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What drives pharmaceutical innovation and knowledge exchange?

A study supporting the use of Knowledge Management within the pharmaceutical industry

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Abstract

Innovation is a key driver of the pharmaceutical company, from an initial discovery of a compound to the final development of a marketable and novel medicine, the web of processes to reach a viable end stage requires innovative behaviour backed by accurate knowledge. This paper analyses the use, importance and sources of knowledge within the drug development process and suggests that a pharmaceutical Knowledge Management strategy should not only address capturing the knowledge within the drug processes, but also the knowledge held within the social networks of the organisation.

Introduction

Innovation has long been associated with the pharmaceutical industry, the development of new medicines is paramount to the longevity of both the organisation and society (Cardinal & Hatfield, 2000), yet the complexity of these processes is largely under researched and few studies exist which shed light upon how drug innovation actually occurs. The following paper aims to shed light upon these hidden processes and address where Knowledge Management can aid and enhance the innovative processes within an R&D organisation.

Knowledge is regarded by many as the true driver of innovation and an organisation's competitive ability (Spender & Grant, 1996). The pharmaceutical industry is a knowledge intensive arena that demands up to date applicable knowledge and to all intents and purposes, Knowledge Management research should be able to provide worthwhile benefits to an organisation and enhance the drug development processes (Alavi & Leidner, 2001). However due to the complexities associated with modern drug development, little research has been conducted on the effectiveness of Knowledge Management strategies within the drug development industries. Howells (2002) notes the challenge of the pharmaceutical industry is to keep abreast of the sheer volume of information and knowledge within the pharmaceutical domain, while competing with rivals on the quality and efficacy of its drug products. From a strategic perspective the role of the R&D function within large pharmaceutical companies is changing, research by Kneller (2003) indicates the basis of drug development is migrating from the in-house R&D model, to one of external acquisition of innovation and drug technology through Universities and BioTechnology firms. While this transition is occurring, research within the drug industry suggests companies are slow to accept such change and embrace Knowledge Management strategies as a means to adapt (Davenport & Peitsch, 2005).

Such issues are effecting all pharmaceutical organisations as they compete within the global economy, when coupled with the need to assimilate external knowledge into the burgeoning wealth of knowledge and information across the large pharmaceutical organisations, such change is merely compounding these problems. The following paper uses a series of case studies to examine the responses to the changing pattern of innovation within a large UK pharmaceutical company and discusses the Knowledge Management measures the organisation has implemented to retain a competitive edge. The authors then speculate on possible Knowledge Management led strategies which address the mounting challenge of effective pharmaceutical knowledge and information management.

Drug Discovery - a web of processes and knowledge

The company under scrutiny is a world leader in a number of therapeutic areas, and these include cancer, gastrointestinal, cardiovascular and respiratory related diseases. Within each of these Therapeutic Areas the drug development process begins within the Discovery wing of the company. Here the knowledge of the employees and strategists is applied to develop compounds that are pharmacologically active against a biological target. Such initial stages of drug discovery is labelled as the development of a New Chemical Entity (NCE). The NCE is designed to have a pharmacologically active effect on a key marker for the disease, whether this is to relieve symptoms of a disease, such as lowering blood pressure or attack the root of the disease and provide a cure. Once a number of NCEs that specifically target a receptor, protein or enzyme involved within the disease state are identified, these compounds are then forwarded to the Clinical wing of the organisation. Essentially Discovery is responsible for providing and discovering worthwhile NCEs to the organisation. When a suitable NCE is forwarded within the organisation to the Clinical wing, it becomes a Candidate Drugs (CDs), where the credentials of the compound are verified with regards to their efficacy and performance within biological models. Timescales within this process may be up to five years, yet there still remains a substantial amount of work to achieve before a CD can be released to market, in most cases this is a further six years of work. Only once a CD has passed a rigorous series of internal and external control points, trials and safety measures may the drug be released to market as a New Medical Entity. At any point within these processes a drug may fail to meet strict criteria, thus cutting this attrition and identifying potential failures earlier within the processes is essential (Kneller, 2003). Research by Alanine et al. (2003) suggests the success of this process overall may be as low as 1-5%, evidently an organisation charged with addressing the high failure rate of compounds must address the fundamental core processes associated with drug development.

Knowledge is at the crux of drug development and the knowledge required to innovate and drive the drug discovery processes may be considered as the main asset of an organisation (Kandampully, 2002). KM to all intents and purposes, would appear to be an ideal vehicle with which to reduce the amount of resource involved with the laborious process of converting a NCE to a NME (Nahapiet & Ghoshal, 1998). The drug discovery processes may be viewed from a linear perspective, yet research by Orsenigo et al. (2001) suggests drug development functions as a network of interrelated processes and innovations. The Knowledge Management literature is clear to promote Knowledge Management as a suitable vehicle with which to address the knowledge activities of the employees, yet few papers accurately describe the Knowledge Management strategies an organisation should implement. Studies by Jennex & Weiss (2002) and KanKanhalli (2001) recognise the benefits of Knowledge Management within a research-based organisation, however little research targets

the applicability of Knowledge Management within the pharmaceutical R&D environment. Research by Schmid & Smith (2004) suggests luck plays an important role within drug discovery, while Sundgren & Styhre (2004) promote the role of intuition as a basis for drug discovery. The following study begins to clarify the basis of innovation and spread further light upon the use and potential of Knowledge Management within the industry.

Pharmaceutical Innovation and Knowledge Management

This paper is primarily concerned with pharmaceutical innovation, yet the concept of pharmaceutical innovation is ill defined. The process of innovation stems from a variety of interconnected areas such as competitive advantage, risk management, technological management, collaborative activity, creativity and KM amongst other related fields (Nieto, 2004). Innovation is commonly referred to as the creation of value through the use of such assets, whether they are intangible or tangible assets, so in many senses innovation relates to the creation of new tangible product (Nonaka & Takeuchi, 1995).

Although innovation may be described as the formation of a tangible product, Cooper (2003) and Montes, Moreno & Morales (2005) argue innovation may also be construed as a strategic concept, where the option to improve the organisation and therefore induce a competitive advantage, arises through the use of innovative business practices. The definition of innovative processes with regard to drug development, supplied by Terziovski & Morgan (2004) will define the boundaries and form the basis of the study.

Terziovski & Morgan (2004) define innovation as:

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

The definition relies upon the provision of knowledge to facilitate product development through the use of processes, which allow creative and innovative behaviour. Essentially the application of the *correct* personnel and *their* knowledge carries a drug development into practice. The use of adaptive business process behaviour allows innovation, which in turn allows the company to produce marketable products from their knowledge, thoughts mirrored by Yeoh & Roth (1999). Studies of innovative practice by Leavitt (2003) within the pharmaceutical industry suggest Knowledge Management may play a positive role within drug development, particularly with regard to enhancing the access speeds to information and knowledge by the employees across the organisational domain. However Knowledge Management embraces more facets than technology, Darroch & McNaughton (2002) note Knowledge Management seeks to create or locate local knowledge, manage the organisational flow of knowledge and ensure the effective use in order to provide a long term cultural benefit to the organisation. In light of these benefits, the studies principle aim is to discuss the use of Knowledge Management within the organisation and suggest strategies to allow an increase in efficiency within the R&D drug development processes.

Methodology

The following paper is based upon a study which relates to the use of innovative practice and drug development innovation within a leading UK pharmaceutical organisation. The objectives of the research were: to assess Knowledge Management as an aid to innovative work within the drug development realm, propose new Knowledge Management strategies and discuss the impact that Knowledge Management may have within the dynamic environment of the pharmaceutical innovation with regards to the barriers and enablers of Knowledge Management. In order to study these facets the paper is based upon the results of thirty three semi-structured interviews conducted with known innovators within the pharmaceutical organisation.

Due to the abstract nature of the problem scope, the paper adopts a case study approach in under to further define the boundaries of innovation and apply structure to the problem (Rowley, 2002). Qualitative data analysis inline with Cresswell (1994) was employed to gather and analyse the data, while the sample population 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 across the hierarchies of the organisational culture.

A primary criteria for inclusion within the study was 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 renowned by the senior management, for providing maverick contributions within the development of chemical compounds or processes. The use of semi-structured interviews throughout the case study was chosen so as to yield a rich account of the use of knowledge within the drug development processes and provide the real life context of the actors within the social tapestry of the case research area (Yin, 1989). The interviews sought to elaborate and reveal the knowledge sharing behaviour of the staff with regards to Knowledge Management tools and to yield rich qualitative data concerning the innovative processes of key managerial and ground level personnel across the organisations R&D domain. Each case study utilises a series of semi-structured interviews, which are based upon work by Scarborough et al. (1999), Sundgren & Styhre (2004), Dorabjee et al. (1998) and Coombs et al. (1998). The study has yielded rich and detailed qualitative data, not only concerning the role of knowledge within drug development, but also the potential use of KM within innovation. The results of the analysis and case study will be discussed in further detail within the following section.

Analysis

The results of the research study are now presented and discussed in line with the interview structure, the key findings and critical observations, revealed while discussing the role of Knowledge Management within the drug development processes. The study examined the following areas:

1. Knowledge Management Strategy and Technology
2. Combining the Social and Technical Aspects of Knowledge Management

The results are intended to provide an insight into the R&D processes, and provide a justification for the use of Knowledge Management within the pharmaceutical environment. The results uncovered question the importance and relevance of a Knowledge Management strategy that aligns with the organisation's strategy of drug development; while hinting that although the areas of technology and organisational knowledge appear distinct, they naturally support each other. As such the results provide a number of interesting areas for the development of KM strategies and allied areas of further research, which will be covered in later papers.

Knowledge Management Strategy and Technology

The interviews were conducted to obtain an accurate qualitative picture of the organisations Knowledge Management strategy. While the studied organisation is a market leading R&D company, it is also typical of many large organisations. Disparate information and knowledge sources lay across the organisation and employees struggle to access relevant information. Such is the demand for diverse sources of information and knowledge across pharmaceutical drug development, that this aspect was expected, in line with research by Henderson (1994).

However the organisation has a long-standing Knowledge Management strategy that has attempted to address these discrepancies. In-house research conducted by the IS department, utilising web based data capture systems and quantitative surveys has found that the strategy would appear to be fulfilling the criteria of knowledge and information sharing, although to date little research has attempted to clarify the intangible aspects of this research.

From a theoretical viewpoint, an organisations Knowledge Management strategy should provide a route or map by which an organisation may effectively guide its employees in line with Knowledge Management methodologies and tools (Jashapara, 2004), yet if such a strategy is misaligned little value will be returned (Willoughby, 2003). Examining the organisations strategy from an innovators viewpoint reveals the Knowledge Management technology falls short. Innovators overwhelmingly rely upon their personal networks of colleagues and acquaintances to acquire innovative knowledge. When this factor was discussed with regard to the initial sources of innovation, employees suggested that the majority of drug innovation is in fact in-licensed or *bought* into the organisation from external research entities. The innovative ideas and research stems directly from the employees network of collaborators and acquaintances. Initial ideas appear to be generated externally to the company and then acquired by the R&D functions of the organisation, on the recommendation of the employees and strategists. Innovators were confident that the traditional model of in-house drug innovation suggested by Dimasi et al. (2002) was redundant. Senior interviewees suggested upwards of 99% of initial drug work was bought in and only then would the organisations resource and knowledge be bought to bear upon the development processes. Opinions over the extent of innovation acquisition varied, principal scientists and employees connected with the Discovery wing of the organisation alleged the majority of Candidate Drugs had their origins external to the organisation. While staff involved with progressing Candidate Drugs to market launch within the Clinical wing, acknowledged that they worked upon drugs that had originated from the organisation.

The discrepancy may be explained by the time scales involved within the drug development process, the five year development stages from initial compound to Candidate Drug implies that many staff are simply unaware of the origins of the initial drug. While this aspect is not overly concerning, the finding has further implications when the knowledge aspect of the innovation is discussed. Knowledge within the organisation is a fluid entity and staff of both functions were unsure as to how and where to acquire background knowledge residing within the organisation on the multitude of Candidate Drugs within the organisation. Staff noted their principal means of locating knowledge on the organisations Candidate Drugs, was through networks of colleagues, both internal and external. Although this process is fuelling innovative processes, the case study found the Knowledge Management strategy of the organisation does not reflect this. An employee remarked upon the typical means of knowledge acquisition within their work:

"I don't have time to cover the material so I rely on overviews and headlines, but mainly on talking to people as five minutes with someone who's written five papers is usually enough. 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."

Early Knowledge Management literature such as Wiig (1997) focused upon the capture of such knowledge as employee and staff turnover naturally affected the availability of knowledge within the organisation. While work such as this advocates capturing such knowledge it is still relatively unclear how an organisation may achieve this.

The Knowledge Management strategy employed by the organisation relies upon the conglomeration of the existing knowledge and information sources within two principal document management systems. Although the systems used to manage documents are adequate in that respect, the strategy behind what and how it is stored is lacking. As previously noted the interviewees favour the use of knowledge networks to gain knowledge and few interviewees actively sought information within the document management stores. It is also interesting to note that the location and extent of the knowledge and information residing within the employee knowledge networks is not captured, this information is only present within the mind of the employee. This finding was investigated further across the organisational hierarchy, including scientists, senior directors and physicians within the drug processes and was found to be the norm and not an isolated case. Neglecting to address the location of knowledge outside of the explicit knowledge stores is considered a key failing of Knowledge Management systems in general (Cooper, 2003; Tiwana, 2000). Yet unless the organisation adopts a rigid strategy that dictates the employees capture the sources of knowledge used within their work, the knowledge and nature of these networks will remain unknown.

This finding directly relates the concepts of Human Capital to the availability of knowledge within the organisation. Lerner & Merges (1997) note collaboration forms the basis of biotechnology interactions and this case study implies they also form the basis of pharmaceutical innovation. Edvinsson & Malone (1997) consider Human Capital to be the knowledge that an employee will take with them once they leave an organisation. Within this study this would appear to be the knowledge or 'know-how' of the social networks that are intrinsically linked to the drug innovative practices, an observation also found within the software development industry (Ashworth & Carley, 2006). Although the Knowledge Management strategy of the organisation recognises the need to capture such knowledge, there is no physical Knowledge Management provision to achieve this. The strategy focuses

upon supply the minimum of knowledge needed for the employee to fulfil their role, but innovative knowledge appears to be derived from extended personal communities of practice. Clearly knowledge within the organisation operates on two tiers, as Adair (2004) suggests there is the knowledge to perform ones role and then supplementary knowledge to innovate. The organisational Knowledge Management strategy should seek to address the second tier of *supplementary* knowledge, by providing the means and technology to retain such social knowledge. The following quote from a senior managerial interviewee, who is responsible for leading R&D within multiple disease areas, illustrates the problem associated with the discovery, capture and dissemination of innovative knowledge:

"I found that each disease area had done an awful lot of innovative methodology work but had refused to implement any learning's from that, sometimes they even refused to draw conclusions."

This example applies to capturing and enhancing the knowledge and processes of designing and running innovative clinical trials. Innovative work had occurred outside of the traditional scope of a project, yet employees simply were unaware of how to progress such work further and how to *apply* such work within the organisation once completed. The employees, who were within the immediate social network and hence directly involved were aware of the potential scope and existence of these projects, yet few outside knew of the work. Ensuring that innovative work such as this is not neglected and employees are able to locate and refer back to such work, equates to the design of a strategy that not only provides access to the core level of process-based knowledge, but also provides sufficient remit to capture this additional innovative social knowledge. While the provision of Knowledge Management tools such as document management systems, case based reasoning tools and expert systems to capture explicit process-based knowledge is established within the organisation; the social aspects of knowledge management are neglected within the organisation and within the pharmaceutical industry as a whole (Davenport & Peitsch, 2005).

Kankanhalli et al. (2003) suggests the use of social IT systems to forward Knowledge Management initiatives can support the personalisation of knowledge sources that is required in these situations. To examine these finding in greater detail within the context of the organisation the following section will examine Knowledge Management tools and strategies to support the social networks found internally and externally to the organisation.

Combining the Social and Technical Aspects of Knowledge Management

So far the case study has linked the concepts of human capital with the concept of a second tier of innovative knowledge, Human Capital is represented by Edvinsson & Malone (1997) as the know how, the experience, flexibility, and creativity of the employee within an organisation. As we have witnessed this is the knowledge that drives pharmaceutical innovation, yet the organisation is failing to uphold these areas through a Knowledge Management strategy.

The case study research and literature by Saito et al. (2006), Gunnlaugsdottir (2003) and Wiig (1997) suggests these failings may be addressed through the provision of Knowledge Management tools. The mentioned authors suggest collaboration may be supported through file sharing, expert location systems, meetings, groupware & decision support technology and shared applications. While a sense of community may be supported through discussion forums, community management, Web Logs (Blogs), Wikis and social network analysis software. With such a variety of tools available to the practitioner it is little wonder that within the organisation, the survey revealed an unstructured and under used array of such technology, masquerading under the banner of a Knowledge Management strategy. Supporting collaboration and knowledge networks requires the active management of these communities and social networks. At its simplest sense simply providing a discussion forum may aid the formation and dissemination of information within the organisation (Wenger & Snyder, 2000). The case study suggests communities of practice that are centred upon document management systems exist across the organisation. It appears that where there is a purpose, a community of practice forms, Hildreth et al. (2000) defines a community of practice as clusters or aggregations of both external and internal sources of knowledge. In this light the community or network should be identified and allowed to evolve through the use of Knowledge Management technology. This should include document management systems, communicative media and traditional face-to-face interaction, to become a working community capable of providing the human capital necessary to drive innovation.

Thus a Knowledge Management strategy should address this aspect, sparking initial community formation around drug projects, followed by the provision of specific tools to encourage collaboration across the organisation and capture the minutiae of the knowledge networks. It is well known that technology-aided collaboration is widely adopted by R&D organisations that are seeking to leverage intellectual capital and knowledge assets from their workforce in order to enhance product development processes (Lemon, 2004). What is unclear however, is whether the focus should rest with tools such as discussion forums, Web Logs (Blogs), Wikis or with simple groupware document based systems. What is interesting within the organisation is the interviewees unanimously accepted and visualised using such additional collaborative systems such as Web Logs and Wikis, when provided with visual examples of these tools, an employee commented:

"Personnel want to share best practices and learn from others within the company, we have to have a culture that makes it easy to share knowledge and learning"

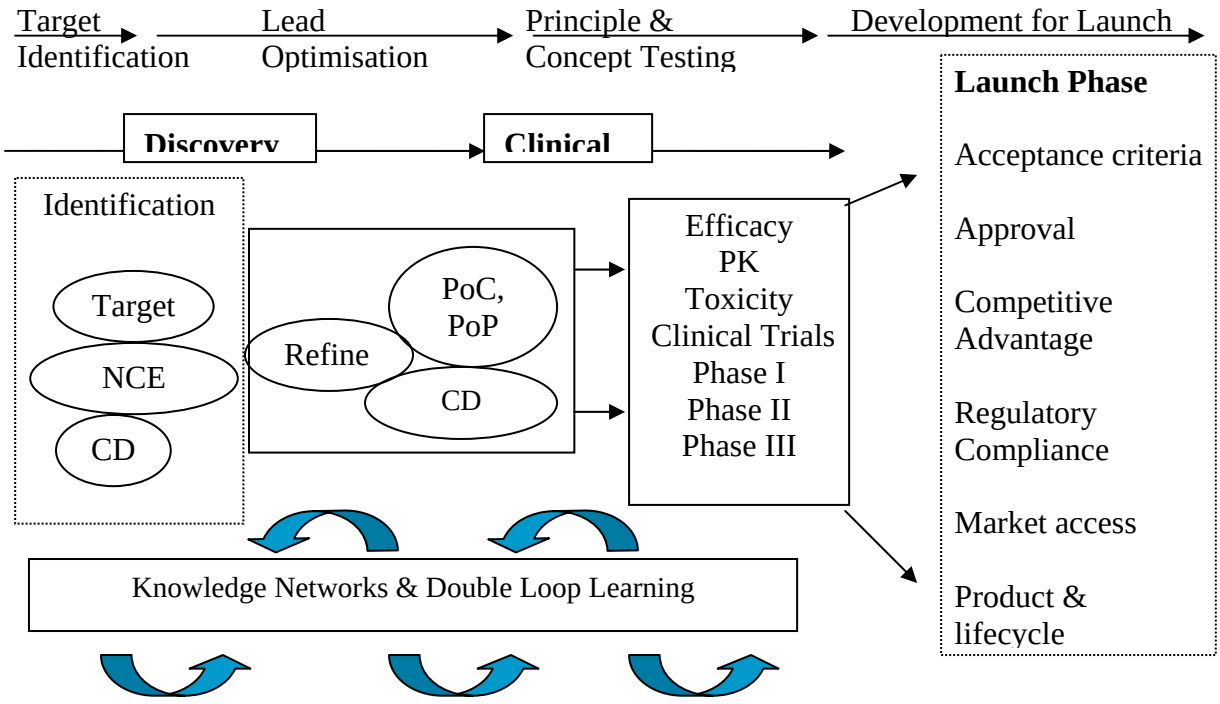
Supplying the means to achieve this via technology may allow innovation through the formation of knowledge networks, in essence a combination of social and collaborative software specifically tailored to target the second tier of innovative knowledge.

A further important aspect of the research suggests that the provision of social software is particularly important on the interface of organisational departments. In this case between the Discovery wing and the Clinical wing. Drug projects within the organisation progress in a linear manner as in a traditional drug discovery model (DiMasi et al. 2003). Yet the knowledge interactions surrounding these processes and documentation is an iterative, double loop learning process. The discovery of double looped learning implies the organisation actively challenges drug development assumptions and processes, rather that simply reacting to a challenge, as is the case regarding single loop learning (Rubenstein-Montano et al., 2001). Although the study recognises that such work occurs, little capture or dissemination of this knowledge and innovative is then carried out using the Knowledge Management tools. An overview of the drug development process and the tiers of knowledge that are inherent within the organisations drug processes is illustrated in Figure 1. The diagram in Figure 1 illustrates that the traditional linear processes of drug development and project documentation occurs as a series of milestones. Within these processes the study revealed that knowledge loops and collaborative practice occur across multiple processes and multiple actors, which are in fact fuelling innovation within the organisation.

The model derived from the case study work does not however address the sources of innovation. As previously discussed, the initial innovative compound is increasingly likely to be sourced externally to the organisation. This process essentially is an acquisition of intellectual capital, yet the study revealed that rarely is the human capital i.e. the expertise and know-how behind the innovation captured and disseminated throughout the organisation. Employees within the Discovery organisation simply acquire the rights to a compound and then revalidate existing data and information regarding the drug performance metrics in-house. In a similar stance Clinical employees also expressed a mistrust of initial external data and required revalidation of public clinical data in-house, including peer reviewed journal findings. While the study found collaborations with external sources of innovative knowledge do occur, they are unstructured and rely upon traditional communications media, such as email, face to face and the telephone. Attempts by other employees to discover knowledge on external drug acquisitions and collaborations thus fails, resulting in a reiteration of this process with different actors across the organisation.

In light of the case study findings, conclusions and recommendations relating to innovation and social networks will now be discussed. Further research and possible avenues for a Knowledge Management strategy to drive innovation are then suggested.

Figure 1. An overview of the Drug Development Processes



Conclusions and Recommendations

The study has revealed a changing model of pharmaceutical innovation, one where in-house R&D has given way to the process of intellectual capital acquisition. However this process is far from adequate, while the rights to a compound are acquired the associated human capital is often overlooked. The innovative knowledge within internal and external collaborations constitutes an integral aspect of the human capital within the organisation. Capturing and encouraging this knowledge of collaboration through social Knowledge Management tools such as discussion forums, Web Blogs and Wikis would thus appear to be a prudent strategy. However there is an attitude of mistrust between the R&D functions of the organisation and external organisations R&D companies. This requires careful consideration and suggests further research with the application of specific collaborative tools is necessitated. The research suggests that tailoring collaborative tools to specific projects is a recommended strategy. Aligning the resource needs of the employees with a Knowledge Management strategy that not only provides base project knowledge but also allows the means to facilitate and mange internal and external interaction so as to drive innovation. As the pharmaceutical industry is an inherently high-risk area, failure at any point of the development process results in a substantial resource cost. Employing a tailored and collaborative Knowledge Management strategy in line with the organisational strategy could certainly help to address these issues and aid drug development.

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