are areas of AstraZeneca's innovation policy that are successful and others that are less so and this research has helped to determine the factors that are crucial in driving or hindering these processes. Drawing in all these critical sources of knowledge, information and data will ultimately allow the innovator to proceed and if all goes to plan, help the development of life saving medical drugs.

APPENDIX 1

AUTHOR'S PUBLICATIONS LIST

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Parsons, T., Jackson, T., Dawson, R. & Adelmann, H. (2007 in print). Developing a Knowledge Management portal, *Encyclopaedia of Portal Technology and Applications*, Tatnall, A. (ed.), Idea Group, Hershey, PA, US, IRMA, Diego, California, USA.

APPENDIX 2

KM TOOL SET SELECTION

Table A2.1: Content Management Tools

Type of Tool	Example tool, rationale and key themes	Value to driving innovation	Representative themes
Storage	Databases – access latest information and data i.e. SCRIP.	**High**	Innovation Theme: 25 Knowledge Management Theme: 19
	File repositories – e.g. GEL & eRoom. To view what work has already occurred within AstraZeneca.	**High**	
	File-servers & shared drives – used for informal information sharing outside of a defined eRoom. Version control/ out of date problems however.	**Medium**	
	Data warehouses & data marts – to share Clinical Trial results, useful for gaining credibility once a concept has been launched.	**Medium**	
Authoring	Office suites – capture the innovative concept i.e. Word/ PowerPoint.	**High**	Innovation Theme: 24 Knowledge Management Themes: 11
	Desktop Publishing – to promote the innovative concept for example FrontPage.	**High**	
	Graphic suites & multimedia tools – gain impact for presentations i.e. Photoshop.	**High**	

Table A2.2: Knowledge Sharing Tools

Type of Tools	Example and rationale	Value to driving innovation	Representative themes
Distribution	Web - essential for external information research & access.	**High**	Innovation Theme: 9 Knowledge Management Themes: 19
	Enterprise portals/ intranets – at present important but not essential in terms of innovation due to lack of relevant information.	**High**	
	Extranets – important with regards to tracking down information i.e. FDA, PubMed.	**High**	
	Personalisation – innovators would prefer a system that "pushes" relevant information to them.	**High**	
	Audio/video streaming – teleconferences and video conferences are essential.	**High**	
	RSS syndication – potentially useful for dissemination of innovative concepts.	**Medium**	

Table A2.2: Knowledge Sharing Tools continued

Connectivity	Internet – essential for external information research & access.	**High**	Innovation Theme: 13 Knowledge Management Theme: 20
	Security – a balance is required between open access and regulatory security issues.	**Medium**	
	Authentication – essential for a secure environment.	**Medium**	
	Wireless networking/ mobile computing – facilitates mobile working and gathering of information at conferences or "water cooler talk".	**High**	
	Peer-to-peer (P2P) – personal folders shared across a network would be useful within AstraZeneca to share innovative concepts quickly.	**High**	
	Personalization – a system that remembers and pulls information/ knowledge according to your requirements – similar to the R&D portal.	**High**	
	Audio/video streaming – essential to conduct meetings and attempt to mimic a face to face environment (as much as possible).	**High**	

Table A2.2: Knowledge Sharing Tools continued

E-learning	Interactive multimedia – functionality is rarely used within AstraZeneca .	**Low**	Innovation Theme: 2 Knowledge Management Theme: 12
	Computer-based training- particularly applicable when introducing new software tools etc.	**Medium**	
	Web seminars – potentially useful for disseminating information and holding discussions.	**Medium**	
	Simulations – technique rarely used for innovation if at all.	**Low**	
	Learning objects – insufficient number of learning related material related to innovation available.	**Low**	

Table A2.2: Knowledge Sharing Tools continued

Collaboration	Calendaring – useful to locate and plan meetings.	**High**	Innovation Theme: 4 Knowledge Management Theme : 18
	File sharing – prerequisite of innovation and now supported by eRooms.	**High**	
	Meeting support - prerequisite of innovation but few employees structure meetings effectively	**High**	
	Application sharing – essential for collaboration across sites and globally.	**High**	
	Groupware & decision support technology – tools such as the Medical Science Knowledge Objects, have been independently shown to support innovative work. Also relevant when confronting scientific bias.	**High**	
Community	Community management – essential for a CoP to flourish.	**High**	Innovation Theme: 4 Knowledge Management Theme : 18
	Web Logs (Blogs) – untested but hold potential.	**Medium**	
	Wikis - untested but hold potential.	**Medium**	
	Social Network Analysis (SNA) – useful tool to target specific innovators with the toolset within AstraZeneca.	**High**	

Table A2.2: Knowledge Sharing Tools continued

Creativity	Mind Maps/ Cognitive mapping – useful tool for capturing discussion.	**Medium**	Innovation Theme: 7 Knowledge Management Theme: 17
	Idea generation – essential to drive innovation yet more important at the individual level rather than the group level.	**High**	

Table A2.3: Knowledge Search & Retrieval Systems

Type of Tools	Example and rationale	Value to driving innovation	Representative themes
Search	Search engines – Essential for comparative work and locating information i.e. Autonomy, Kartoo etc.	**High**	Innovation Theme: 25 Knowledge Management Theme: 11
	Search agents - untested but holds potential for autonomous information retrieval.	**Medium**	
	Indexing – essential for rapid information retrieval i.e. Lucene, conversion of GEL to XML to facilitate indexing.	**High**	
	Glossaries – Important to allow cross site and global collaboration	**High**	
	Thesauri - Important to allow cross site and global collaboration i.e. WordNet.	**High**	

Table A2.3: Knowledge Search & Retrieval Systems continued

Search	Taxonomies/ ontologies – Highly important for linking disparate information, knowledge, employees and creating rules to manage information.	**High**	Innovation Theme: 25 Knowledge Management Theme: 11
	Collaborative filtering – untested but holds potential for reducing the notion of information overload.	**Medium**	
	The Semantic Web – untested but widely used in similar pharmaceutical organisations such as Pfizer.	**High**	
Analytics	Querying – more applicable to data management and Discovery.	**Low**	Innovation Theme: 23 Knowledge Management Theme: 16
	Reporting – AstraZeneca use Business Objects to report data but little use for innovative work.	**Low**	
	Multi-dimensional analysis – the ability to interrogate multiple sources of data (i.e. biomarker data) could prove useful.	**Medium**	
	On-line analytical processing – useful for validating an innovative strategy such as clinical trial data.	**Medium**	

Table A2.3: Knowledge Search & Retrieval Systems continued

Workflow	Process modelling – essential to understand where and how the innovation should be managed (e.g. within the 3D grid of AstraZeneca).	**High**	Innovation Theme: 17 Knowledge Management Theme: 21
	Process engines – backend server software that co-ordinates user requests, useful for semantic web and rule based information filtering applications.	**Medium**	
Data mining	Statistical techniques – applicable only once an innovation has been tested, however would be useful to gain credibility by analysing existing similar work i.e. "me too" or "fast follower" drugs.	**Medium**	Innovation Theme: 15 Knowledge Management Theme: 1
	Neural networks – untested but hold potential.	**Medium**	
	Neural networks – untested but hold potential.	**Medium**	

Table A2.3: Knowledge Search & Retrieval Systems continued

Text mining	Semantic analysis – important to explore large bodies of unstructured text.	**High**	Innovation Theme: 12 Knowledge Management Theme: 1
	Bayesian inference – possible use of Bayesian networks to compare innovative drugs.	**Medium**	
	Natural language processing (NLP) – untested, but may be important when extracting machine readable knowledge from sources across AstraZeneca.	**Medium**	
Web mining	Collaborative profiling – important means of identifying like minded individuals and progressing collaborative groups.	**High**	Innovation Theme: 25 Knowledge Management Theme: 5
	Intelligent agents – untested but potentially useful for uncovering knowledge, information & data across multiple sources.	**Medium**	
Visualization	2D and 3D navigation – useful means of navigating disparate information and knowledge sources across AstraZeneca.	**High**	Innovation Theme: 5 Knowledge Management Theme: 5
	Knowledge/ geographic mapping - useful means of identifying disparate information and knowledge sources across AstraZeneca.	**High**	

Table A2.3: Knowledge Search & Retrieval Systems continued

Organization	Ontology/ Taxonomy development - essential for AstraZeneca to manage its sources of information and knowledge.	**High**	Innovation Theme: 3 Knowledge Management Theme: 9
	Ontology/ Taxonomy acquisition – also essential as this provides new links between concepts i.e. using MESH or BioWisdom.	**High**	
	Glossaries – Important to allow cross site and global collaboration.	**High**	
	Thesauri - Important to allow cross site and global collaboration i.e. WordNet.	**High**	

Table A2.3: Knowledge Search & Retrieval Systems continued

Reasoning	Rule-based expert systems – use within innovation is unknown at present but holds potential for future work.	**Medium**	Innovation Theme: 3 Knowledge Management Theme: 7
	Case-based reasoning - use within innovation is unknown at present but holds potential for future work.	**Medium**	
	Knowledge-bases/ Knowledge Objects – use within innovation is currently being tested, holds high promise.	**High**	
	Machine learning - within innovation is unknown at present but holds potential for future work.	**Medium**	
	Fuzzy logic – application within innovation is unknown at present but holds potential for future work.	**Medium**	

APPENDIX 3

EXPERIMENTAL MEDICINE

DISCUSSION FORUM SPECIFICATION

1.0 INTRODUCTION

The following report aims to clarify the user requirements of the new Experimental Medicine (EM) portal forum. The study is based upon the pilot KM scheme within Charnwood EM Department and has gone some way to providing conclusive evidence that the EM department has benefited from the use of a threaded message discussion group.

As part of the evolution of Knowledge Management within AstraZeneca, a strategy has been outlined which aims to replace the current simple threaded message forum with a robust alternative which satisfies the future scope and functional requirements laid out within this document. This report firstly concentrates on the novel idea of dynamic categorisation, before continuing onto the required functionality of the new forum. These requirements were uncovered using ongoing interviews and investigative techniques with the staff of the EM department. A further final section then outlines a brief synopsis of the technology required to fulfil the forums needs.

2.0 A BACKGROUND TO KM

The advent of KM has introduced a wide range of strategies and aligned methodologies which all proclaim to be the definitive answer to knowledge sharing and creation within the business environment. Of these the community-based approach is widely recognised as one of the most valuable adaptations, focusing upon encouraging dialogue and communication through the establishment of social networks (Brown, & Duguid, 1991). Communities of Practice allow information to be informally shared between colleagues, thus encouraging the creation and interaction of knowledge and allowing the reuse of existing knowledge and information inherent within the organisation.

It is the ability of these networks to utilise asynchronous electronic communication, which is their key to success. The arrival and proliferation of the virtual community, a medium that undeniably increases knowledge creation (Jordan & Jones, 1997; Nonaka, 1994; Alavi & Leidner, 2001), has provided a sound foundation for the introduction of a KM scheme within the EM department. Koh & Kim (2004) believe their success rests upon encouraging these types of interactions:

- Informal networks
- Person to Person contact
- Encouraged dialogue
- They bypass traditional hierarchical channels
- Information is distributed electronically thus saving time and resource

It is fair to say that the true use of the Community of Practice has been within the e-business arena, they are widely used to increase customer interaction and create a business to customer relationship with the site (Hagel & Armstrong, 1997). The Community of Practice employed in a similar manner within the EM department, yet is a closed community, where membership is static and new employees are added as they start work. It is evident that the driving factors are similar though; a commercial community aims to induce value from customer interaction, while the EM community induces value through staff-to-staff interaction. The remit of the forum is to provide the means to discuss topics and information based upon scientific matters, these discussions can then be carried forward to a meeting thus saving valuable face-to-face meeting time by ensuring all parties have prior exposure to the topics to be discussed.

The report will deal with aspects of the design and future specification, which will allow a greater sense of interaction and information exchange to be carried out. A key point of the future design is the offer of a concept labelled as Dynamic Categorisation. The concept and rationale behind the idea will be discussed in the following section.

3.0 CATEGORISATION AND DYNAMIC CATEGORISATION

The proposal for the new EM forum includes a novel approach to the current guise of the threaded message forum, in that they will offer the opportunity to view the forum without static categorisation. A typical web based forum offers distinct categories under which users post threads relating to that particular field or topic. Due to the scale of the proposed forum and the scope of the users work, the solution of Dynamic Categorisation was suggested by Dr Holger Adelmann. As membership within the Global EM groups forum is expected to reach approximately 450 users and with such a large user base, the potential problems in assigning categories and determining which area or field a post should sit under was deemed to be too great. Although forums of this size and larger operate within many businesses, this approach may offer a greater return on use and value than a traditional view.

The approach is certainly innovative and an outline of the proposed model is described as such. The key idea is that threads are posted onto one main forum, and are not compartmentalised by categorisation. Hence the task of extracting meaningful information from the forum relies upon the use of an intelligent search facility, which in turn is linked to a structured ontology. Hence the design and deployment of these areas are crucial, as the failure to correctly design and develop such a system will negate the appreciated benefits of the forum. When a user searches for a specific term the ontology provides "abstract categorisation" and returns all the threads linked to the searched term. The idea allows the search facility to return threads based upon a single keyword. Terms that are linked via the ontology to the keyword are located in the titles of the threads and duly returned to the user. This allows the return of higher-level concepts and ensures the results returned reflect the *context* of the search term.

The reality and success of the theory rests in the correct development of the ontology and the welcome screen, with no visual clue to guide the user through the forum the user must have a distinct request that he/ she requires answering or wishes to answer. This has obvious drawbacks.

A common failing of threaded forums, and one which was seen in the previous EM incarnation, is the shielding of information, presenting the user with a search facility and nothing else effectively hides all the information from the user. The current model of a thread-based forum is particularly successful because the information contained within the forum is evident, thread titles allow a browsing user to visualise the information within the forum quickly and quickly navigate to their desired topics. However the applicability of dynamic categorisation is that it prevents the user being confronted with hundreds of threads and hence being overwhelmed by the lack of order and purpose of the threads. A large business forum, such as AstraZeneca intranet forums, may contain upwards of a thousand threads. Upon accessing the forum the user has little choice but to browse or search the forum using a free text facility, to attempt to locate the information required.

A point, which should be carefully considered, is that the average user browses a forum. They have no specific goal or information in mind, instead they access the forum to gain knowledge and answer posts that are relevant to their field. Prior research and other similar case study research by Preece (2001), illustrates that this forms a major part of forum participation. Hence without the display of these posts and a notion of where relevant posts may lay without specific searching, a user presented with a blank canvas or unstructured posts will quickly lose heart and quit the forum. In this sense it is imperative to apply a structure to the forum, as without some form of categorisation the users will be unable to locate information and comment on posts that may overlap their fields of expertise. The key idea is that users must be able to locate and comment upon posts that they hold knowledge on, the phrase *"we don't know what we know"* is applicable here.

Often people browse and have an area of interest *outside* of their work remit and these are the actions that build a successful community and allow knowledge to be generated. A solution to this problem would be the personalisation of the forum views for each user. Initially with a standard structure the user's interests and search patterns would generate their areas of interest and hence provide the user with a structured and tailored view. This approach relies upon:

- The user declaring their areas of interest- an idea, which could be linked to the email expert location system which is currently being developed by Loughborough University

- The ontology backed search returning worthwhile results and making the correct links between terminology and fields

- A degree of intelligence within the interaction of the search/ indexer engine, which in essence fuses terms together when provided by users and notices inferred terminology

An intermediary answer may be to provide both a standard or limited view of the forum and a view that focuses upon dynamic categorisation. This could be accomplished using existing technology and supplement the dynamic search page. Adding this fail safe view to the novel search page would ensure that users would still utilise the system. After all, it must be noted that the traditional threaded discussion forum offers a good rate of success. However, once a user had gained in experience and built up areas of interest provided by the search/ email system the dynamic page would provide an imminently more tailored view. This view would reflect both the users' current interests and posts that may interest the user, through a process of inferred categorisation from the search/ indexer.

The area of dynamic categorisation is innovative and one which may require thorough testing and training within a production environment. Though I believe that with refinement and if used in conjunction with a standard view the results could be worthwhile. The following sections continue to outline some of the more standard technical and usability functionality that we would expect to see in a virtual community setting.

4.0 FORUM REQUIREMENTS

This information has been obtained using unstructured interviews conducted over the period of June 2003 to March 2004; the information is based upon 14 current users of the EM forum and other staff who are new to both the department and the forum.

It is important to recognise that the forum must be operated in conjunction with the current structured methodology of knowledge creation and capture present within the department. (see Adelmann et al., 2003) Many aspects relate directly to this methodology although these requirements could be tailored to reflect the needs of an altered methodology or stand alone community.

4.1 IIIGII LEVEL REQUIREMENTS

These points outline the basis of the forum. While many appear obvious; highlighting them allows each aspect to be taken into account when looking at a replacement forum tool.

- The system must provide structured information exchange to be used for the creation and retention of relevant knowledge.

- The relevant information should be easily identifiable as at present the information is often obscured

- 'Dynamic Categorisation' should be offered

- The server must be reliable in order to enhance the site usability and provide faith to the users that the system is being supported and backed

- The portal should be standardised with other AstraZeneca sites to maintain a consistent 'look and feel' to the intranet, the Clinical PKD or the PKT portal are proposed as worthy models

- A clean uncluttered interface must be used- this is highly important when dealing with users who are not technologically minded

- Time for compulsory basic training must be assigned combined with a dedicated support channel

- Training documents should be available online, ranging from basic to advanced

- The system must build upon the pilot study and continue to promote the positive aspects previously identified in the separate report

- The system should provide means for qualitative and quantitative metrics in order to track the usability and effectiveness of the forum

- The forum engine should be modular and use an agreed standard framework so that it can easily be incorporated within sites such as the R&D portal.

4.2 FUNCTIONALITY REQUIREMENTS

The following points outline a baseline measure of the new forums functionality, these factors though not exhaustive, are key points that have been discussed and raised with both the users and developers.

4.2.1 FORUM ACCESS AND IDENTIFICATION

- The process of forum access should be simple to utilise for less technologically inclined individuals- this should be linked to Windows usernames as at present

- Automated attachment of user details when replying and summarising posts, this could included a personalised tag, which lists name and contact details such as email, telephone and job details. This would be important for obscure usernames and to gain the context of the post

- Personalisation of the portal and forum should be provided, although maintaining a standard look and feel. This may list recent posts first, automatically highlight relevant threads and display topics that mirror previous searches.

4.2.2 POSTING THREADS

- Posting threads should be easily achieved and replying to threads should be self-explanatory. The icons used must be evident and visually striking; the current forum is an example of poor visual design with these crucial factors being hidden within other similar options

- When posting a thread a simple drop down menu or graphical menu should display a choice of post types to the user, this would be Question, Information, Comment or Summary. The choice should be mandatory and when replying the [RE] default must not be used, users must choose from the list again. Most if not all, current forums utilise the [RE] as a default reply so this would have to be addressed at the development stage

- Posts could be colour coded in terms of relevance when posted (see Adelmann et al. (2003) for further details). Ideally this would be via a menu and not via HTML code as is currently used. A similar schema is in use within other AstraZeneca forums, and when coupled with the use of the methodology it provides a powerful additional visual aid to knowledge creation. However the use of icons may be more suited in terms of accessibility issues.

- A menu of commonly used and controlled keywords should be available when compiling threads. These should be compliant with the established AZ glossary and linked to the terminology of the underlying ontology.

- Users would like the ability to post graphics within the text; this would include graphs and figures, which would prove useful when explaining difficult concepts within the prose. Drawbacks would include size, formatting (an XML based forum would need SVG) and their overuse. Ideally the forum would be able to display images and figures created using Microsoft products- all users utilise these products, so an automated process of conversion or at the least an easy step to integrate these should be included. Potentially this could be linked to the Clipboard on a drag/drop basis, similar to the E-Room functionality.

- When making a post, the forum should return to the post to show the user what has been added- some forums do this while others default to the homepage.

- Posts should have a rating of importance to them, similar to the exclamation and flag used in the MS Outlook products for highlighting urgent threads or more mundane topics. When using the dynamic view, these could be displayed prominently to the user regardless of the term searched for. This could be tied into the proposed expert locator system so as to alert experts whenever a relevant critical or important message is posted.

4.2.3 POSTING LINKS

- Reference papers should be easily introduced into the forum, either as links, whole documents or as key parts of text. The ideal would be to link this to an existing citation management system such as Reference Manager or Ref Works.

- Users who frequently utilise online medical texts would like the ability to copy and paste multiple links into a thread, at present the clipboard functionality of the current forum only holds one link.

4.2.4 SUMMARISING THREADS

- Users requested the ability to automatically export the message information to a Word document or PowerPoint file in plain text. This would allow users to easily manipulate the information within the forum with a tool they are familiar with. A further option would be to automatically export text to a defined template if needed. Currently users must copy then paste all information from the web page, this inevitably leads to users highlighting extraneous information and the HTML formatting.

- Notification when a summary is completed. At present the system flags when a new post have been added, but does not give a purpose or insight into the nature of the posts. The Shell oil company use an email newsletter, which summarises all posts to all users at the end of each week. A similar scheme could email users when a relevant post is summarised. Once again this would be tied in with

personalisation of the forum and users who search or post in particular areas, would receive summary details of other relevant posts.

4.2.5 SEARCH FUNCTIONALITY

- The bare minimum would be a free text search, with the opportunity to search by keywords.

- An ontology-linked search to provide context to the search and some degree of intelligence, would be preferable and is essential to allow the aspect of dynamic categorisation. The search would be linked to RDF/ XML or similar underlying metadata to allow complex queries.

- The search capability would allow the concurrent searching of multiple forums, in the event of additional forums being made available within AZ. The current idea of a single forum should be utilised at present, but there may be links between other forums of similar nature in the future.

- Search results should be represented graphically with links between results. The tools Kartoo and Spectacle were deemed an ideal vehicle due to the ability of the technology to provide logical links between results, without pre-empting the user to follow a certain path. Representing the results as a Topic Map allows convenient navigation through a large return of interesting results.

- Information should be colour coded in terms of relevance when searched, it is essential that a rating system can be utilised to provide relevance to the results. Threads should be ranked and displayed according to their relevance to the original query; this could be linked to the relative site of key terms within the ontology.

- A brief synopsis of the thread should be included with the results, which could be hidden if not required. Kartoo's ability to display this when users hover over a link was particularly welcomed.

4.3 MISCELLANEOUS REQUIREMENTS

- RSS news feeds may be incorporated into the view of the forum; these may link to similar areas and threads.

- Fresh posts should be highlighted at all times, until the user reads them- the ability to flag posts of interest could also be considered. These may be threads that detail answers or require answering by the user at a later date when more information is available. These threads could be categorised (e.g. "Important answer!" or "Return to later") and highlighted within the personalised space of the forum view

- Intelligent web agents could be used to crawl the web and return information/ links that are relevant to posted threads and discussions

- Support must be provided to the users and the staff who run the system, either externally or internally.

4.4 TECHNOLOGICAL REQUIREMENTS

- The forum must be based on an underlying architecture that provides the degree of scalability and stability to allow its use in the future. The current contender is MS SQL Server 2000 and as such, the forum is based upon the use of this database

- Stability is a key factor

- The forum must be supported by AstraZeneca IS, this will involve utilising a package that runs on a Windows platform

- asp.net using VB was highlighted as the preferred web architecture

- Software that requires user licences may cost a large amount. The potential for expansion is considerable so this must be reflected in the cost of the forum

- Intelligent search facility, fuzzy searches and the ability to learn from user search terms
- The source code should be available for development and refinement
- Documentation of the source and build are important to allow further development work and effective version control

5.0 CONCLUSIONS

The report has set out a specification based on the requirements of the Charnwood EM staff and as such can be used to provide a system which reflects the work flow and business processes that the staff utilise on a daily basis. The requirements are designed to complement existing measures rather than simply replace them and should be used in conjunction with a KM methodology to achieve the greatest benefit. The use of Dynamic Categorisation is currently being developed and should be a positive benefit over the older system of categorisation. Indeed this will be the first time a structured ontology has been used to provide intelligent information searching within EM. If successful the technology and KM methodology could be implemented in a wide variety of similar areas over AZ, which would allow the company to benefit as a whole.

APPENDIX 4

EXPERIMENTAL MEDICINE GLOBAL FORUM BUSINESS LOGIC AND DESIGN

The following is an excerpt from a report commissioned by AstraZeneca in January 2005 to investigate the use of "Dynamic Categorisation" for a threaded discussion forum. The primary concept and software associated with "Dynamic Categorisation" was created by Dr Holger Adelmann of AstraZeneca and this report was commissioned to explain the rationale behind it. The researcher did however; contribute discussion and ideas for the concept design and how the concept could be exploited within AstraZeneca.

1.0 INTRODUCTION

The use of Knowledge Management within Experimental Medicine (EM), AstraZeneca Charnwood has led to the important steps of knowledge sharing, capture and reuse throughout the department. In order to follow on from these successes we have carefully designed and detailed an enhanced knowledge based tool to supersede the current EM Knowledge Community. The scope of this report is to analyse the business rationale and logic for introducing a new forum, explore the functionality and processes which underpin and justify the new forums design. This article is expected to evolve with the forum over time, and as such will initially capture the design principles, that have led to the novel use of an ontology and dynamic categorisation to yield a design which is better suited to knowledge generation than the previous incarnate.

2.0 KNOWLEDGE MANAGEMENT WITHIN EXPERIMENTAL MEDICINE

2. 1 APPLYING KNOWLEDGE MANAGEMENT

Knowledge Management (KM) is now firmly established within the Experimental Medicine Department and considerable interest is being generated within AstraZeneca and Clinical in particular.

In order to explain the success of KM within Experimental Medicine, a detailed case study was conducted to explore the staff's perception of KM and how the science may benefit their working roles. The case study covered a wide variety of experience and job roles and exposed a number of interesting findings which have been analysed and discussed to produce the prototype forum.

At present the EM Department utilises a simple threaded message board that since its inception has been plagued by both design and technical issues. The forum offers an outdated interface that is far from user friendly and the acts of extracting worthwhile information from the forum are often too specialised for the average user. A detailed examination of the role and success of the forum highlighted a number of failings which could unfortunately only be addressed by the development of a suitable replacement. However, it must be noted that the forum displayed a remarkable ability to generate and retain information, regardless of the interface. The staff felt the forum was providing a tangible benefit to the company.

This is due to the fact that AstraZeneca appears to naturally foster an atmosphere which is conducive to knowledge sharing and with the introduction of a suitable tool this environment can be encouraged. Evidently we must strive to retain the benefit and progress so far achieved, while introducing a system which truly reflects the business needs and usability concerns of the EM staff. The new design takes account of these failings and when used with a tailored Knowledge Management methodology, can actively create and promote a knowledge rich environment where users can freely interact and apply their tacit knowledge to common problem areas.

2.2 THE R&D PORTAL PROJECT AND THE KM FORUMS ROLE

The use of a Knowledge Management ethos and principle has been combined with the traditional aspects of Information Management, to yield an exciting development within AstraZeneca. The R&D Portal Project stems from the companies need to consolidate the vast and ever increasing amounts of unstructured data and information which has been collated as part of the daily work of the company.

The proposal is to provide an integrated enterprise portal which will become the universal interface for staff to access information and knowledge. The role of the portal has evolved from one of a static content management system, to a dynamic and responsive environment which encourages interaction and information exchange. Knowledge creation is encouraged through the availability of relevant documents and the relevant people. The EM KM project is expected to fit within the realms of both a knowledge facilitating environment and a knowledge store.

Initially the forum will occupy the role of a think tank for ideas and practice. For instance a physician wanting to know specific details of safety constraints relating to a developmental drug would post their question within the forum. Experts located across the company would then respond and a web based discussion would occur. This would have the probable outcome of a consensus on existing data and information regarding the topics. At the minimum the discussion would identify that the participants were experts within the field and serve to publicise this within the company. The creation of informal networks such as this, allows like minded individuals spread over geographically distinct regions to converse freely and form alliances.

2.3 E-ROOM DISCUSSION FUNCTIONALITY

The R&D portal project is based on a content management system provided by Documentum. This incorporates a variety of Information, Knowledge and Project Management tools including eRoom. The remit of the KM forum is essentially complementary in operation and aim.

The eRoom discussion module allows a closed group of staff to gather and discuss a specific project area. The fundamental provision of eRoom is to provide a closed environment where attendees are *invited* to discuss areas of concern. Related documents and folders can be created and hence will prove a very valuable tool where project members can collaborate independently of geography and time constraints. The KM Forum on the other hand, is very much an open system- input is invited from all and membership is not reserved to specific project members.

In this way we invite external collaboration and encourage the dissemination of knowledge and information across the company, as overlapping issues are common within drug development and innovation. The functionality of the system does show similarities however, yet the eRoom module is rather limited in scope beyond that of a simple nested discussion forum. The key difference in the forum is the presentation and utilisation of the data sources. The KM Forum utilises a novel concept which has evolved from research with the Experimental Medicine department, hence it specifically meets the needs of the pharmaceutical community.

The following section provides an overview and explanation of the novel concepts and associated thinking which forms the backbone of the KM Forum.

3.0 DESIGN OVERVIEW

The following section discusses the key points of the forum which differ in functionality to a normal threaded message forum. It also provides an insight into the nature of Dynamic Categorisation and the possible further application of this approach.

3.1 DYNAMIC CATEGORISATION

The most notable innovation is the idea of Dynamic Categorisation developed by Dr Holger Adelmann. The concept is unique and seeks to allow the user to tailor their view point of the forum according to their areas of interest. All available commercial forums centre upon the use of categories to define and manage the threads and subjects. The use of categories often causes threads to be assigned to incorrect categories. Users may be unsure of where to post a thread if it overlaps many subject areas and this often leads to problems with lack of response to posts. Users who place a thread in an incorrect category effectively "pigeon hole" their thread and a user, who could answer such posts, may fail to visit the category resulting in the thread going unanswered. This is a common occurrence and one which can be avoided by providing the categories "on the fly" according to the preferences and request of the user.

A further advantage is the avoidance of the extremely complicated and crucial assignment of categories. Within our model we negate the need to reassign threads and reorder incorrectly placed threads. The need to continuously check and reiterate threads dependent on content is automatically handled by the design, so as to supply a list of relevant threads which enable user based discussions according to their knowledge and interests.

In order for the system to function correctly we must ensure that the user is aware of the threads that are related to their subject speciality and needs. A user submits a keyword and additional supporting information to an intelligent search engine which then returns the required categories.

The engine achieves this by linking with a structured ontology which in this case is designed to be applicable to the areas and fields of AstraZeneca and in particular the Experimental Medicine Department. The following section covers the individual steps which must occur to provide the viewer with a dynamic view of the forum categories.

4.0 KM FORUM PROCESS OVERVIEW

The individual principles of the processes are outlined in the Workflow Map (Figure 1) and each stage is covered in greater detail in the following section:

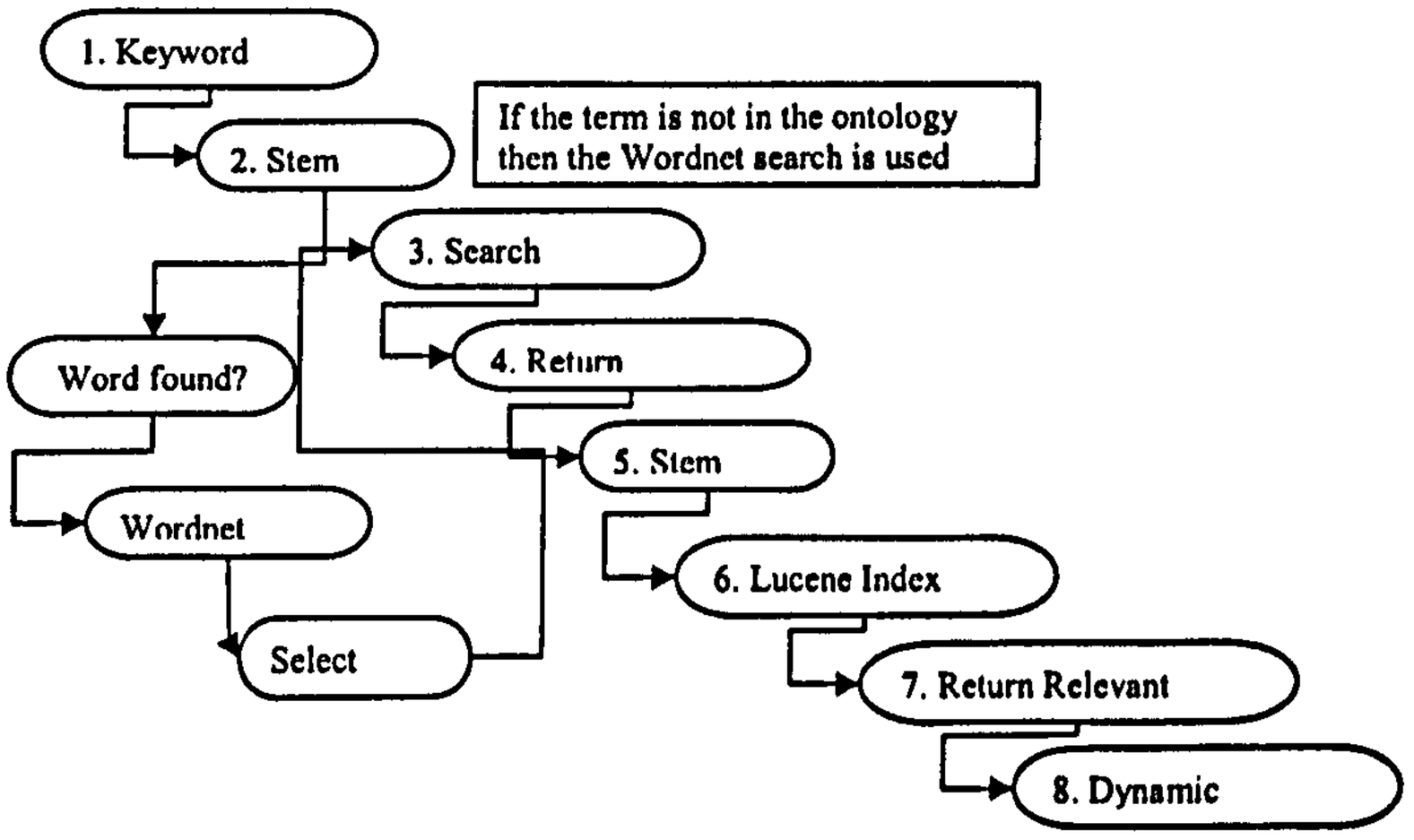

Figure 1: Workflow Map for the forum

1. Keyword Search

The forum is designed to complement and assist users within clinical to locate and share information and knowledge on specific subjects relating to their work. A user must enter a keyword or phrase which is indicative of their work, for example this may be LFT or Liver Function Test. Hyphenated words are also accommodated, though at present phrases asking questions may lead to complications.

2. Snowball Analyser

The words are initially stemmed using the functionality offered by the Lucene Snowball Analyser, this has the effect of reducing words to their constituent parts using a specific algorithm. The Snowball stemmer is an amalgamation of available stemmers and allows words to be reduced to their constituent parts: the stem and the suffix. A stemmed word is the output from the stemmer. The stemmed word will have letters removed from the right and these will then be presented to the Java based Lucene search engine. An example of a phrase may be "conducting a clinical trial" and this is stemmed to "conduct~ing a clinic~al trial". Hence the words conduct*, a clinical* and trial will be passed to the next stage which is a check against the ontology. For example the search term "ECG" would result in the following concepts being stemmed to these constituent parts by the Snowball Analyser as illustrated in Fig. 2.

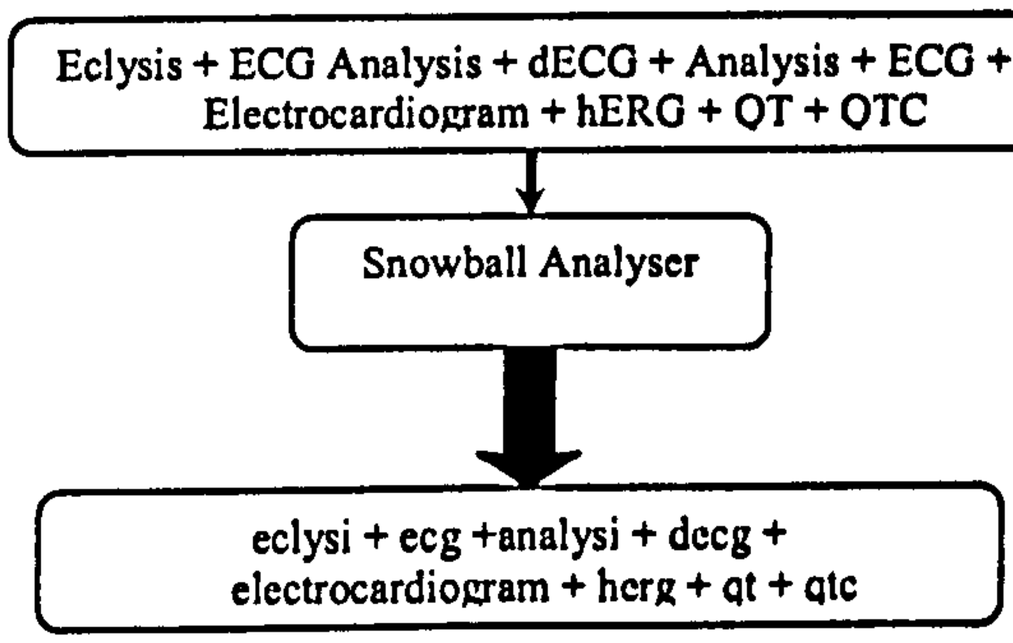

Figure 2: String input and stemmed output

The initial keyword undergoes a number of checks, the first of which is against the ontology. If the search term(s) are within the ontology then the word is stemmed and the relevant terms passed to the ontology search.

However if the terms are not present within the ontology, then a web service based using the open source WordNet Java library is invoked. The result is a dictionary lookup of the user's keyword against a standard dictionary. Words relating to the term are displayed and the user asked to chose a relevant "sense" from the presented list

For example this sets the context of words such as "tissue" to a medical setting. The selected term is then stemmed and searched against the ontology and if found, the cycle continues. If a related term in the ontology is not found, then the default action at present is to notify the user that "no relevant areas exist and the ontology should be updated to reflect this".

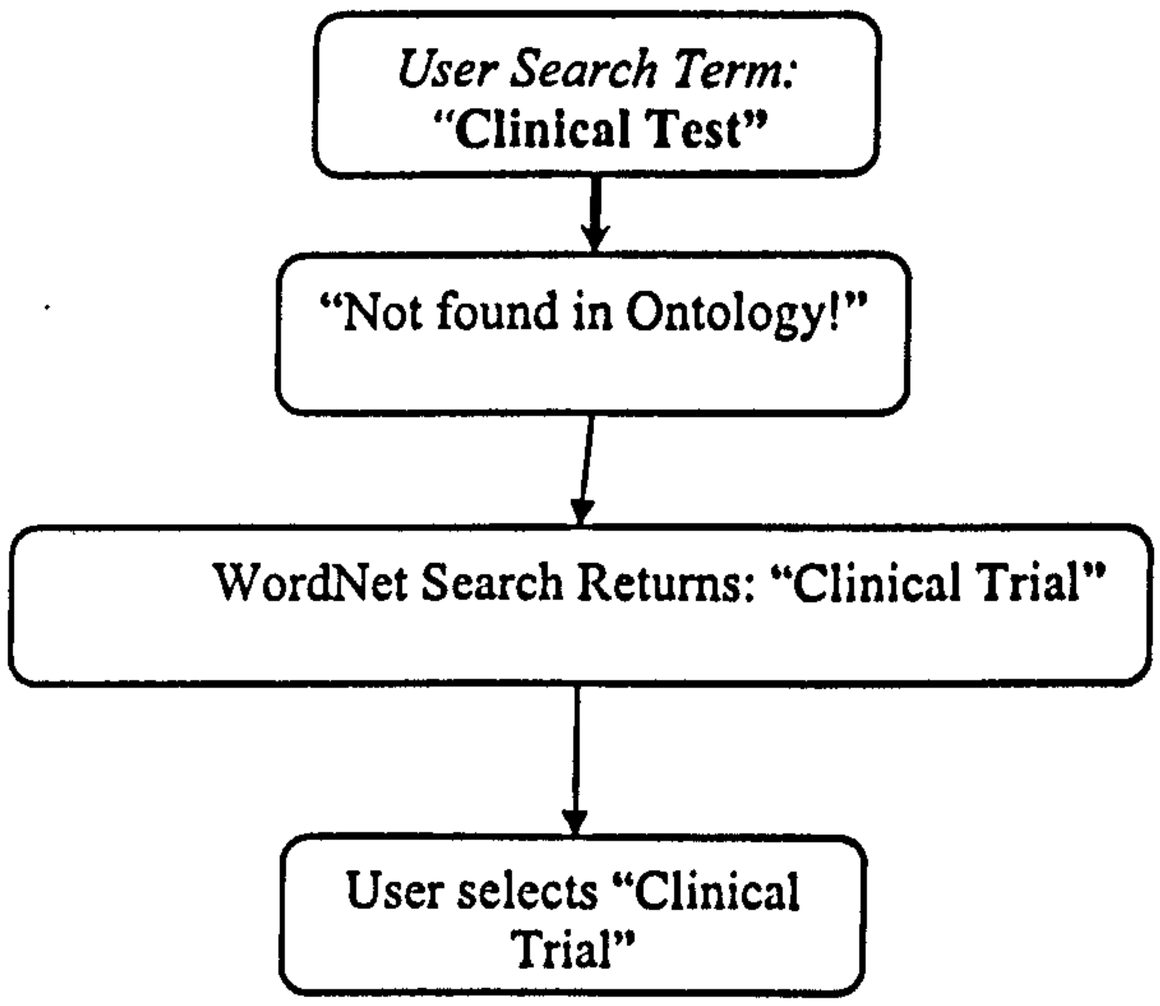

Figure 3: WordNet Search

3. Ontology Search

The stemmed words are passed to the KAON Web Service, this is a small Java program which operates independently of the asp.net forum and handles requests for terminology and ontology lookup. The program was written using the freely available KAON APIs and is documented within the source code. The service handles requests via SOAP messages which results in the output of related terms to the original keywords entered by the user. Hence from a keyword of ECG the following terms are derived, including the related synonyms and sub concepts.

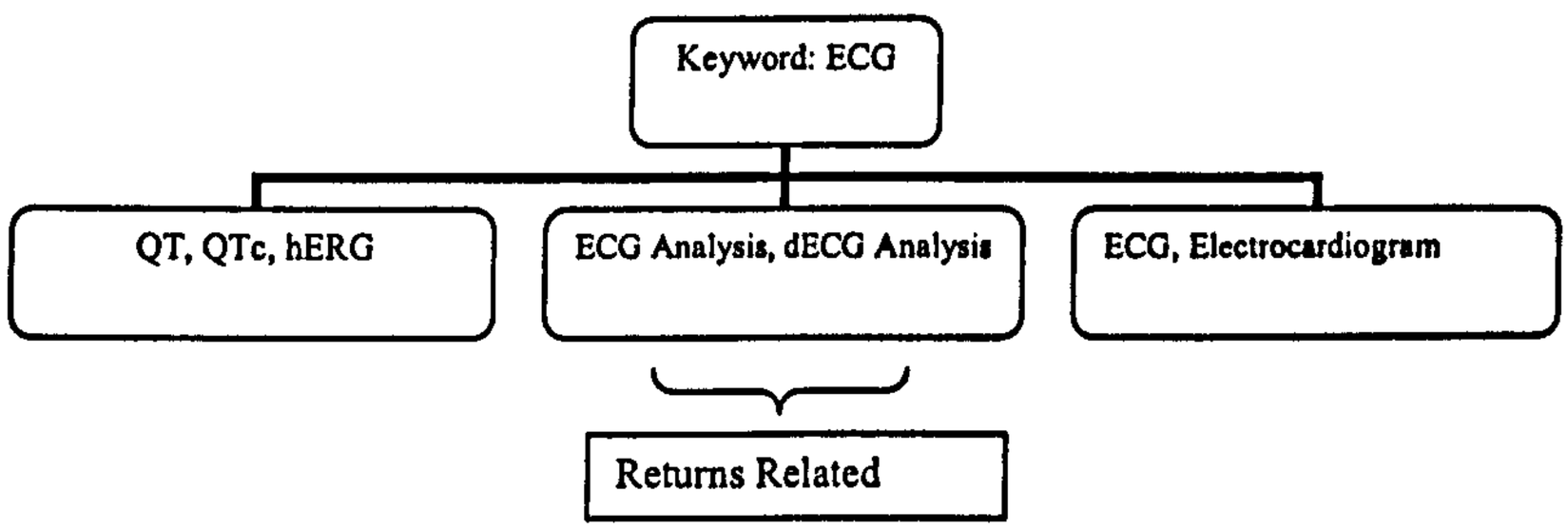

Figure 4: The "ECG" keyword returns the related sub concepts and synonyms

The user's keyword, which in this case is ECG is then passed onto the KAON web service, from where related terminology, sub concepts and synonyms are retrieved and passed on down the chain.

4. Return Sub concepts

KAON is a powerful open source ontology based tool which allows the creation and visualisation of a structured ontology. The various higher level concepts and sub concepts can be linked and designed to reflect the logical relationships and thought process behind the subject. This approach is particularly useful in this scenario as we reveal the knowledge path a user of the forum would follow.

A single keyword or key phrase returns words and concepts which are linked.

These reflect the existing business processes of the company by including disease areas and target areas. By applying the structure at this level we can be assured of returning useful information and knowledge to the user when they request posts on a specific thread. For instance the keyword ECG will return the synonym Electrocardiogram and QT amongst others, QT is strongly linked to safety within clinical trials so from a simple starting point we see that a web of inter-related topics emerges offering the user a high chance of locating the required knowledge. Figure 4 demonstrates the high level concepts which link from "Tissue" and will return areas of interest that are applicable to development involving tissue research.

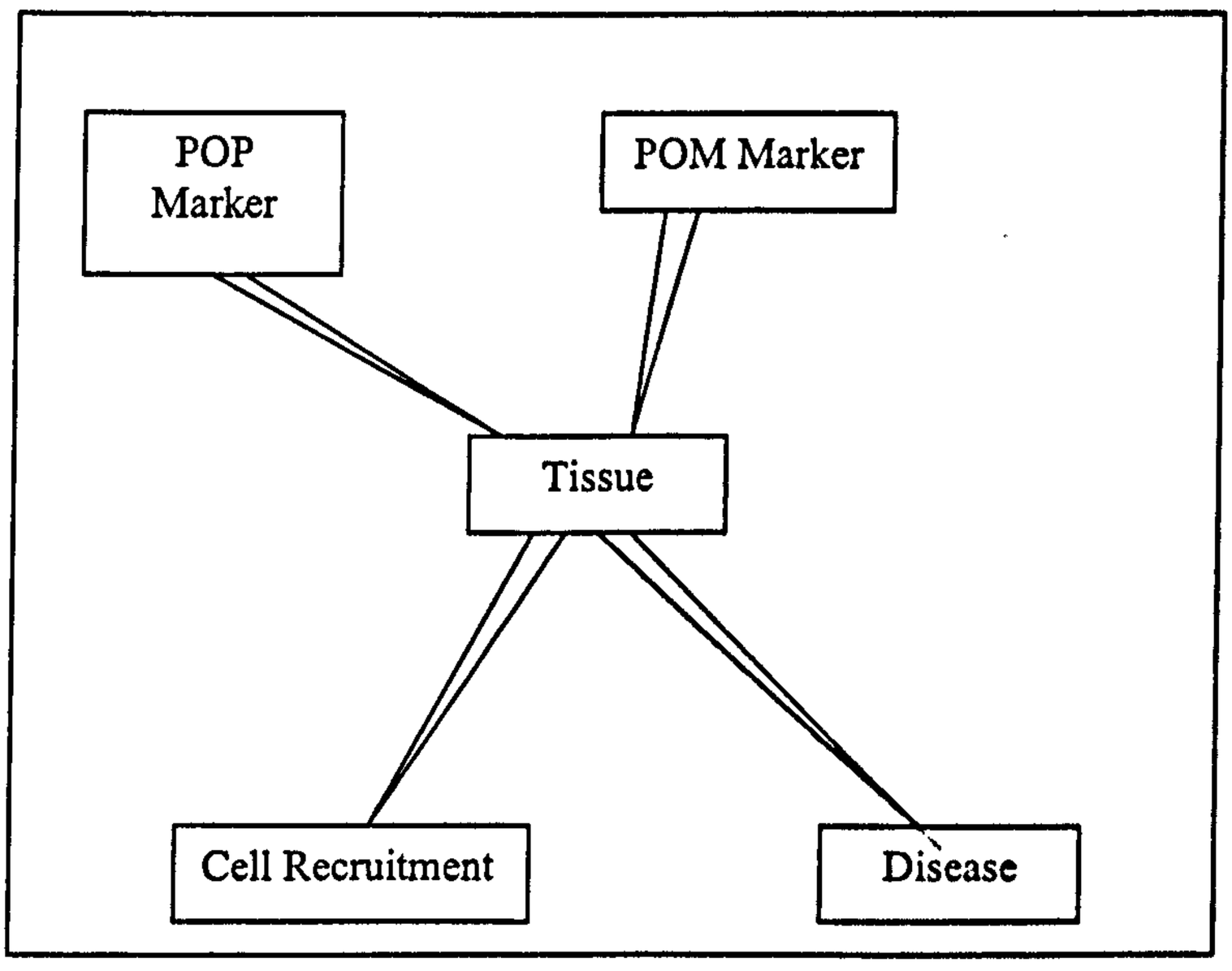

Figure 5: Visualised Ontology Concepts

5. Stem Words

This step is identical in operation to Step 2 and serves to ensure that the search terms are stemmed to provide the highest possible return on the initial query. This stages results in a comma delimited string.

6. Lucene Index Search

The stemmed concepts and related sub concepts are then passed to Lucene in the form of a string, and the index files of Lucene checked against the keywords. Lucene is extremely quick at searching documents for key terms and is designed to search and index data in the order of millions of documents. This was a crucial factor in settling upon Lucene as the chosen search engine. We believe this aspect will not be tested by the new forum regardless of the size and growth of the forum. A further factor is the ability of Lucene to allow upwards of 250 search terms to be searched concurrently when supplied in a comma delimited format. Lucene is based on a collection of Java libraries and has been compiled to run as a web service utilising SOAP messages.

By presenting the search functionality as a web service we have allowed the search capability to be open to external sites which require an ontology based search. Within the present design, Lucene is configured to search XML files as the native data store for the forum messages and threads. Although this can easily be adapted to search many other file formats including MS Word, .pdf and text based files. The potential exists to implement a database driven search through a JDBC interface and this is currently being explored as a possible data storage solution.

7. Return Relevant Threads

Lucene returns the file pointer of the relevant threads and these are then passed onto asp.net C# code, which then forms the categories governed by the input terms.

8. Dynamic Categorisation

The final stage in the process returns the threads in a structured view by providing recent and relevant threads first and related threads in an ordered view, sorted by date and time. The final view of the data is still under development and is expected to evolve as users request and functionality is improved to offer a rounded solution.

5.0 FUTURE WORK AND CONCLUSION

The development of the forum is progressing well and the backbone of the forum exists within a reliable and ordered code. It is estimated that a prototype will be introduced within September 2004 that will utilise the existing ontology driven system with a revamped asp.net backend. Work is currently being undertaken to utilise C# as the preferred development language so as to provide a stable and reusable modular forum. A key facet of the work is the enhanced search functionality provided by the use of a relevant ontology to retrieve results. In depth discussion has occurred which has concluded that this functionality could be applied to other file stores such as MS SQL data stores, Word and pdf documents and other common formats.

In conclusion the KM Forum is an exciting and unique development. Which shows substantial promise in fulfilling the ultimate aim of providing a structured area for knowledge reuse, information exchange and knowledge creation.

APPENDIX 5

KNOWLEDGE MAPPING

The following is an excerpt from a report commissioned by AstraZeneca in June 2005 to investigate the use of knowledge mapping for decision capture.

1.0 KNOWLEDGE MAPPING FOR PHARMACEUTICAL INNOVATION

There are a number of potentially interesting and valuable areas which may be mapped by the use of a knowledge led Case Based Reasoning template. When attempting to map non-linear processes such as the Piggybacking project, it is wise to uncover aspects that directly relate to resource and process management; and the novel practices which have led to the key decisions.

The principle benefit of undertaking the mapping process is that it allows a review of the work carried out with the key actors. It is rare within industry for companies to conduct such study (Newell et al. 2002), providing data on unorthodox processes and the need of employees to bypass established guidelines in order to complete the project. AstraZeneca currently lacks a formulised reflective process when analysing project work and the Knowledge Map should aim to uncover the extent of organisational and individual based learning. Until now, there was no formal template for organisational knowledge capture. Hence valuable knowledge concerning the knowledge capabilities of the key players within a defined process can be captured. The outcomes of using this template may allow an individual to learn from a project and for the organisation to learn of the project. Knowledge mapping will also allow individuals skills to be mapped to similar projects once identified.

2.0 QUESTIONS FOR KNOWLEDGE MAPPING

Mapping a project can provide an extra level of validity to current AstraZeneca processes. A knowledge map may be formed by asking questions such as:

- Are there certain areas where AZ processes negatively impact upon a project?

- Are project teams offered sufficient resource to reflect upon their work? Or is reflection simply not an option?

- Are deadlines too stringent or do they push a team to fulfil its obligations?

- Are people actively producing new knowledge and innovation? Or are they simply rehashing established procedures in a "cut and paste" style?

- What do we do differently? Is there value in this?

- What do people do best? Are their skills unique? Can we capture the knowledge of skills for future reference?

- Do we see examples of nested collaborative learning?

- Do different levels of team interactions stimulate learning and knowledge interactions throughout the entire project?

- What are the power relations and hierarchical layers within the projects? How are they affecting the progress and outcome?

- What management pressure exists?

- Do we observe vested interests?

- Are there key players or process champions who are essential to drive a process forward and create the required knowledge?

- What skills have we learnt? Are these skills useful and can they and the employee be applied elsewhere in similar areas?

These questions ask what occurs inside a project and can be used to assess the knowledge outputs of a project, regardless of whether it meets expectations. In the case of the Piggybacking project it maybe that the difficulty in running the two projects side by side, was due to the lack of a legitimatised business processes that facilitate this process.

Employees within the projects can adapt and absorb new information in order to achieve this task. Yet in this case the established guidelines and time constraints may have hindered this process and hence a potentially viable and cost reducing methodology was not utilised. The piggybacking example gave the following indicators of what areas should be assessed when developing a Knowledge Map:

Key Information to capture:

- Project keyword – author, departments, employees involved, dates etc
- Map of the process – where and why are the key steps occurring?

Capture eventual outcome with regards to:

- Pending issues
- Best/ Worst Practice
- Commonality of assumptions across projects
- Study Cancellation/ Rejection
- Outcome - Positive/ Negative

Capture the factors which lead a project to succeed/ fail:

- Clinical Development Plan problems
- Time issues and highlighted hold-ups
- Unique and common compound safety concerns
- Safety pathways i.e. what guidelines have to be followed?
- Adequate Patient Safety Information for regulatory authorities

- Novel approaches to Clinical Study techniques – e.g. piggybacking, micro plaque delivery approach

Capture human management and resource problems:

- Cost & Resource Management
- Identifying shared resource and teams
- Skill Base of Participants
- Number of patients required for studies
- Patient recruitment difficulties
- Departmental audit trail – which departments are using what resource, are there problems with interdepartmental relations?
- Success according to TA or application methods
- Process and advantages of using external collaborations- Biotechs or small scale manufacturing

Capture compound characteristics to find out whether certain compounds more likely to succeed:

- What are the pointers for success?
- What are the biomarkers?
- Chemical similarities between other compounds
- Proof of Concept issues
- Animal Model Identification issues
- Problems with application of compound i.e. specificity, target etc

- Predicting success rates – common findings relating to compound efficacy/ application at the early stages
- Does the project allow cross over with other projects?

3.0 CONCLUSION

This report was written to be used as a guide to knowledge mapping. The initial results of this exercise are proving valuable. With further research, the technique could be aligned with semantic technology to aid information and knowledge retrieval.

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