A framework for decision support, capture and re-use

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A Framework for Decision Support, Capture and Re-use

By

Dr Holger Georg Adelmann

A Doctoral Thesis
Submitted in partial fulfilment of the requirements for the award of
Doctor of Philosophy of Loughborough University

October 2008

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Abstract
Pharmaceutical Research and Development (R&D) is a 'knowledge intensive' business, requiring frequent and comprehensive knowledge transactions. One necessary class of knowledge transactions concerns the constant evaluation of incoming data from experiments, discussion of the data amongst scientists and physicians and the ability to make informed operational and strategic decisions amidst some uncertainty, particularly in the early phase of development. Because of these uncertainties, it is important to constantly review decisions to verify their validity as a drug development project moves on. As the decision-making is inextricably bound to appropriate risk awareness and risk management, the consideration of options and appropriate scenario planning, the application of past experience to present information should help provide a balanced assessment of risks prior to decision making. Experienced employees often immediately apply what they remember of their past experience to present problems. This past experience, together with the ability to abstract from past solutions in order to be able to apply them to new problems may be the key to robust sustainable decisions.

The author's research has used a combination of pilot studies, brainstorming sessions, review meetings and surveys combined with actual working practice in an iterative manner, which has been proven useful to address the specific aims and objectives for the development, implementation and testing of a decision support framework for clinical drug development called EPISTEME. All the aims and objectives set at the outset of this research have been achieved.

AstraZeneca top management has also recently used the EPISTEME decision support framework successfully to assess the impact of restructuring scenarios. This and the endorsement and adoption of the final information model and decision support framework by the AstraZeneca company, means that this research project was successful, and can now provide the basis for many further research projects on related topics at AstraZeneca and elsewhere.
Keywords

Decision support, scenarios, value mapping, case based reasoning, CBR, metadata, Dublin core, XML, RDF, knowledge management, information model, semantic search expansion, taxonomy, tag cloud
Acknowledgements

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Special thanks go to my all-time supporter Tony Croft, AstraZeneca, whose extensive networks within the company always named me new contacts within AZ that provided very valuable input into the discussions and brainstorming around the concepts of knowledge management and decision support discussed in this work.

Special praise must go to Ray Dawson of Loughborough University, who has been absolutely fantastic in his support. Ray has been a great supervisor who always had the right words at hand when I was struggling to explain my simple concepts!

Last but not least, big thanks go to my lovely partner Dr. Andrea Kamphausen, Cologne, who has helped me tremendously in pushing me to finish off, or – at times – stopping me from working too much!

Dr. Holger G. Adelmann, December 2007
This research is dedicated to the memory of my dear parents

Hilde Lina Adelmann
Walter Adelmann
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Chapter 1 - Introduction

1.1 Scope

This chapter gives the background of the company environment in which this research takes place and the background and motivation of the author carrying out the research. This leads to a description of the aims and objectives of the research project described in this thesis. The chapter finishes with an overview of the remainder of this thesis.

1.2 Background of the Environment for this Research Project

AstraZeneca (AZ) is one of the world's leading pharmaceutical companies. It provides innovative, effective medicines designed to fight disease in important areas of medical need: cancer, cardiovascular, gastrointestinal, infection, neuroscience and respiratory. The company's broad product portfolio includes many world leaders and a range of high potential therapies for treating cancer (Casodex, Arimidex and Faslodex), gastrointestinal disease (Nexum), asthma (Symbicort), hypertension (Atacand), high cholesterol (Crestor), migraine (Zomig) and schizophrenia (Seroquel). AstraZeneca products are available in over 100 countries.

Sales in 2007 totaled $29.5 billion with an operating profit of over $8 billion. AstraZeneca spends over $16 million every working day on the research and development of new medicines that meet patient needs. The total spent in Research and Development (R&D) in 2007 amounted to over $5 billion.

AstraZeneca employs around 12,000 people at 16 research and development centres in 8 countries. Over 66,000 employees work for AstraZeneca (58% in
Europe, 27% in the Americas and 15% in Asia, Africa and Australasia). AstraZeneca is active in over 100 countries with growing presence in important emerging markets. The corporate office is based in London, UK, and major R&D sites are located in Sweden, the UK and the US.

Drug development is a business that greatly relies on knowledge and innovation in order to develop drugs that meet and exceed future needs in an environment that is competitive, highly regulated and ethically constrained. In this environment, tangible as well as intangible resources need to work together in order to deliver value to the patient, the company and the shareholder. One of these intangible assets is individual and corporate knowledge. Knowledge Management (KM) has been proclaimed as the essential driver of the today’s business (Cortada and Woods, 2000). It is about the management of individual and organisational knowledge in order to help create business value and a competitive advantage.

Pharmaceutical Research and Development (R&D) is a ‘knowledge intensive’ business in that it requires frequent and comprehensive knowledge transactions that involve many staff and a huge amount of information. One necessary class of knowledge transactions concerns the constant evaluation of incoming data from experiments, their discussions amongst scientists and physicians and finally the ability to make informed operational and strategic decisions, that are transparent. Transparency is particularly a focus in the pharmaceutical industry after a few high-level drug withdrawals from the market (e.g. Rezulin in 2000 Lipobay in 2001) because of frequent fatal outcomes after intake of the marketed drugs. In cases like this, thorough investigations are undertaken on the company’s communications, correspondence and decision making processes in order to identify possible early indicators of disaster and how the company handled those. This topic is often occurring in Global Corruption Reports, e.g. Cohen (2006) or Bale (2006), hence research to improve the quality, robustness and transparency of decisions is highly relevant to this industry.
Particularly in the early phase of drug development, these decisions are made with some uncertainty, though this uncertainty then reduces as the project advances in development. Because of these uncertainties it is important to constantly review decisions to verify their validity as a drug development project moves on. In this context, decision making is inextricably bound to appropriate risk awareness and risk management. As risk has to be accepted as part of the business because risk avoidance is difficult to achieve in drug development, a proper risk management can make risks manageable. Applying past experience to present information can provide a balanced assessment of risks prior to decision making. Past experience is in the heads of experienced employees and they will immediately apply what they will remember of their past experience to present problems. This past experience, together with the ability to abstract from past solutions to apply them to new problems may support robust decisions, if the effect of individual memory bias (Loftus et al 1989), for example a memory bias for negative events over positive events, is controlled.

1.3 Motivation for the Research

Starting in 2002 in a new position as head of a group of scientists and medics within AstraZeneca Clinical Development, the author explored the structures and processes for decision making, knowledge generation, dissemination, and reuse in his own group and in the wider Clinical Development where his group is embedded, as his initial staff interviews revealed areas for improvement.

Areas under observation included:

- Handling of scientific data and information (corporate systems, newsfeeds, etc.)
- Collaboration and dialog (meetings, email, telephone, videoconferences)
- Reasoning processes (individual as well as group)
- Reuse of existing knowledge (awareness, accessibility)

- 3 -
- Creation of new knowledge
- Capture and storage of knowledge
- Dissemination and retrieval of knowledge
- Decision support systems and techniques

In these processes, weaknesses in the knowledge gathering process as well as in group-group and group-project communication were discovered. Some examples identified were:

- Unstructured information sharing, mainly via email
- Unstructured internal consulting
- Inefficient group reasoning
- No adequate capture of knowledge created with storage of corporate knowledge being in semantically unstructured flat text documents (e.g. .doc or .pdf files)
- Therefore, insufficient pre-requisites for the interrogation and reuse of the knowledge generated

Presentations of the status quo, a description of the weaknesses identified and first ideas for resolution created visibility and acceptance by the AZ senior management. The senior management was immediately interested in the improvement of decision quality, transparency and the ability to review and reuse past decisions in order to close the learning loop to support the AZ paradigm of a learning organisation. They furthermore recognised that, because of the generic importance of decision making for many functions within the company, improvements in these areas could have major benefits to the wider AstraZeneca. A number of AZ internal information and knowledge management resources were identified in an attempt to ensure that the research was in line with recent AZ improvements in internal information and knowledge handling.
As AZ already had excellent research collaborations with Loughborough University, the author approached academic staff in the Computer Science and Information Science departments. These departments had already installed research groups such as the Knowledge Management Research Group (whose research included knowledge culture and organisational learning, knowledge communication and language representation), which were found to be an invaluable resource for the presentation and discussion of this thesis's research aims and objectives.

1.4 Aims and Objectives

This thesis has two aims:

1. To improve the way that knowledge around decisions made in a drug development environment is produced, captured and stored so that it can be re-used and re-visited for organisational learning

2. To deliver a framework and an information model to form a basis for a usable decision capture / storage application that can be adopted and used by the wider AZ business

The objectives in order to achieve the aims are as follows:

1. To identify from the literature, best practice on individual and group decision making and to determine possible decision storing formats to be used with the capture process in a format superior to plain text files such as .doc or .pdf files.

2. To implement a process whereby decisions made in meetings can be captured as a group digest and summary.
3. To evaluate the process and storage format to detect shortcomings when used in practice from an internal company point of view.

4. To identify experts in KM and Information Systems (IS) and use brainstorming techniques to derive a better information model.

5. To evaluate the improved model by involving customer input to determine shortcomings as perceived from an external customer's point of view.

6. To further improve the information model by more brainstorming with further experts taking into account the external customer needs.

7. To test the final framework with independent expert opinion from internal and external sources.

1.5 Thesis outline

A brief summary of the content of each chapter is given here.

1.5.1 Chapter 1 – Introduction

This chapter introduces the scope, background and motivation of the research. It states the aims and objectives.

1.5.2 Chapter 2 – Literature Review

This chapter reviews important and actual literature around

- Human cognition and the decision making process
- Currently available IS Tools for decision support
- Information architectures suitable for decision capture
- Metadata
1.5.3 Chapter 3 – Research Methodology

This chapter describes the research methodology for the thesis. It contains the underlying research philosophy chosen and the research strategy employed in the pursuit of the aims and objectives and in the quest for the solution to the key questions.

1.5.4 Chapter 4 – Group Reasoning and Digest

This chapter describes the status quo of decision processes and decision capture in AZ’Clinical, particularly Experimental Medicine, prior to the start of this research in summer 2002. It then focuses on the research objectives around the implementation of a novel process of a group digest and summary and on the introduction of a novel decision capture format. The final part of this chapter evaluates the novel process.

1.5.5 Chapter 5 – RDF/XML Knowledge Objects with Metadata

This chapter introduces a novel decision capture format, Knowledge Object Version 1 (KNO v1), and evaluates this novel storage format in order to identify the benefits and also the shortcomings when used in practice.

1.5.6 Chapter 6 – RDF Knowledge Objects with Decision Attributes

This chapter describes the next refinement of the KNO information model, according to the aims and objectives of this thesis and the concepts around decision mapping and case based reasoning. It describes an enhanced information model, KNO v2, with the introduction of decision related metadata. The new information model is then evaluated according to the aims and objectives of this thesis.
1.5.7 Chapter 7 – RDF Knowledge Objects with Decision Attributes, Scenarios and Risk Management Features

This chapter describes further refinement work that was started about three months after the implementation and subsequent evaluation of KNO v2. It also reports on an external survey by an independent consultant which provided an additional validation of the aims and objectives of this research project. As a result of the refinement work, an extended information model, KNO v3, was created which now also includes scenarios and risk management features. Chapter 7 is concluded with a comprehensive evaluation of KNO v3 and the process around it which is now known as the EPISTEME framework.

1.5.8 Chapter 8 – Conclusion and Outlook

This chapter evaluates the overall achievements of the research in the light of its aims and objectives. An explanation of an AZ process for improvement projects is given with the rationale for internal evaluation of EPISTEME as a global asset for AZ. It furthermore identifies limitations of the current research and gives an outlook for further research and development in that area.

1.5.9 Appendices

This thesis has 5 appendices:

- Appendix 1 – PES\(^1\) Process
- Appendix 2 – EPISTEME Business Case
- Appendix 3a – Cost/Benefit Analysis for EPISTEME
- Appendix 3b – EPISTEME Benefit Mapping
- Appendix 4 – Use Case Analysis
- Appendix 5 – Post-Assessments of Decisions captured
- Appendix 6 – Decision support interview
- Appendix 7 – MS advice feedback pre-scenarios

\(^1\) PES = Processes and Enabling Solutions. An AstraZeneca Process for the governance of improvement projects
Chapter 2 - Literature Review

2.1 Scope

This chapter represents a review of relevant literature around the topics that are core to the aims and objectives of this thesis. The focus is on both the human decision making process and on suitable information architectures and IS tools to support the objectives. The aim of the literature review is to identify current best practice as well as limitations and areas for improvement in themes relevant to the current research.

2.2 Aspects of Human Cognition and Human Decision making

As outlined in chapter one, the aim of this research is to improve the way that knowledge from decisions made in a drug development environment is captured and stored so that it can be re-used and re-visited for organisational learning and, furthermore, to design a usable decision capture / storage system that can be adopted and used by the wider AZ company.

As stated already by Wallsten (1980), an understanding of the human decision making process is a necessary precondition for its successful mapping, capture and re-use. Therefore, a literature research was carried out into what makes up human decision making and what needs to be captured in order to provide value for future review and possibly re-use. A comprehensive review of the foundation of human decision making in cognitive science and even philosophy is given in a SANDIA report by Senglaub et al. (2001). According to Lee and Cummins (2004), the consideration of past experience in the form of ‘evidence-accumulation’ is a necessary but not a sufficient pre-requisite for problem solving. By taking theoretical and experimental results from human cognitive psychology into account, they argue that human problem solving and learning are processes that involve the representation and utilization of several types of knowledge and the combination of several reasoning methods such as Bayesian
and heuristic approaches. Strube (1998) argues that an architecture for intelligence, where the reuse of previous experience is at the centre, should also incorporate other types of knowledge or reasoning processes in one form or another. This is congruent with the findings by Nonaka (1994) where new tacit and explicit knowledge continuously flows into the knowledge generating cycle.

*Fig. 2.01: Nonaka’s knowledge creation framework SECI (Nonaka, 1994)*

According to Nonaka, knowledge creation is a spiral process between tacit and explicit knowledge as well as *explication* and *internalisation*. Tacit knowledge is combined with other tacit knowledge by ‘*socialisation*’ and explicit knowledge with other explicit knowledge by ‘*combination*’.

Argyris and Schoen (1974) regard organisational knowledge creation as an extension of individual learning. They distinguish between single-loop and double-loop learning. They argue that single-loop learning is the search and application of an alternative approach within the bounds of the current governing variables (which are almost taken for granted) whereas double-loop learning is questioning the current governing variables themselves which enables the individual and organization to review the validity of the underlying beliefs and allow for an adaptive change of strategy.
Very similar to the generation of new knowledge, human decision making is a complex process of taking a person’s own previous experience plus explicated facts into consideration. Those explicated facts could include documented experience from someone else. Davenport (1996) describes the process of generating new knowledge as an abstraction from precedents and an attempt to map this previous experience onto a new problem. Gupta et al. (2004) suggested that the usability of previous experience (e.g. in a case base – see Section 2.2.4) is, however, dependant on its clarity to the knowledge worker so that they can really compare it to the current problem being addressed. Tiwana (2000) found that clarity depends on how rich a previous decision scenario has been captured, because a previous decision may not be understandable if the context in which this decision was made is not known. According to Goffman (1959), an understanding of front-versions (public, visible to everyone) vs. back-versions (hidden, how things are done behind the scenes) of organisational behavior is important to make sustainable decisions.

Lehner (2001) linked the concept of decision closely to the well-known and interrelated concepts of data, information and knowledge as shown in Figure 2.02.

Fig. 2.02: The relationship of the concept ‘decision’ to those of ‘data’, ‘information’ and ‘knowledge’ (Lehner, 2001)
For Beckman (1997), decision-making is a core application of knowledge as shown in Table 2.01.

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<td><strong>Sell:</strong></td>
</tr>
</tbody>
</table>

Table 2.01: Beckman’s Knowledge-Related Knowledge Management Tasks (Beckman, 1997)

The literature reviewed thus far indicates, that it would be useful to describe a decision making process in its genuine richness and to make the decisions transparent for other (non-involved) readers so that the decision could be understood and evaluated for application on a different occasion. Several authors found that the mapping of a previous decision onto a new problem is improved by capturing some aspects around the decision that denote the ‘environment’ of a decision, such as the underlying assumptions. This mapping process was found to benefit from knowledge ‘categorization’ or ‘normalization’, frequently applied in the literature in form of attribute tagging, e.g. with attributes such as activities, domain, form, type, products and services, time, and location (van Heijst et al., 1998) or procedure, guidelines, protocol, manual, reference, time line, worst practice report, best practice report, note, memo, failure report, success report, press release, and competitive intelligence report (Borghoff and Pareschi, 1998). An interesting and more decision-related set of tags, previous issue, previous action, outcome, rejections, and assumptions, is proposed by Tiwana (2000). A concept that tries to capture the actionable aspect of decisions, ART (action-reflex-trigger), is proposed by Nonaka and Reinmoeller (1998). An early model of structured knowledge entities that populate a KM system, in an example
application from clinical medicine, is proposed by Wiig (1993), who discusses the issue of an appropriate level of granularity for such an application. This clinical data record of a patient (level 1) had to accommodate data of various qualities (e.g. anamnesis, diagnosis, patient history, lab data ... - level 2) which all need qualifiers such as data, unit, creator etc – level 3. The level of granularity relevant to the author’s current systems design will be discussed in Section 5.2.

The previous research reviewed concerning attribute tagging reveals that the attributes reported were suitable in their respective domain but none of them were directly derived from case studies within the domain of pharmaceutical development. Nevertheless the concept of attribute tagging will be investigated by the author and extended into his domain in order to derive a more generalized set of decision descriptors that may be suitable for the pharmaceutical development domain to fit with the aims and objectives of the research reported in this thesis. As pointed out by Leveson (2000), cognitive psychology has robustly established that the representation of a problem to the problem solver can affect their performance, therefore a rich problem and decision capture and explication may be useful in itself. The knowledge worker who generates the decision mapping will have to think more deeply about all facets of the problem and decision, which will improve the decision quality. Debriefing the decision aspects during the process by explicating them will also reduce the mental load, which has been found to be a limiting factor for human reasoning according to Payne et al. (1992). The improvement of problem solving performance by providing representations that reduce the problem solver’s memory load has also been validated through research by Kotovsky et al. (1985). Furthermore, a human reader at case recall will be in a much better position to understand why and how the decision was made. This is supported by Leake et al. (2002), who have pointed out that clear concept mapping intended for human readers rather than for machine reasoning, could prove useful for organisational knowledge management. This would enable a clearer visualisation and thus promote a better understanding and re-use of expert knowledge.
In addition to appropriate codification and representation of decision making, the process of human reasoning was and still is subject to considerable multidisciplinary research. Over the past 4 decades, human rationality and reasoning has been in the focus of a substantial amount and depth of research by psychologists, philosophers, economists, statisticians and others. This research can be divided in three big areas:

a) **descriptive research** on actual human reasoning behaviour, quality, and psychological mechanisms that underlie them

b) **normative research** on how correct or rational reasoning should look like - the 'Standard Picture'(Stein, 1996), where principles of reasoning are based on rules of logic, probability theory, and decision theory.

c) **evaluative research** on how observed human reasoning accords with what is set as appropriate normative standards in b) above

The results of the descriptive research have been described as a pretty unsettling picture of the human ability to reason properly from the application of a variety of experimental settings by many researchers. Reviews can be found in Baron (2001) and Piattelli-Palmarini (1984). These impairments of human reasoning are often described as 'reasoning errors' or 'reasoning biases'. Several of these experiments revealed different aspects of reasoning biases, e.g.: selection bias (Wason, 1966), conjunction fallacy (Kahneman and Tversky, 1982), base rate neglect (Kahneman and Tversky, 1973), overconfidence (Lichtenstein, et al, 1982), anchoring (Tversky and Kahneman, 1974; Pious, 1989). Early critics of the pessimistic drawing from the descriptive research have argued that this may simply be attributable to how subjects interpreted that tasks they were given.

This would support techniques such as problem rephrasing and problem inversion that the author frequently adopted in group reasoning meetings led by him.
A joint analysis of these reasoning errors indicates that it is generally not just a problem of reasoning performance, i.e. a quantitative issue, but more often, the reasoning just seems to be irrational and not following rules or not even clearly discernible constraints, but more or less simple heuristics. It is more described as an issue of reasoning competence, in analogy to linguistic competence (Chomsky, 1980). In more recent years, evolutionary psychologists, in particular Gigerenzer (1996), have challenged the pessimistic view of most of the descriptive researchers and explained the findings as a consequence of the problem presentation ('probabilist' versus 'frequentist') to the respondent. A more recent paper by Kahneman and Tversky (1996) also supports the interpretation, that it is not so much absence of appropriate reasoning competence but the lack of its exploitation in some cases of inappropriate reasoning, which is still a hotly debated question that gives hope to possible improvements of the unsettled picture of human reasoning originally painted by descriptive research.

The author argues that a group reasoning setting may enforce exploitation of reasoning competence over an individual setting if it is genuinely present.

A problem with the normative research is, that it is far from clear what set of rules can be derived from the rules of logic, probability theory, and decision theory that form an appropriate benchmark for reasoning competence, i.e. the Standard Picture (e.g. Harman, 1983 or Goldman, 1986). These difficulties of defining the normative approach in theory are furthermore confined by the question on how to apply it in practice, as these rules seem to be difficult to explicate (Samuels et al, 2004).

The author is hypothesising that a group reasoning process may help to inject more appropriate reasoning rules in order to improve the reasoning competence of a group over that of individuals, potentially by tacit exchange of knowledge and joint validation of rules to be applied to a reasoning problem.
2.3 IS enabled paradigms for human decision support

In order to review information systems that may be useful for human decision support, it is important to identify what IS domain is most closely related to human cognition. Rech and Althoff (2004) categorise Artificial Intelligence (AI) as a discipline of Computer Science that is directly linked to human cognition as depicted in Figure 2.03.

![Figure 2.03: AI as bridge between Computer Science and human cognition (from Rech and Althoff, 2004)](image)

Therefore, literature in the AI field was reviewed and will be described in this chapter in order to identify what tools and methodologies have been designed and evaluated around human cognition, particularly for decision support, and it became obvious that four different paradigms have been studied and applied extensively:

- Genetic algorithms
- Neural networks (model based reasoning)
- Rule based systems (rule based reasoning)
- Case based reasoning
2.3.1 Genetic algorithms

Genetic algorithms (GA) were developed in the early 1970s by John Holland (1975). They are based on the biological metaphor of Charles Darwin's 'survival of the fittest'. It is an extrapolation of this paradigm to computer science. According to Luger (2002), "... genetic algorithms are based on a biological metaphor: They view learning as a competition among a population of evolving candidate problem solutions. A 'fitness' function evaluates each solution to decide whether it will contribute to the next generation of solutions. Then, through operations analogous to gene transfer in sexual reproduction, the algorithm creates a new population of candidate solutions". According to Goldberg (1989), genetic algorithm experiments provide novel solutions to problems by running many slightly different algorithms in parallel - if a solution is not successful it is discarded but if it is, it is subject to 'genetic refinement'. Similar to neural networks, GA do not rely on a priori expert knowledge but can, according to Lee and Takagi (1993), be designed to take expert knowledge injection, which is difficult for neural networks (see also discussion in Section 2.2.2 below). Genetic algorithms were found by Dhar & Stein (1997) to help a decision maker by presenting possible solutions and enable him or her to say "I don't know how to build a good solution but I will recognize it when I see it".

A classic scenario to solve with a GA is the "Traveling Salesperson Problem" as discussed, for example, in MacGregor and Ormerod (1996). A derived application was reported by Hamamoto (1999), where a GA clearly outperformed human designers in the conception of pharmaceutical plant design to minimize goods travel time by maximizing plant throughput. Recently, Blau et al (2004) report the successful application of a GA to product portfolio selection in the pharmaceutical industry where the aim was to select a series of interdependent candidates that would maximize the profit and minimize the development risks given a fixed resource to process them. Butina et al (2002) describe the

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1 Given a series of cities plus the cost of travel between each pair of them, the "Traveling Salesperson Problem" describes the issue of finding the cheapest way of visiting all of the cities and returning to the starting point. GA were found to deliver superior results over other computational or even human solutions.
application of GAs in the prediction of pharmacokinetic\textsuperscript{2} properties of drugs in humans in the presence of only animal data, which represents a numerical scaling or extrapolation problem. Clearly, the applications of GAs reviewed by the author can be more or less classified as optimisation problems, which is different to the aims and objectives of the author's research.

According to Fogel (2005) GAs were found to be limited to addressing problems for which people already have answers (maybe not the best ones though). This seems to be partly similar to the aims and objectives of the author's research where decisions made are intended to be captured and identified as possibly suitable solutions to a similar problem by someone who is not necessarily in a position to come up with a solution immediately, but has the expertise to rate whether an already captured decision is useful for his problem. The difference, however, is clearly the way that the solutions are being created. In the scope of the author's research, they are not subject to computerized evolution by the use of genetic algorithms but produced by debriefing of real world decisions made by domain experts.

The applicability of genetic algorithms to the decision capture aspired for in the context of this thesis appears to be very limited as the generation of solutions within the aims and objectives of this research is not the result of GA application as discussed above. The question whether GAs may be able to provide \textit{completely new and useful} solutions based on an evolutionary processing of existing cases is an interesting question for further research, but beyond the scope of this thesis.

2.3.2 Neural networks

Neural networks, like genetic algorithms, have their conceptual roots in biology. A neural network is defined in the Merriam-Webster Dictionary (MW, 2006) as a \textit{‘networked computing architecture in which a number of processors are}

\textsuperscript{2} Pharmacokinetic properties of drugs are e.g. absorption, distribution, metabolism and excretion—what the organism does to the drug
interconnected in a manner suggestive of the connections between neurons in a human brain that can learn by a process of trial and error'. Levine and Aparicio, (1994) describe neural networks as very helpful if one has large quantities of information but lack of expertise to make a judgement based on it, e.g. because the reviewer is not a domain expert. These authors conclude that neural networks can identify patterns in these data without the need for a domain expert to look at it.

Hertz et al, (1991), Widrow and Lehr (1990) and others found consistently that, in order to deliver that pattern recognition, neural networks need substantial training before they are really useful. In fact, all 'knowledge' within a neural network is acquired by training only and it is very difficult to build hybrid systems that enable the use of a priori knowledge, as discussed by Hinton (1991). The scalability to vast amount of data and the training ability in order to identify a certain pattern are clearly the strength of the neural network paradigm when applied to huge amounts of more or less unknown data.

The applicability of this paradigm to the decision capture and retrieval problem considered in this thesis appears to be, again, very limited as the problem described does not deal with a vast amount of fairly unknown information with hidden regular and fairly constant patterns, but has few previous and quite well described cases that appear more or less similar to an interrogation. A priori knowledge might be contained within the system already through the anticipated decision mapping, which will produce linked attributes.

According to Beale and Jackson (1990), the recognition performance of neural networks is relatively immune to low level of noise or variation if the training is based on more general models or representations. Hertz et al (1991) found that the training success is proportional to the number of similar cases but inversely correlated to the number of attributes to discriminate. They state that a complex feature set, together with only few cases, causes 'overlearning' of the system to adopt idiosyncratic features in the test set which will result in poor performance on cases not seen in the training phase.
The author recognizes a likely offset between complexity and frequency of similar cases in his research that will probably not train the network appropriately. Another inherent neural network feature is reiterated by Vamplew (1996), namely the inability to assess the internal decision making of the network. It is not possible to interrogate the network as to why a particular result has been produced because there are no hard-wired rules. This makes it difficult to benchmark and refine the retrieval, which is also of concern for this research.

2.3.3 Rule based expert systems

According to Abecker et al (2002), a rule based expert system is a computer system that mimics specialist knowledge and reasoning capabilities within a limited and well defined area in order to be able to solve problems in that area with a capability that is comparable to that of an expert. Rule based expert systems have a high dependence on domain experts and specialists, and work well if one knows what the variables in the problem are and when they can be expressed in hard figures. As stated by Abecker et al (2002), it is necessary to set up rules that cover most, if not all variables in the system and there should be no parallel, independent rules that determine an outcome. Luger (2002) points out that there must be some validation of the rules, i.e. a reason for these rules is needed that is rooted in current knowledge about the domain. Refining the rules is described as an iterative process where known settings are fed into the system and the expert then rates the reasoning process and refines the rules if the outcome is not as appropriate. Tiwana, (2000) argues that rule based expert systems are diametrically opposite to genetic algorithms: In genetic algorithms some universally applicable conditions are specified under which a solution would be considered appropriate but it is not possible to apply expert knowledge on how to actually solve the problem, whereas in rule based expert systems it is possible to bring in expert knowledge in terms of predefined rules but not to specify universally applicable conditions that would denote a 'good solution'.

- 20 -
Kingston (1987) found that representing knowledge as an unordered set of rules fails to take advantage of any explicit structure the knowledge may already have, such as taxonomies, or cause-effect relations. This would, according to him, not only limit the system's reasoning, but would also make it difficult to provide sensible explanations of cause and effect to the user.

Finally, Shwe et al. (1992) point out that despite the popularity and technical elegance of rule based systems, as well as the enhanced readability they have brought, they have been less successful in achieving modularity and reusability of knowledge. According to these authors, this is explained through practical observation that rules can be written in a procedural way and frequently depend upon being carefully crafted to ensure that they are only applied in specific situations, making their transfer to other applications difficult.

There is a significant amount of literature around argumentation, particularly in the context of Knowledge-based Expert Systems for toxicity and metabolism prediction, e.g. DEREK, METEOR and StAR (Hardman and Ayton, 1997; Fox, 1999). These systems use rules to describe the relationship between chemical structure and either toxicity in the case of DEREK and StAR, or metabolic fate in the case of METEOR. The StAR approach has been implemented in the domain of toxicological risk assessment. It is a decision support system that gives quantitative assessments where appropriate, but which is also able to provide qualitative risk assessments based on arguments for and against the presence of risk. This system essentially follows the scheme for arguments proposed by Toulmin (1958). It constructs arguments that are "for" or "against" propositions. These arguments are presented to the user together with a conclusion in the form of a linguistically expressed statement of risk. The system has its origins in the work of Fox (1980), which found that non-probabilistic decision models were as good as or better than probabilistic ones in accounting for people's behaviour in a clinical decision making task. Hardman and Ayton argue that a natural way for people to think about novel decisions, or decisions where information is lacking, is to construct arguments. According to Fox (1999), these techniques are
intended to fill some of the gaps in the current armoury of risk analysis techniques, and to extend the capabilities of quantitative statistical methods.

Even though rule based expert systems have been applied in the pharmaceutical business context, e.g. the prediction of human pharmacokinetics from animal data (Hussain et al, 1993), the applicability of this paradigm for the decision capture intended in the current thesis appears to be, at least, difficult as

- the generation of rules from real-life situations usually cause a contextual abstraction as reiterated by Tiwana (2000), which violates the fact that context has been identified as important decision attribute (see above)

- the more strategic issues to be addressed within drug development are usually complex combinations of scenarios, thus appear too difficult to be reduced to simple and stable rules (see particularly the findings by Kingston (1987) and Shwe et al (1992))

The method proposed by the argumentation technique, a qualitative approach to find arguments that are "for" or "against" propositions, was considered to be of relevance to the current thesis and has informed the action research around scenarios and risk management in Chapter 7.

2.3.4 Case based reasoning

Case based reasoning (CBR) is another problem solving paradigm that seeks to solve present problems by looking up previous solutions, according to Kolodner (1993). He states that CBR is able to utilize the specific knowledge of previously experienced real-life problem situations (cases). Chappell & Mitchell (1997) applied the CBR paradigm in their application of an intelligent tutoring system, where a new problem is solved by finding a similar past case that best matches the present one, and reusing its solution in the new problem situation. Aamod & Plaza (1994) propose 4 distinct terms to describe this cyclic process: retrieve, re-use, revise and retain. The research by these authors furthermore indicates that learning in case based reasoning occurs as a natural by-product of problem-
solving. Case based reasoning is, therefore, seen as an approach to incremental, sustained organizational learning since a new experience is retained in a case base each time a problem has been solved, thus making it immediately available for future problems.

As pointed out by Kolodner (1993), queries as well as previous problems and their solution in case based reasoning are usually submitted / stored in singular attribute-value pairs, which are more or less connected to each other. More advanced, 'structured', CBR systems map attribute-value pairs in a manner that is derived from object-oriented programming, using concepts such as inheritance and parent-descendant relationships ('is-a', 'part-of') to link attribute-value pairs together in a manner useful for retrieval (Manago et al., 1994; Arcos and Plaza, 1996). According to Rech and Althoff (2004), these relationships can take the form of conceptual domain models that are supported by, for example, domain taxonomies in order to map the relationships and interdependencies of attribute-value pairs in a manner that is useful for a given domain. Table 2.02 summarises the different CBR paradigms.

Upon retrieval, the case based reasoning engine tries to match queries with existing cases, attribute-value pair by attribute-value pair. Each attribute-value pair comparison results in a local similarity measure that is combined with other local similarity measures, usually using a weighted sum (according to the conceptual domain model), to produce a global similarity measure that is an overall indicator of case similarity and is ultimately used for ranking retrievals. As reported by Lenz et al. (1998), and Bergmann & Schaaf (2003), CBR has been applied very successfully in technical domains, particularly engineering, because there, the values of the attribute-value pairs are often just numeric, such as air pressure, motor temperature, etc. The numerical information in these examples makes it quite easy for a computer as a 'CBR engine' to digest the query, calculate similarities and finally compare cases.
Numerical or qualitative attribute-value pairs that are

- unconnected or
- partially connected

Numerical or qualitative attribute-value pairs that are

- Structured by a markup language, e.g. XML\(^3\)
- Structured within an object-oriented model
- Structured by a conceptual domain model

Textual attribute-value pairs that are

- unconnected (e.g. FAQs) or
- structured by a conceptual domain model

<table>
<thead>
<tr>
<th>Simple CBR</th>
<th>Structural CBR</th>
<th>Textual CBR</th>
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<tbody>
<tr>
<td>Numerical or qualitative attribute-value pairs that are</td>
<td>• Structured by a markup language, e.g. XML(^3)</td>
<td>Textual attribute-value pairs that are</td>
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<td>• unconnected or</td>
<td>• Structured within an object-oriented model</td>
<td>• unconnected (e.g. FAQs) or</td>
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<tr>
<td>• partially connected</td>
<td>• Structured by a conceptual domain model</td>
<td>• structured by a conceptual domain model</td>
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**Table 2.02 A comparison of CBR paradigms**

Textual CBR is a CBR speciality that deals with textual information and was originally developed for application in knowledge management (Lenz et al, 1998), (Minor & Hanft, 2000). In that context, it relied mainly on text mining in and information extraction from huge corporate information stores and data warehouses and was, therefore, designed to scale to huge amounts of textual information, both structured and unstructured. Examples include mapping of big corporate FAQs\(^4\), e.g. 'Yoda's Help Desk' as implemented by LucasArts (2005) as well as implementations in eCommerce, as reported by, for example, Lenz et al (1998). As pointed out by Lenz et al. (1998), textual CBR was designed to handle textual information at both query and case (content) ends, but they state that in these processes, textual CBR is in fact reducing rich natural language texts by some pre-processing into single keywords or keyphrases when the mapping of concepts in the user query or the stored case onto attribute-value pairs is performed. From the review of this literature, the author concludes that

\(^3\) See Section 2.4.1

\(^4\) The mapping of FAQs and related problems is sometimes referred to as conversational CBR or dialog oriented CBR (Aha and Breslow 1997). In that respect, a conceptual domain model is not necessary as there is no absolute need for linking concepts within different questions (or answers). This should not be confused with dialog-based support of textual case authoring (Rech and Althoff, 2004)
the information models of numerical and textual CBR are generally not hugely different. As pointed out by Lenz et al. (1998), textual CBR is more sophisticated than numerical CBR only in that it uses lexical concept processing (e.g. stemming, synonyms) and concept distance within taxonomies for its similarity calculation. Sense disambiguation, which was found a general issue in Text Mining (Frakes and Baeza-Yates, 1992) and Information Retrieval (Uzuner et al, 1999), is usually not seen as a big issue in CBR, according to Lenz et al. (1998), as CBR is usually applied in a defined and limited domain, so it is unlikely that concepts have more than one sense within the same domain.

2.4 The potential of Case Based Reasoning for Decision Support

CBR was originally designed for knowledge management. As pointed out already by Kolodner (1993), a CBR case is a kind of knowledge representation technique. Already in the early days of CBR, he gave a definition that puts CBR very close to knowledge management: "A case is a piece of knowledge representing an experience that teaches a lesson fundamental to achieving the goals of the reasoner". Brueninghaus and Ashley (1999) showed that with the advent of powerful computer technologies to support text mining and information extraction, the latter were used to build large case bases from huge structured and unstructured enterprise content. This also led to the use of the term 'knowledge management' in a much wider sense. Nowadays, authors such as Despre and Chauvel (2000), use the term knowledge management in a stricter sense which involves more the interaction of humans (e.g. by storytelling and group reasoning), to create and disseminate knowledge. As this recent interpretation of the term knowledge management is much more related to the context and the aims and objectives of the author's work, the literature review is extended to examine if there are current applications of (T)CBR in the stricter definition of knowledge management, particularly around decision support. The relationship between CBR and rule-based knowledge management is reiterated.
in a paper by Bergmann & Schaaf (2003). They investigated this relationship because CBR and rule-based knowledge management are widely discussed as key technologies for building organisational memory information systems. They conclude that CBR complements KM systems based on logic reasoning, reflecting the fact that one cannot always get 100% matches as would be required by rule based inferencing. This is exactly the case with decision capture, where there is likelihood of a similarity with a previous case, but not a perfect match. They further discuss the use of metadata for case annotation in CBR, a concept that will be expanded in Section 2.4.3.

The most advanced conceptual extrapolation of CBR from the well known ‘diagnosis/solution’ paradigm to a ‘decision support’ paradigm has been outlined by Rech and Althoff (2004) and is depicted in Figures 2.04a and 2.04b. TlWana (2000) argues that one of the biggest problems in knowledge codification (Jashapara 2004), namely the loss of the original context, can be avoided by the CBR paradigm. He sees CBR as being particularly useful for knowledge management in general as, in CBR, concepts are stored as ‘real cases’, not as derived rules, the original context being preserved with the case. The use of contextual information with CBR appeared to the author to be useful for his research as context was found to be an important decision attribute, even though context alone would not be sufficient to capture the richness of a decision as discussed above. CBR as applied in the literature cited is, however, different to the aims of the author’s research as it usually stores solutions to problems. The anticipated decision capture that is the aim of the author’s research will store decisions first hand. It is therefore concluded that there would be a need to assess and annotate the captured decision at a later time to state whether it indeed led to a desired outcome, i.e. provided a ‘solution’ in CBR terms.
The review of CBR as a decision support technology, in particular its limitations due to the attribute-value pair simplification, indicates that research is needed on how human decision essentials can be mapped successfully to decision attributes within a CBR paradigm without losing important context and content due to oversimplification. Research by Ashley and Lenz (1998) on CBR...
supported by Text Mining and Information Retrieval has indicated that some normalisation or simplification of natural language is indeed important in order to improve both the recall and precision of Text Mining and Information Retrieval. Sowa (2002) describes simplified natural language as one key success factor for intelligent systems architecture. According to earlier work by Brueninghaus and Ashley (1999), further ‘language control’ could be achieved by using controlled vocabularies. The ‘FallO’ (Lenz et al., 1998) and ‘FAQ FINDER’ (Burke et al., 1997) projects have used the lexical semantics in WordNet (Fellbaum, 1998) to better represent the similarity among words. Recently introduced Semantic Web technologies make extensive use of controlled vocabularies in the form of domain taxonomies and ontologies (see Section 2.4). The author agrees with Sowa (2002), that language simplification and the use of controlled vocabularies are important in order to keep a captured decision machine understandable, which is one aspiration of the author. This may help later extension of the research into decision retrieval, based on the information model for decision capture the author is aiming for. This would then enable a future, advanced decision base application to use computer algorithms for interrogation of a ‘decision base’ in order to retrieve similar past decisions or issues. As the use of simplified natural language and controlled vocabularies is already important at the case creation stage, it will therefore be considered in this research (see later chapters), but a thorough review of natural language concepts is beyond the scope of the research in this thesis.

The literature review thus far has already provided first insights for this research on what describes a human decision making process and what decision aspects are important to provide value for human review and re-use. It is at present unclear, however, what decision attributes would best and most comprehensively describe those aspects, an aspiration which is directly linked to the aims of this research.

It was also found that CBR could possibly provide a useful container and interrogation paradigm for the anticipated decision mapping system. Furthermore, the attribute-value pair architecture is, in principle, a paradigm
suitable for machine exploitation. According to Strube and Ponzetto (2006), attribute-value pairs are "a fundamental data representation in many computing systems and applications. Designers often desire an open-ended data structure that allows for future extension without modifying existing code or data. In such situations, all or part of the data model may be expressed as a collection of so called tuples <attribute name, value>; each element is an attribute-value pair". Some of the applications where information is represented as attribute-value pairs, according to the same source, are listed below:

- Electronic mail, in RFC 2822 headers
- Optional elements in network protocols, such as IP, where they often appear as TLV (type-length-value) tuples
- Bibliographic information, as in BibTeX and Dublin Core metadata
- Element attributes in SGML and XML
- General metadata in RDF
- Some kinds of database systems

Richer decision capture would, however, involve more than the simple capture and storage of singular, sometimes plain numerical data. From the literature review thus far, the author has identified shortcomings of current CBR implementations with respect to the suitability of the currently used, simple information models for decision mapping. The work by Rech and Althoff (2004) proposed the use of CBR for decision making but this paradigm is currently limited to the outline of the principle as given in Figure 2.04. No details are given for its implementation. It is clear from the current applications of CBR that more research needs to be done in order to find out on how to extend the current CBR paradigm to capture the complex process of human decision making as examined earlier in this review. The attribute-value pair approach is an interesting starting point: There is an analogy with the 'attributes' of a decision making process as discussed above. The conceptual model that links these attribute-value pairs would need more research in order to be able to map a decision making process.
Another limitation or difficulty that comes out of the literature review is that current CBR engines lack an understanding of the meaning of natural language. This together with a lack of a structured presence (the conceptual model) of richer attributes complicates the comprehension of 'decision cases' stated in natural language. These difficulties are recognised by the author as the two main limitations that makes it difficult to compare an actual decision making problem to a stored case and thus to fully exploit the CBR paradigm for decision support.

The author hypothesises, therefore, that a simplification / normalisation of the language used in the case base together with a suitable information model that is able to describe the conceptual CBR model for decision support is possibly a solution to the shortcomings of current CBR for use within the aims and objectives of his research.

In order to identify information models that could overcome the two limitations mentioned above, the literature review is extended into current semantic web technologies. In the next section, technologies such as XML, RDF and related concepts such as metadata will be assessed to determine, whether they could assist in the desired decision capture together with an appealing organisational learning paradigm (store, interrogate and review/refine) that is at the heart of CBR.

2.5 An assessment of novel Semantic Web technologies for knowledge management and decision capture

Many authors, for example Berners-Lee et al. (2001), Fensel et al. (2003) and Hendler (2001), argue that the current Information architecture (particularly document formats) is very limited for the use with information systems beyond storage, retrieval and print actions. Particularly Berners-Lee et al. (2001), and Heflin & Hendler (2001) reiterate, that these documents are machine readable, but not machine understandable. They argue further that this would limit their usefulness in information exploitation, particularly in knowledge management.
Similar constraints affect the current World Wide Web as the HTML pages that make up most of the Web are designed and usable to human readers only, as observed by Berners-Lee et al. (2001). They particularly argue that modern information systems can distribute these documents but cannot understand their content, which often renders automated, information retrieval useless. Therefore an extension (not a replacement) to the current Web, the 'Semantic Web' was outlined by its 'father', Tim Berners-Lee and colleagues (Berners-Lee et al., 2001). Clearly there are some parallels here with the author's research aims when it comes to the shortcomings of the use of current information models (which would include document formats) for decision mapping. Therefore, a thorough review of the wealth of novel information models and document formats that have been designed around the advent of the Semantic Web is appropriate.

As reported by Hendler (2001) and Berners-Lee et al. (2001), the introduction of the Semantic Web idea started a discussion and re-assessment of recent web technologies for their use in knowledge management, as one of the main paradigms of the Semantic Web is the ability of computers to read and understand digital information to an extent that enables machines to interact with each other in order to perform automated tasks to support human information management. The following sub-sections cover an investigation of Semantic Web technologies that appear to offer ways of overcoming the shortcomings of traditional document formats

2.5.1 XML

The more recent literature around knowledge management discusses the shortcomings of traditional document formats for knowledge capture and retrieval as presented above and increasingly describes the adoption of a novel information format, the eXtensible Markup Language (XML), described by Bray et al. (1998).
XML is derived from the older SGML, the Standard Generalized Markup Language (ISO 8879) dated 1986, revised by Cover (1992). According to a W3C recommendation (W3C, 2000), XML documents are text documents made up of markup and content. The XML markup encodes a description of the document's storage layout and logical document structure as shown in the example in Fig 2.05. XML therefore provides a well defined, and to a certain extent, self explanatory data and information container. The similarity to the attribute-value pairs seen with CBR is immediately striking.

```xml
<?xml version="1.0" encoding="ISO-8859-1" ?>
<root-tag attribute1="attrib-value">
   <sub-tag1>tag-value</sub-tag1>
   <sub-tag2 attribute2="attrib-value">tag-value</sub-tag2>
</root-tag>
```

Fig. 2.05: Example XML

Figure 2.05 is a simple example XML file created by the author with a text editor and rendered with Microsoft Internet Explorer.

XML has been designed with an easier means of computer exploitation and IS interoperability in mind, also for use with CBR (Hayes et al., 1998). According to the specification, an XML document is able to keep the data together with the data structure, thus providing a means for extending data into information. By providing a standardized structure within a plain text document format, the benefits of XML as a common data and information interchange format across disparate information systems is now widely recognized in various domains, e.g. eBusiness (NACS, 2000), Clinical Data Interchange Standards Consortium ‘CDISC’ (Russel and Kubick, 2001), and Architecture, Engineering and Construction (Zhu, 2001). Lawton (2001) has suggested the wider use of XML for knowledge management purposes because of its interoperability features and
ability to provide "information about information" with additional metadata tags. Despite the wide success of XML, authors like Gil and Ratnakar (2002) have found its expressiveness to be insufficient to assign semantic meaning to the information. This was also recognized in the knowledge management arena by Auffret (2001). Two XML-based case representations have been proposed, CBML (Hayes and Cunningham, 1999) and OML (Bergmann & Schaaf, 2003). Chen and Wu (2003) recognize them as an instance of structural CBR as discussed in Section 2.2.4, but point out that XML is not capable of expressing meaning. They therefore conclude that XML, in itself, does not enable a conceptual domain model for CBR.

The lack of XML's ability to express and transport semantic meaning limited its use in the Semantic Web and ultimately led to the development of the resource description framework (RDF). The literature review was therefore extended into more expressive knowledge representation languages such as RDF.

2.5.2 RDF

The Resource Description Framework (RDF) was developed as a language for the Semantic Web by representing information and metadata about resources in the World Wide Web (Manola and Miller, 2004). In the view of Berners-Lee et al. (2001), RDF was particularly intended as a first step in a series that should ultimately lead to the Semantic Web. The aim of RDF was to assign more meaning to information by representing metadata such as the title, author, modification date, copyright and licensing information, or the availability schedule for some shared resource. However, by generalizing the concept of a "Web resource", other authors, like Manola and Miller (2004), stated that RDF could also be used to represent information about things that can be identified on the Web, even when they can't be directly retrieved from the Web.

According to its specification (Klyne and Carroll, 2004), RDF is based on the idea of identifying things using Uniform Resource Identifiers (URIs) (Berners-Lee et al,
1998), and describing resources in terms of simple properties and property values. As expressed in the specification, this would enable RDF to represent simple statements about resources as a graph of nodes and arcs representing the resources, and their properties, values and relations, e.g. a Person (subject) has (predicate) a title (object) Dr, has an email address x and is a member of society y. These SPO units are the atomic makeup of RDF and are called triples (Manola and Miller, 2004). An example is given in Figure 2.06.

![Graph of RDF triples](image)

**Fig 2.06:** RDF directed graph ('triple') from the W3C web site

According to the 'RDF primer' (Manola and Miller, 2004), these triples in the form of subject-predicate-object can be chained so that an object of one triple becomes a subject of another triple that describes its properties and relations and so on. It was recognized by several authors (e.g. Chen et al, 2004 and 2006; Fuchs et al, 2003; Hendler, 2003), that this would enable RDF to describe domain concepts and their properties and relations, thus representing a kind of domain knowledge map (a kind of an ontology) that is supposed to be both machine readable and machine understandable.
Fig 2.07: RDF chained directed graph (from the W3C web site)

As this RDF concept of directed graphs is generic, there are multiple ways of a serialization of the concept into a document instance (Beckett, 2004), but as RDF's main purpose was to support the semantic web, its XML serialization has gained the widest practical adoption. The snippet of RDF shown in Figure 2.08 maps the directed graph from Figure 2.05 onto RDF XML. This example is taken from the W3C web site (Beckett, 2004).

RDF's capability to add metadata description to resource in a standardized and machine interpretable way was soon exploited for life science information by Hendler (2003) and within the development of Life Science Identifiers (OMG, 2002). Dieng (2000), Nilsson (2003) and Lassila (1998) expressed the excellent usability of RDF metadata for knowledge management purposes. The application of RDF in the field of knowledge management was particularly of interest to the author because of the similarities of knowledge capture and decision capture as discussed earlier in this review.
Although RDF provides an elegant means for semantic descriptions of information within document instances, authors such as Berners-Lee (1999) and Decker et al (2000) stated an overall need for more elaborate expression of an ontological framework around these concepts. RDFS (Brickley and Guha, 2004), the so-called RDF Schema, was provided as a simple means for taxonomical representations of the concepts expressed in the corresponding RDF instance document and to indicate the way they relate to one another. Even though RDFS was able to provide some ontological framework for the concepts used in its RDF instance documents, general RDFS shortcomings in expressiveness to reflect rules and idioms amongst these concepts were widely recognized by, for example, Staab et al. (2000), Hendler and McGuinness (2000) and Connolly et al. (2001). These authors designed their own proprietary RDFS extensions to overcome the problem, such as the DARPA Agent Markup Language (DAML) described by Hendler & McGuinness (2000), or the Ontology Inference Layer (OIL) by Fensel et al. (2001), and finally a combination of DAML plus OIL (McGuinness et al, 2002). These extensions have been integrated more recently.
to form what is now called the Ontology Web Language, "OWL" (Patel-Schneider et al., 2004). The review thus far has revealed that RDF and derived concepts such as RDFS and OWL, all expressed in RDF syntax, provide a common framework for expressing information and related semantics. This was seen as an important precondition in order for information to be exchanged between applications without loss of meaning. The ability to exchange information between different applications means that the information can be made available to applications other than those for which it was originally created, which attracted its use in knowledge management by authors such as Hendler and McGuinness (2000), and van Harmelen and Horrocks (2000).

The literature reviewed stimulated an investigation of RDF for the development of an information model that is suitable to capture and map a human decision making process. RDF triples appear to be a suitable means for mapping decision attributes within an appropriate semantic context in order to keep meaning across domains, and also IS systems that might work on them. The XML serialization of RDF appears convincing as being a format that widely supports storage and query/retrieval of such information with the help of computer systems as discussed above.

A thorough search revealed that an RDF-XML information model derived from case based reasoning (CBR) has been publicized by Chen and Wu (2003). Their model is very close to the CBR concept as their intention is to complement the strict logical reasoning in the Semantic Web by the 'less sharp', similarity-based approach of CBR. Their concept involves the expression of the classic CBR paradigms (textual, simple attribute-value pairs, structured CBR) in RDFS which could improve the conceptual domain modeling for items in domains like sales and engineering, but still inherits the shortcomings of current CBR for the purpose of capturing human decisions as discussed earlier. Their model is depicted in Figure 2.09.

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Fig 2.09: CaseML, a RDF-Based Case Markup Language for Case-Based Reasoning in the Semantic Web (Chen and Wu, 2003)

However, the publication by Chen and Wu triggered the investigation of whether a more complex RDF(S) information model that incorporates a richer set of decision attributes to be developed as part of this research would be better suited to successfully map a human decision making process. This investigation is discussed in Chapter 5.
2.5.3 Metadata

Following the paradigm of attribute-value pairs, some standardization of the attributes would clearly facilitate their machine interpretation and cross-domain usability as investigated by Baker (2005). This is similar to a domain categorization process as proposed by Rodriguez and Martin (1996) and would facilitate the wider implementation of a solution within AZ. A useful concept of providing domain categorization is by using standardized metadata (ISO/IEC, 2003). Metadata is machine and human understandable information about data or information. A good definition is given in the Sedona Principles document (Redgrave et al, 2004): “Metadata is information about a particular data set which may describe, for example, how, when, and by whom it was received, created, accessed, and/or modified and how it is formatted. Some metadata, such as file dates and sizes, can easily be seen by users; other metadata can be hidden or embedded and unavailable to computer users who are not technically adept ...”.

Metadata can be highly standardized in order to share a common meaning across domains, such as, for example the Dublin Core (see below). These would then describe ‘general’ document attributes or information properties such as creator, date of creation, format, publisher, etc. If the domains are closer related, the metadata can be more specific as described in the research by Pancerella et al. (2003). These authors propose a metadata framework for related sub-domains such as Quantum Chemistry, Thermo Chemistry, Kinetics, Chemical Mechanisms and Reacting Flow that all belong to the Multi-Scale Chemical Science domain. Parchoma (2002) designed what he called “Learning Objects” that include subjective metadata such as level, learner profile, level of interactivity and pre-requisites as well as objective metadata such as creator, subject and medium. His metadata approach suggested a useful starting point for the author’s research in order to find suitable metadata to describe decisions properties. It furthermore prompted a literature review around some currently available metadata frameworks to determine their possible suitability for providing useful descriptors for decision properties.
Amongst those examples for highly standardized metadata that is reviewed in this thesis are vCard (Sourceforge, 2006), IMS Global Learning Consortium (IMS 2003), and the Dublin Core Metadata terms (Dublin Core, 2005). Several authors, e.g. Kamel Boulos et al. (2002) and Sintek and Decker (2001), describe their use with RDF documents, Dublin Core in particular. Wolfe (2000) and many others have found the Dublin Core metadata to be useful to provide a standard set of document descriptors. It was evident for the author’s research that even a generic decision capture entity would need such metadata as creator, creation date, format, publisher, title, identifier, language and relation (e.g. to source documents or websites). An example of the use of some of the Dublin Core metadata set is given in Figure 2.10.

```xml
<?xml version="1.0" ?>
<record xmlns="http://example.org/learningapp/
 xmlns xs="http://www.w3.org/2001/XMLSchema-instance"
 xsi:schemaLocation="http://example.org/learningapp/
 http://example.org/learningapp/schema xsd"
 xmlns dc="http://purl.org/dcelements/1.1/"
 xmlns ims="http://www.imsglobal.org/xsd/imsmd_v1p2">
  <dc title>Frog maths</dc title>
  <dc identifier>http://somewhere.com/frogmaths/</dc identifier>
  <dc description>Simple maths games for 5-7 year olds</dc description>
  <ims:typicallearningtime>
    <ims datetime>2000-00-00T00:15</ims datetime>
  </ims typicallearningtime>
</record>
```

Fig 2.10: Use of Dublin Core metadata and IMS metadata in XML.

The Dublin Core namespace definition is xmlns dc="http://purl.org/dcelements/1.1/" within the XML snippet in Figure 2.10 (Dublin Core, 2005).
Highly standardized metadata 'on their own' would, of course, be too generic to describe a certain domain sufficiently. An example of the use of domain specific metadata is the metadata implementation by the Geological Data Center (GDC, 2006). The domain specific metadata approach would also apply to the anticipated research in order to design an information model that is able to map and capture a human decision process with a rich set of descriptors to be developed. The work by Bergmann & Schaaf (2003) encourages the use of metadata annotations with CBR. They argue that the natural language parts of the CBR knowledge base should be assigned metadata attributes that are derived from a domain ontology. The tagged content linked to a structured domain ontology would thereby form a 2nd knowledge base within the case base that would allow additional machine inferencing. This is an interesting concept and will be discussed in later chapters of this thesis.

Technically, the XML syntax enables one to provide highly standardized as well as custom metadata by placing them into different XML namespaces as outlined by the XML namespace specification (Bray et al, 2006). An example of the use of the Dublin Core namespace within an RDF/XML document is given in Figure 2.07.

2.6 Summary of the Literature Research and Validation of the Aims and Objectives of this Thesis

The objective for the literature review was to understand the human decision making process, to identify best practice on individual and group decision making as a means to identify important decision descriptors, to determine starting points for the development of information models for decision capture, and to determine storage formats to be used with a suitable IS decision support tool.

The literature review confirmed the aims of this research, as there is no gold standard for capturing complex human decisions made in a drug development
environment in a way that can be fully reviewed and understood later or can be exploited with the help of information systems.

CBR was found to be the best matching paradigm for the aims and objectives of this thesis as it tries to map a new issue or situation onto a stored case. However, the currently used information models, mainly from domains like eCommerce and engineering, are not suitable to map a decision making process because of the rich set of attributes in natural language that would be necessary for decision mapping. CBR applications in Knowledge Management have mainly evolved around Text Mining and Information Extraction which is not in line with the more narrow view of KM as discussed. Textual CBR may evolve into a suitable paradigm for direct support of human decision processes as proposed and outlined by Rech and Althoff (2003), and this is investigated in Chapter 5. The lexical processing and taxonomy distance calculations used in textual CBR may be investigated further as useful tools for the case matching and retrieval that is beyond the scope of this research and is, therefore, a suggestion for further research.

However, the work done by other authors in the fields of human cognition and decision support, CBR and the Semantic Web are a useful foundation for the research in this thesis. These technologies provide a potential means to improve the way that knowledge from decisions is captured and stored so that it can be re-used and re-visited for organisational learning and ultimately for delivery of a usable decision capture / storage system that can be adopted and used by the wider AZ company.

The stepwise evolution of the information model and IS system developed by the author, builds on the insights as well as the shortcomings of systems identified from the literature. This evolution and the steps involved are explained in Chapters 4 to 6 of this thesis.

First, however, the next chapter reviews different research methodologies in order to identify and propose a research strategy that is suitable for the research undertaken and reported in the later chapters of this thesis.
Chapter 3 – Research Methodology

3.1 Scope

This chapter will review and compare different research philosophies as well as the derived research methodologies and will conclude with the appropriateness of the research strategy finally chosen for assessing the research aims and objectives outlined in Chapter 1.

3.2 Introduction

It is important to choose and apply the appropriate research methodology because the choice will influence the observations, the outcome and the conclusion.

"We have to remember that what we observe is not nature in itself, but nature exposed to our method of questioning"

Werner Heisenberg (1901 - 1976)

Any research attempt may be described by the research methodology which is derived from general philosophies of research which will be reviewed below. Research methods can be classified in various ways; however, one of the most common distinctions is between qualitative and quantitative research methods. Several research philosophies form the building blocks of the research methodologies and are therefore reviewed first.

3.3 Research Philosophies

All research is based on some underlying assumptions about what constitutes 'valid' research and which research methods are appropriate. In order to conduct and/or evaluate research properly, it is therefore important to know what these
assumptions are, particularly because these assumptions are often silent, i.e. not consciously perceived. A certain set of linked assumptions forms a research philosophy which is a belief about the way a phenomenon should be assessed in terms of data acquisition, analysis and interpretation. The purpose of research is to test hypotheses, i.e. to test whether what is believed to be true ('doxology') is actually true ('epistemology': what is known to be true) – doxa to episteme.

Galliers (1992) reviews the two major research philosophies that were identified in the tradition of science:

- The positivist ('scientific', what, seeking generalisation)
- The interpretivist ('anti-positivist', how and why, seeking explanation, understanding)

At the heart of positivism is Popperian falsification: The philosopher Popper (1963) claims that a scientific theory must make predictions that can be falsified by observation. According to him, a theory is scientific if it exposes itself to the possibility to be proven false. Consequently, a theory should be more seen as truth the more times it escapes falsification. Software engineering theory is preliminary rather than final - it is not possible to confirm it, it can only escape falsification. The more falsifications it escapes, the more confidence software engineering researchers and practitioners have in its usefulness.

Post-Popperian Positivism: While the positivist epistemology deals with observed and measured knowledge only, the post-positivist epistemology on the other hand recognizes that such an approach would result in making many important aspects of psychology irrelevant, because feelings and perceptions cannot be readily measured. In post-positivist understanding, pure empiricism, i.e., deriving knowledge only through observation and measurement, is understood to be too demanding. Instead, post-positivism is based on the concept of critical realism, that there is a real world out there independent of our perception of it and that the
objective of science is to try and understand it, combined with triangulation, i.e., the recognition that observations and measurements are inherently imperfect and hence the need to measure phenomena in many ways. The post-positivist epistemology regards the acquisition of knowledge as a process that is more than mere deduction. Knowledge is acquired through both deduction and induction (Cook and Campbell, 1979).

Different and unrelated research areas such as, for example, natural sciences and social sciences may have needs for different research strategies because of the very distinct nature and robustness of their phenomena and the quantitative or qualitative nature of their measurables.

Orlikowski and Baroudi (1991), following a proposal from Chua (1986), suggest three categories of research philosophies, based on the underlying research epistemology:

- Positivist
- Interpretive
- Critical

This three-fold classification is adopted for review in this thesis. However, Myers (1997) pointed out that, while these three research epistemologies are philosophically distinct (as ideal types), in the practice of social research these distinctions are not always so clear cut, which has already been found by Lee (1989) as well. In the literature reviewed, interpretivism is likewise often strictly assigned 'qualitative'. But as reiterated by Myers (1997), the word 'qualitative' in terms of research methodology is not a synonym for 'interpretive' - qualitative research may or may not be interpretive, depending upon the underlying philosophical assumptions of the researcher. Myers states consequently, that qualitative research can in fact be positivist, interpretive, as well as critical as discussed in section 3.4.2. He follows from this, that the choice of a specific
qualitative research method (such as the case study method, see below) is independent of the underlying philosophical position adopted.

There is considerable disagreement in the literature as to whether these research paradigms or underlying epistemologies are necessarily opposed or can be accommodated within the one study (see discussion in section 3.5).

3.3.1 Positivism

According to Lewin (1946), who is considered as one of the fathers of action research, positivists generally assume that reality is objectively given and stable and can be described by measurable properties which are independent of the observer (researcher) and his or her instruments, i.e., that they can be observed without interfering with the phenomenon under observation. The observer is seen as being objective and completely detached from the phenomenon. He furthermore states that positivist studies generally attempt to test theory, in an attempt to increase the predictive understanding of phenomena. Positivists strive for a clear distinction between reason and feeling, between fact and value judgments. They aim to discover the external 'reality' with a rational and logic approach. They expect quantitative data and quantitative results that are highly reproducible. According to Straub et al (2004), quantitative research methods were originally developed in the natural sciences to study natural phenomena. They furthermore state that examples of quantitative methods are now well accepted, for example, survey methods, laboratory experiments, formal methods (e.g. econometrics) and numerical methods such as mathematical modeling.

Research in computer science may be seen as an extension to physical sciences where the positivists' approach may be regarded appropriate because of the quantitative nature of the determinants and the robustness of the phenomena. Information science, on the other hand, with its intrinsic involvement of humans and human-computer interaction is to be regarded closer to social sciences and,
therefore, the positivists' paradigm of a non-interfering observer is questionable, hence the use of double-blind experimental designs where feasible. In line with this, Orlikowski and Baroudi (1991) classified Information Systems research as positivist if there was evidence of formal propositions, quantifiable measures of variables, hypothesis testing, and the drawing of inferences about a phenomenon from the sample to a stated population.

Examples of a positivist approach to qualitative research are cited by Myers (1997) and include Yin's (2002) and Benbasat et al's (1987) work on case study research.

3.3.2 Interpretivism

Interpretive researchers begin with the assumption that access to reality (which is given or socially constructed) is only through social constructions such as language, consciousness and shared meanings. The philosophical base of interpretive research is hermeneutics and phenomenology as discussed by Boland (1985). Myers (1997) points out that interpretive studies generally attempt to understand phenomena through the meanings that people assign to them, and Walsham (1993) states that interpretive methods of research in Information Science 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". According to Kaplan and Maxwell (1994), interpretive research does not predefine dependent and independent variables, but focuses on the full complexity of human sense making as the situation emerges.

Interpretivists believe that they cannot study a phenomenon without interfering, thus affecting it. They even think that active intervention and subjective interpretation is the key to the understanding of the phenomenon. By allowing subjective interpretation, they allow actions to be governed by feeling and
subjective reasoning. They acknowledge that, by intervention, they partially create what they are studying. The distinction between value judgments and facts is therefore much less clear than for the positivist. They also accept that there is influence from both scientific facts and personal experience. Their results are primarily expected to be more qualitative in nature. As pointed out by Myers (1997), qualitative research involves the use of qualitative data, such as interviews, documents, and participant observation data, to understand and explain social phenomena. According to him, qualitative research methods were developed in the social sciences to enable researchers to study social and cultural phenomena.

Examples of qualitative approaches are action research, case study research and ethnography. Qualitative data sources include observation and participant observation (fieldwork), interviews and questionnaires, documents and texts, and the researcher's impressions and reactions. Kaplan and Maxwell (1994) argue that the goal of understanding a phenomenon from the point of view of the participants, as well as its particular social and institutional context is often lost when an attempt is made to quantify data obtained through qualitative research, so this data should be treated and processed with caution.

Examples of an interpretive approach to qualitative research are given in Myers (1997) and include Boland's (1991) work on Information System use as a hermeneutic process, and Walsham's (1993) work on Information systems research in organisations. A paper by Klein and Myers (1999) suggests a set of principles for the conduct and evaluation of interpretive research.

### 3.3.3 Critical Research

As stated by Myers (1997), critical researchers “assume that social reality is historically constituted and that it is produced and reproduced by people”. He furthermore concludes that, although people can act consciously to change their
social or economic circumstances, critical research recognises that their ability to do so is actually constrained by diverse forms of social, cultural, and political domination. The main task of critical research is seen by Hirschheim and Klein (1994) as being one of social critique, "whereby the restrictive and alienating conditions of the status quo are brought to light". According to Myers (1997), critical research focuses on the oppositions, conflicts and contradictions in contemporary society, and seeks to be emancipatory, i.e. it should help to eliminate the causes of alienation and domination.

One of the most prominent exponents of contemporary critical social theory is Juergen Habermas (born 1929), who is regarded as one of the leading philosophers of the 20th century. Habermas was a member of the Frankfurt School, which included figures such as Adorno, Horkheimer, Lukacs, and Marcuse (Bottomore, 1984).

Examples of a critical approach to qualitative research are given in Myers (1997) and include work by Ngwenyama and Lee (1997), and Hirschheim and Klein (1994).

3.4 Research Methodologies

There are various philosophical perspectives which can inform qualitative research, likewise there are various qualitative research methods. A research method is a strategy of inquiry which extends from the underlying philosophical assumptions to the research design and the data collection principles. The choice of the research method determines the way in which the researcher collects his or her data.
3.4.1 Quantitative Research Methodologies

A good review of quantitative, positivist research methods in information systems (IS) is given by Straub et al (2005). Quantitative, positivist research methods and techniques allow IS researchers to answer research questions about the interaction of humans and computers. According to Straub et al (2005), there are two main assumptions in this research approach. The first assumption is the emphasis on quantitative data. The second assumption is the emphasis on positivist philosophy as discussed in Section 3.3.1.

They state further that, regarding the first assumption, “these methods and techniques tend to specialize in quantities in the sense that numbers come to represent values and levels of theoretical constructs and concepts and the interpretation of the numbers is viewed as strong scientific evidence of how a phenomenon works”. The presence of quantities is so predominant in quantitative, positivist research methods that statistical tools and packages are an essential element in the researcher’s toolkit. Sources of data are of less concern in identifying an approach as being a quantitative, positivist research approach than the fact that empirically derived numbers lie at the core of the scientific evidence assembled. A quantitative, positivist research method’s researcher may use archival data or gather it through structured interviews. In both cases, the researcher is motivated by the numerical outputs and how to derive meaning from them. This emphasis on numerical analysis is also key to the second assumption, positivism, which defines a scientific theory as one that can be falsified.
3.4.2 Qualitative Research Methodologies

Two qualitative research methodologies have been widely used for research in information science and will be discussed in the following section: action research and case study research.

3.4.2.1 Action Research

Action research is an established research method in the social and medical sciences since the mid 20\textsuperscript{th} century, and has gained increased importance for information systems research toward the end of the 1990s. Its particular philosophic context is largely influenced by interpretive research ideals.

The most widely cited definition of action research is proposed by Rapoport (1970): "Action research aims to contribute both to the practical concerns of people in an immediate problematic situation and to the goals of social science by joint collaboration within a mutually acceptable ethical framework". Rapoport's definition focuses on the collaborative aspect of action research. Clark (1972) emphasizes that action research is concerned with enlarging the amount of knowledge within social science. According to Myers (1997), it is this aspect of action research that distinguishes it from other applied social science, where the goal is simply to apply social scientific knowledge but not to add to the body of knowledge.

According to Baskerville (1999), the key assumptions that the action researcher makes, namely

1. social settings cannot be reduced for study, and
2. action brings understanding,

imply a philosophy that allows interpretivism, idiographic studies, and qualitative data. Action research methodology is strongly anchored to post-positivist
According to Baskerville (1999), action researchers are among those who assume that complex social systems cannot be reduced for meaningful study and that the fundamental contention of the action researcher is therefore, that complex social processes can be studied best by introducing changes into these processes and observing the effects of these changes. The typical (iterative) action research cycle is outlined by Susman and Evered (1978):

1. diagnosing,
2. action planning,
3. action taking,
4. evaluating and
5. specifying learning (then back to 1.)

Kemmis and McTaggart (1988) point out that action research has been accepted as a valid research method in applied fields such as organization development and education. In information systems, however, action research was for a long time largely ignored, apart from a few exceptions such as Checkland (1991), Mansell (1991), and Lau (1997), who published a review on the use of action research in information systems studies.

Limitations of action research are discussed by Baskerville (1999): "In the constellations of available information system research methods, action research is among the more qualitative approaches. It is parked solidly outside of valid positivist techniques. Its qualitative and interpretive foundations make journal-length articles difficult. The lack of generally agreed criteria for evaluating action research further complicates the publication review process. These constraints make the approach a difficult choice for academics tied tightly into the journal system of scholarly communication". The collaborative framework that is at the heart of action research diminishes the researcher's ability to control the
research process and its outcomes. The lack of control makes it difficult to apply action research as an instrument in a large orchestrated research program.


3.4.2.2 Case Study Research

The term case study can have multiple meanings. According to Myers (1997), it can be used to describe a unit of analysis (e.g. a case study of, or within a particular organisation) or to describe a research method in itself. The review and discussion here focuses on the use of a case study as a research method.

According to the definition in the ReCAPP Research Glossary (2006), a case study is "an in-depth exploration of one particular case (situation or subject) for the purpose of gaining depth of understanding into the issues being investigated". Many authors agree that case study research is the most common qualitative method used in information systems (Orlikowski and Baroudi, 1991; Alavi and Carlson, 1992). Although there are numerous definitions in the literature, Yin (2002) provides a very useful definition of the scope of a case study. According to him, a case study is an empirical inquiry that:

- investigates a contemporary phenomenon within its real-life context, especially when
- the boundaries between phenomenon and context are not clearly evident.

Clearly, the case study research method is particularly well-suited to IS research, since the object of our discipline is the study of information systems in organizations, and "interest has shifted to organizational rather than technical issues", as stated by Benbasat et al (1987).
Myers (1997) provides a good discussion on the different philosophical groundings of case study research. According to that discussion, case study research can be positivist, interpretive, or critical, depending upon the underlying philosophical assumptions of the researcher. Yin (2002) and Benbasat et al (1987) are known advocates of positivist case study research, whereas Walsham (1993) is an advocate of interpretive in-depth case study research.

A case study is an account of an activity, an event or a problem that contains a real or even hypothetical situation and includes the complexities one would encounter such as in the workplace. Case studies are used to help to see how the complexities of real life influence decisions. According to Feagin et al (1991), a case study is an ideal methodology when a holistic, in-depth investigation is needed.

Kardos & Smith (1979) state, that the analysis of a case study requires the application of a researcher's knowledge and thinking skills to a real situation; To learn from a case study analysis the researcher will be "analysing, applying knowledge, reasoning and drawing conclusions".

Yin (1994) presented at least four applications for a case study model:

- To explain complex causal links in real-life interventions
- To describe the real-life context in which the intervention has occurred
- To describe the intervention itself
- To explore those situations in which the intervention being evaluated has no clear set of outcomes.

According to Tellis (1997), research in information technologies involves all four of the above categories. One typical type of a case study is an historical case study where the researcher analyses the causes and consequences of a situation and discuss the lessons learned. The researcher is essentially outside the situation.
Other types of case studies require the researcher to imagine or even role play that he is in the situation and to make plausible recommendations to, for example, senior management. The latter type of case studies usually require the researcher to solve a problem by developing something new and are therefore called problem orientated case studies.

Yin (1994) states, that several authors criticize case studies because they believe that the study of a small number of cases can offer no grounds for establishing reliability or generality of findings. Others feel that the intense exposure to study of the case biases the findings. Some dismiss case study research as useful only as an exploratory tool.

3.5 Combined and Alternative Approaches for IS Research

McLean and Monod (2005) point out that the current epistemological and methodological debate in Information Systems (IS) still relies on distinctions like positivism versus interpretivism and critical 'research philosophies' despite the fact that many other alternative research trends in IS tend to challenge these classical distinctions. Myers (1997) observed a general shift in IS research away from technological to managerial and organizational issues which involves social processes, hence an increasing interest in the application of qualitative research methods.

There has been much debate in the literature about the applicability of the positivism paradigm to social science research (Hirschheim, 1994) and due to the fact that information science is somewhere between natural and social sciences, Remenyi & Williams (1996) argue that research on information systems would therefore probably need a more pluralistic approach.

Several authors present examples, where a certain research methodology is grounded in different research philosophies. Case study research can be positivist (Yin, 2002), interpretive (Walsham, 1993), or critical, just as action
research can be positivist (Clark, 1972), interpretive (Elden and Chisholm, 1993) or critical (Carr and Kemmis, 1986). Olson (1995) pointed out that the question "Quantitative versus qualitative research?" is not appropriate and a focus on a particular method should not drive research. Although most research is still done by either quantitative or qualitative research work, more and more authors have suggested combining one or more research methods in the one study (sometimes called triangulation). Good discussions of such combinations in the domain of Information Science can be found by Kaplan and Duchon (1988), Lee (1991), Gable (1994), and Mingers (2001). An empirical example of the use of triangulation is the paper by El-Shinnawy and Markus (1997) on electronic mail.

There are other distinctions beyond the qualitative / quantitative discussion which are commonly made. Research methods have also been classified, for example, as objective versus subjective by Burrell and Morgan (1979). According to Myers (1997), there are many more such as being concerned with the discovery of general laws (nomothetic) versus being concerned with the uniqueness of each particular situation (idiographic), as aimed at prediction and control versus aimed at explanation and understanding, as taking an outsider (etic) versus taking an insider (emic) perspective, etc.

Considerable controversy seems to continue around the use of these different research paradigms and their combination, however, a detailed discussion is beyond the scope of this thesis. The author of this thesis prefers a pragmatic approach that is driven by the aims and objectives, and the nature of observations and results that form part of his research in order to choose a research strategy for his work that is deemed suitable.

3.6 Discussion and Rationale for Research Strategy chosen

Quantitative Positivist Research is a set of techniques and methods that allow Information Systems researchers to answer research questions about the
interaction of humans and computers. This approach to IS research is characterised by two determinants. The first determinant is the emphasis on the quantitative nature of the data collected. The second determinant is the emphasis on the Positivist philosophy. Regarding the first determinant, these methods and techniques employed tend to deal with quantities in the sense that numbers come to represent values and levels of theoretical constructs / concepts and the interpretation of the numbers is viewed as strong scientific evidence of how the phenomenon under observation works. The data sources are of less concern in identifying an approach as being Quantitative Positivist Research than the fact that empirically derived numbers lie at the core of the scientific evidence assembled. The presence of quantities is so predominant in Quantitative Positivist Research that statistical tools and packages are a predominant element in the researcher’s toolkit. A researcher may use archived data or gather it through structured interviews. In both cases, the research is driven by the numerical outputs and how to derive meaning from them. This emphasis on numerical analysis is also key to the second determinant, Positivism, which defines a scientific theory as one that can be falsified: Empirical testing aims at falsifying the theory with data. When the data do not contradict the hypothesized predictions of the theory, it is temporarily corroborate. The objective of this test is to falsify, not to verify, the predictions of the theory. Verifications can be found for almost any theory if one can pick and choose what to look at. A review of the aims and objectives of the current research gave little scope for the gathering of quantitative data that could be assessed through statistical means, or being used to contradict the hypothesized predictions of the theory and therefore an application of quantitative research methodologies is not considered the optimal approach for this research.

Qualitative research however involves the use of qualitative data, such as interviews, questionnaires, and data from participant observation, to understand and explain social phenomena. To the qualitative researcher, a phenomenon can best be interpreted by studying things like group interactions, relationships
between people and computers, workflows, and the like. In some cases, these sources of data and the techniques, such as interviewing, that are used to gather the data can be rendered into numbers and this research would be classified as a qualitative positivist research according to Myers, (1997). Qualitative researchers can be found in many disciplines and fields, using a variety of approaches, methods and techniques. In Information Systems research there has been a shift away from technological to managerial and organizational issues, particularly in the field of knowledge management, hence an increasing interest in the application of qualitative research methods. Examples of qualitative methods are action research, case study research, ethnography, and grounded theory (Myers, 1997). Qualitative data sources include observation and participant observation (fieldwork), interviews and questionnaires, documents and texts, and the researcher's impressions and reactions.

The main focus of the research, as outlined in the aims and objectives, is the improvement of the way that knowledge from decisions made in a drug development environment is captured and stored so that it can be re-used and re-visited for organisational learning and to design a usable decision capture / storage system that can be adopted and used by the wider AZ company. According to Rapoport (1970), action research aims to contribute both to the practical concerns of people in an immediate problematic situation and to the goals of social science by joint collaboration within a mutually acceptable ethical framework. This definition draws attention to the collaborative aspect of action research, which is recognised to be important according to the aims & objectives of the current thesis. Action research has been accepted as a valid research method in applied fields such as organization development and education (e.g. Kemmis and McTaggart, 1988). In information Systems research, however, action research has become more and more applied form the early 1990ties (e.g. Checkland, 1991), and was well established at the end of that decade (Avison et al 1999). Baskerville (1999) states that action research responds directly to the pronounced needs for relevance in applied information systems research, as it
provides a means to work closely with the practitioner community. He furthermore reiterates that action research enriches the research community by drawing researcher-practitioners into the research process. This matches the aims and objectives of the author's research insofar as the anticipated delivery can be achieved in an iterative research and deployment cycle with participation of the end user.

Avison et al (1999) argue that in action research, the emphasis is more on what practitioners do, rather than on what they say they do. They recommend action research, because "this particular qualitative research method is unique in the way it associates research and practice, so research informs practice and practice informs research synergistically"; Action research combines theory and practice (and researchers and practitioners) through change and reflection in an immediate problematic situation within a mutually acceptable ethical framework and provides an iterative process involving researchers and practitioners acting together on a particular cycle of activities, including problem diagnosis, action intervention, and reflective learning. Interviewing and observing people in these situations without the insight associated with intervention is not action research and might be described instead as case study research. In action research, the researcher wants to try out a theory with practitioners in real situations, gain feedback from this experience, modify the theory as a result of this feedback, and try it again, which is very relevant to the aims and objectives of this thesis. Each iteration of the action research process adds to the theory - in this case a framework for Information Systems development - so it is more likely to be appropriate for a variety of situations. Examples for successful implementation of the cycle of action research include the development of Multiview (Avison and Wood-Harper, 1990), and the Soft Systems methodology (Checkland, 1981), more examples in Avison et al (1999).

Action research as qualitative research strategy can draw upon a palette of methodologies such as e.g. interviews, questionnaires, observation, prototyping,
and other numerous methodologies and their variations (overview in Maiden and Rugg, 1996). Whilst there is a large amount of literature on the individual methodologies, the appropriate choice and correct application is neither standardized nor trivial. Rugg and McGeorge (1999) make an interesting attempt to structure the available methodologies depending on the type of memory models or knowledge types they are supposed to deal with (tacit knowledge, semi-tacit knowledge, explicit knowledge).

The author has employed the following qualitative methodologies to address the action research cycle (problem diagnosis, action intervention, and reflective learning) as mentioned above:

**Interviews**
Formal, semi-structured interviews are employed in Chapter 4 and Chapter 7 to gather the 'as is' status / problem diagnosis prior to the implementation of improvement of the group reasoning process (Chapter 4 - the personalisation element of the current research) and prior to the implementation of the final version of the knowledge objects (Chapter 7 - the codification element of the current research). Interviews are undertaken by the author using a set of questions with a binary scale reply (tend to agree / tend to disagree). The critical incident technique (Flanagan, 1954) is employed in Chapter 4 to give evidence of important past events from own experience in order to improve the robustness of problem diagnosis at the beginning of this research. The interview questions are given in Appendix 6 (used in Chapter 4) and in Appendix 7 (used in Chapter 7).

**Brainstorming / Prototyping**
Brainstorming and prototyping are used in Chapters 4 to 7 to justify action intervention prior to each iterative systems prototyping and to identify and prioritise areas for improvement. They also provide a reflective learning on the shortcomings of the previous prototype.
Brainstorming sessions are usually performed as 3 hr sessions, with mixed audience (details given in Chapters 4-7), but typically including the end user group and external IS experts from Loughborough University. A pre-read is usually not provided. Brainstorming sessions typically start with the reflection on the shortcomings of a previous prototypical implementation. Problem rephrasing (Sloane, 2003) is employed to develop a shared understanding of the problem and its facets. Whiteboarding is then used to capture ideas for improvement, followed by clustering and prioritization of the results.

**Questionnaire**

A formal questionnaire with open questions is used to gather feedback after the implementation of the EPISTEME framework in Chapter 7, which provides an overall evaluation of the combination of personalisation and codification strategies as intended in this research.

### 3.7 Summary of Chapter 3

This chapter has reviewed several research methodologies and their grounding philosophical assumptions, which are discussed and applied in the contemporary literature, particularly concerning information systems.

It was found that qualitative research, particularly the action research methodology, is suitable to provide a conceptual research methodology and framework for the main research aims reported in Chapter 1. That does not preclude other methodologies from being suitable as well and a huge debate in the current literature indicates that there is no common sense on what qualitative methodology is best to apply in each scenario, and whether one should aim for an application of one single research methodology or whether even a combination of research methodologies may be better suited and applied. Given the debate, the author made a conscious decision for one research methodology that appeared suitable in the context of the aims and objectives.
Chapter 4 – Group Reasoning and Digest

4.1 Scope

The first part of chapter 4 summarises briefly the status quo of decision processes and decision capture in AZ Clinical, particularly Experimental Medicine, prior to the start of this research in summer 2002.

The next two parts focus on the research objectives around the implementation of a novel process whereby decisions made by individuals as well as in meetings can be better captured as a group digest and summary and on the introduction of a novel decision capture format. This process has also been published in a paper by the author in 2003 (Adelmann and Jashapara, 2003). Literature on biases affecting group decision making will be discussed and implications for the current research will be derived.

The final part evaluates the novel process introduced in order to identify benefits, but also to detect shortcomings when used in practice from an internal point of view.

Research methodologies employed in this Chapter are a formal, semi-structured interview to gather the ‘as is’ status / problem diagnosis prior to the implementation of improvements of the group reasoning process. Interviews are undertaken by the author using a set of questions with a binary scale reply (tend to agree / tend to disagree). The critical incident technique (Flanagan, 1954) is employed to give evidence of important past events from own experience in order to improve the robustness of problem diagnosis at the beginning of this research. Brainstorming and prototyping are used to justify action intervention prior to each iterative prototyping and to identify and prioritise areas for improvement. They also provide a reflective learning on the shortcomings of the previous prototype. Brainstorming sessions are usually performed as 3 hr
sessions, with mixed audience (details given in Sections 4.3.3 and 4.4 and Section 3.6).

4.2 Status Quo of Decision Processes and Decision Capture

The author started his research on knowledge management around decision processes and decision capture in AZ Clinical at the Charnwood Research and Development site in Loughborough in the summer of 2002. As a manager of a group of highly experienced scientists and physicians in ‘Medicine & Science’, his initial staff interviews were carried out with 14 Medicine and Science staff and eight selected AZ staff external to the Medicine and Science group (customers and collaborating functions) in order to identify staff expertise, staff motivation, how staff communicate within and outside of their department and the way the staff deliverables are integrated into the wider business context. The semi-structured interview included questions on topics related to information and knowledge management and on communication, such as:

- handling of scientific data and information (corporate information systems, public domain information such as databases and newsfeeds, etc.)
- collaboration and dialog (meetings, email, telephone, videoconferences)
- reasoning processes / decision making (individual as well as group)
- creation of new knowledge
- capture and storage of knowledge, e.g. decisions
- reuse of existing decisions (awareness, accessibility)
- dissemination and retrieval of knowledge
- decision support systems and techniques

The respondents underwent an individual semi-structured interview with the author on the topics above. Respondent frequency was calculated on a dual scale (tend to agree / tend to disagree) for each of questions related to the topics above. In addition respondents were asked to give an example from their own past experience which they think was relevant for each of the questions.
It was found that there were issues in the way the group reviewed past decisions, the creation of new knowledge and the communication between staff as well as with the 'outside world' as reported in the author's 2003 paper (Adelmann and Jashapara, 2003). The following main observations were made:

- Information sharing was usually unstructured and mainly via email (only 15% were calling / called into regular reasoning meetings).
- There was a lack of structured internal consultation prior to decision making (57% made their decisions without broad regular consultation).
- Subsequent communication of the decisions outside the team where they matter were reported by 43% of the respondents.
- Knowledge created by individuals and in a group was not captured and stored in a way that was easily accessible and understandable later (78% found it difficult to retrieve previous knowledge if they could not rely on a person they knew was involved).
- As a consequence of the former, pre-requisites were felt insufficient for the review of decisions made or reuse of the knowledge generated (78%).
- Lack of formal knowledge management support in this particularly knowledge intensive department was raised by 93%.

Similar issues were already found and described in knowledge intensive industries by, for example, Dieng et al (1999), and Kuehn and Abecker (1997), who pointed out that the crucial factors in developing a 'Corporate Memory' are the organization of work processes and information interchange, human factors in cooperative problem solving and know-how sharing, cost-benefit considerations for desired system features and functionalities, and technical integration into the available IT infrastructure.

These 'internal' findings were complemented by the external view the author gathered from customers and functions with whom the Medicine & Science staff were frequently interacting. This external view revealed that advice given by the
group was sometimes inconsistent, i.e. it depended on which individual was approached, and this indicated a lack of internal consultation which could be symptomatic of an individual bias such as overconfidence (Lichtenstein et al 1982). Furthermore, external staff made the criticism that actual advice or decisions were sometimes incongruent with past, similar situations, which could be indicative of an insufficient review and reuse of past situations by the Medicine and Science staff.

This lack of robust advice was neither helpful to the customer nor beneficial to the Medicine and Science group's reputation. Furthermore, Medicine and Science staff members were often challenged on the advice they gave and found it more difficult to defend an opinion or decision that was not backed by the wider expert group. A lack of consolidation of advice also kept iterations going between Medicine & Science and its customers in the project teams. As a consequence, a need for an improved 'decision process' in AZ Clinical Development was identified.

A brief analysis of internal company documents that captured decisions from within the drug development context had already indicated that most previous decisions are stored in unstructured documents such as in Microsoft Word (.doc) or Adobe Acrobat (.pdf) format. Documents included the scientific parts of the monthly meeting minutes of the Experimental Medicine management team over a period of two years (including, for example, clinical methodological studies), Medicine and Science input into eight 'Milestone documents' and their input into eight 'Investigator Brochures'. The author found that working through these documents is neither an efficient nor an effective way to become familiar with past decisions. In more than 50% of the cases, the decisions made were unclear to the reader because context or underlying assumptions were not suitably recorded and sometimes even when the context was provided, it was not explicit enough to understand the decision triggers, their importance or the implication for the business. Another observation was that the expressiveness often depended
on the author of the document which indicated that a more formal and structured approach to decision capture would not only increase, but also harmonise the quality and ‘readability’ of the documents.

The situation is even worse if one considers the help of information systems with retrieval. The author agrees with Croft (2000) that computer systems are limited in their ability to provide useful retrieval from complex textual information stored in unstructured documents. Even though search engines and search algorithms are improving, there is, in parallel, a need for better structured content, as pointed out by Chiaramella (2001). Therefore, a need was identified for an improved information model and physical storage format, particularly in support of a decision or knowledge repository in AZ Clinical Development.

4.3 Implementation of a New Decision Making Practice in AZ Clinical

As pointed out in the author’s 2003 paper (Adelmann and Jashapara, 2003), the challenge from a knowledge management perspective is to explore how process and technology could facilitate knowledge sharing, both tacit and explicit, in a group context. At the same time they should be able to reduce biases of group decision making such as ‘groupthink’ (Janis, 1972), a phenomenon where groups strive to reach consensus without critically testing, analyzing, and evaluating ideas, and ‘risky shift’ (Myers and Bishop, 1970), which are sometimes linked. A shift towards a more risky group decision is explained by Wallach et al (1964) by a diffusion of responsibility, where emotional bonds decrease anxieties and risk is perceived as shared, hence the preparedness to take higher risks then group members would have taken individually.

A method to improve group decision making is the Delphi method (Dalkey and Helmer, 1963), an iterative approach where an independent expert panel is

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1 Occasionally, the opposite is true: Groupworkers may not want to let their compatriots down and are therefore becoming risk-averse (this is called ‘safe shift’ or ‘cautious shift’).
answering questions on a problem in writing. An anonymous summary of everyone’s opinion and reasons are then brought back (once or more) to the experts in order to adjust themselves to something which is believed to be closer to a ‘correct answer’. The author foresees difficulties to apply this methodology (which has originally been developed for scalar numerical forecasting) to complex scientific and medical questions in the context of drug development and the huge time consumption of about 30 to 45 days to complete the entire process limits its usefulness for ‘day to day’ drug development decisions. The Delphi method may even produce an iterative amplification of groupthink or risk shifts, generating a manipulated consensus as pointed out by quite a few authors, e.g. Mitroff and Turoff (1975).

The effect of groupthink or risk shifts have not been addressed in this research but would give rise to an additional piece of important research, particularly to investigate whether the mix of codification and personalisation strategies for knowledge management that the author is implementing in the current research would be able to modify group decision bias. The author is hypothesising that, from his experience in several codification sessions, the codification process described in this thesis seems to introduce a certain amount of objectivity, which may help to de-bias groupthink and risk shifts, but this has to be verified through additional research.

A variety of collaboration (‘groupware’) tools were evaluated for their suitability in this environment such as network mind mapping, threaded discussion forums, WIKIs (PortlandPatternRepository, 2003), weblogs and mailing lists. Collaborative tools such as a threaded discussion forum can often foster and recreate the social environment of the staff within the virtual community setting. The idea of a Community of Practice (CoP) being a key part of a successful KM initiative is supported by Dillenbourg & Schneider (1995) who found that people instinctively form groups centred upon a common interest and these groups consist of people who are most similar to themselves or share values both within
the virtual community and a "real life" setting. These collaborations can often be performed asynchronous with computer-assisted offline contribution by the members, which can save time and travel cost. This has been demonstrated to be more efficient than synchronous procedures (e.g. Dowling and St Louis, 2000, for computer-assisted asynchronous implementations of is the nominal group technique [NGT]).

The question for the author to address was how to support his group with technology and methodology without constraining their creativity. A threaded discussion forum is well known from internet newsgroups. This type of collaborative information or groupware tool was readily available on the AstraZeneca intranet, and all users were already familiar with the concept from posting on internet newsgroups, hence this tool was prioritised and was initially chosen by the author as it can form a worthwhile component of a businesses communication and knowledge management strategy (Smolnik and Nastansky 2001) and encourage the establishment of communities of practice. It was decided to start the author's research with a threaded discussion forum. Though this forum is merely a tool for structured information sharing it can be used to 'prepare' and facilitate the knowledge generation process, as introduced and previously discussed in the author's paper (Adelmann and Jashapara, 2003).

To what extent posting of individual opinion prior to a group reasoning is able to reduce group decision bias is another interesting question to be addressed by further research.

4.3.1 The First Pilot Process Implementation

Following the analysis of the decision making processes in the department, with its lack of formal structures, consultation and reuse, the author introduced a more formal decision making process which utilised an online discussion forum. For a period of about one year, 14 medical and scientific staff from the Medicine and Science group within AstraZeneca Clinical Development utilised a threaded,
message-based discussion forum in conjunction with regular group summary and digest meetings. This process pilot became the first instance of the author's implementation of an optimised group reasoning process and was used until a company reorganisation moved the author and several other staff on to a different company group where the improved processes from the first pilot were then implemented a second time (see Section 4.3.2).

This pilot decision making process and knowledge generation cycle had the following basic steps:

1. A new topic for discussion concerning some issue or problem was usually initiated by a member of staff posting on the threaded discussion forum (see Figure 4.1 for a snapshot).

2. These posts then promoted an online discussion in the group through the discussion forum.

3. When all interested parties had contributed their views on the forum a digest and summarisation meeting was called. Prior to the digest and
summarisation meeting, the staff were required to review the respective posts in order to familiarise themselves with the status of the discussion and the opinions of the participants.

4. The face-to-face 'Medicine and Science' meetings discussed the information on the forum, thereby applying the groups' substantial explicit and tacit knowledge surrounding a particular topic. Note that because all parties were aware of each others views from the online forum, there was a "warm" start to the meeting where no time was lost by members having to introduce their views. The face-to-face digest and reasoning meetings could, of course, run without a pre-discussion, but the use of a threaded discussion forum to prepare the meeting was found beneficial as discussed in Section 4.5.

5. The face-to-face group meeting then digested and summarised the consolidated view, prompting the knowledge community to jointly capture the tacit and explicit knowledge applied to the problem. The 'knowledge summary' usually contained.

- the original problem / issue to solve
- the digest of all comments received through the forum plus the actual discussion
- the joint recommendation of the group

The summary aimed to capture and disseminate consolidated knowledge, as shown in Figure 4.02, which gives an overview of the pre-discussion, digest, summarisation and capture procedure introduced by the author and described in this chapter. It could provide lessons learned within the whole knowledge community and made the decisions much more transparent.
6. This summary was stored and a link was then placed back into the forum where it was then available for review at any time in the future, enabling potential reuse of the decisions and recommendation made. The rich contextualised knowledge captured was a reflection the decision-making process of the group, which was stored in XML format under the guise of a Knowledge Object (“KNfY”, see Chapters 5, 6 and 7).

7. The summary could also become the starting point for further online discussion on the same thread of the forum. This, in turn, could lead to a further digest and summarisation meeting and a cycle was formed that could be repeated any number of times.

The whole process was supported by a dedicated resource, the Knowledge Manager, who in this case was a member of staff devoting 50% of his working time to facilitate knowledge and information sharing, capture and reuse within and outside the group.

The Knowledge Manager’s responsibilities included:

- Managing the discussion forum (membership and general housekeeping).
- Initiating the digest and summarisation meetings, giving notice of the meetings and organising the time and place.
- Recording the meeting output and creating the associated knowledge object.
- Placing the link to the knowledge object on the discussion forum for future reference.

The knowledge manager should develop sensitivity for ‘front versions’ and ‘back versions’ (Goffman, 1959) of the items under discussion to enable an objective,
factual discussion. This is a necessary prerequisite to create a knowledge capture that is transparent, robust and re-usable.

Figure 4.02 gives an overview of the pre-discussion, digest, summarisation and capture procedure introduced by the author and described in this chapter.

![Diagram](image)

**Key:**
- \( \Sigma \) denotes the group reasoning meeting ('digest and summarisation').
- KNO denotes the captured consolidated group opinion or decision in the form of a knowledge object (see Chapter 5, 6 and 7).

**Fig. 4.02:** The knowledge generation and capture process with the help of a pre-discussion (e.g. on a forum).

### 4.3.2 The Second Pilot Process Implementation

After a reorganisation of Clinical development in 2005, the author was appointed head of Clinical Pharmacology UK. His new group contained some of his previous staff but was extended to the two AZ research sites in the UK. The concept of regular group meetings was introduced to this group because of the positive previous experience gained from the Medicine and Science department.
In a discussion within the new group of 17 staff it became obvious that staff again appreciated a meeting format to elevate and discuss issues but interestingly, some questions were raised as to whether such an instrument could turn into a micromanagement environment, thereby disempowering individuals. This issue was discussed offline by gathering individual opinion, as well as in a group meeting and, as a result, three members of staff drafted some ground rules based on the comments received that everyone in the group could finally agree:

1. A 'consultation board' would be installed (the notion of a 'review board' was deliberately avoided), that would be populated in a flexible manner with staff relevant to the topic under discussion. Board membership would generally not be limited to a certain level of seniority.
2. The meetings of the board would be set up every month with the possibility of calling additional meetings at short notice in between, if needed.
3. One group member would act as coordinator of the meeting. The coordinator role would rotate every 6 months.
4. The chair of the meeting would rotate among group members from session to session.
5. The outcome of the board discussion would be captured in a suitable format (see Chapter 5) by the Knowledge Manager who sits is the background and takes a much more passive role in the meeting.
6. Issues would be usually raised by the single point of contact (SPOC\(^2\)), or possibly by a line manager.
7. Attendance and contribution at the consultation board meetings would be open to all group members.
8. Attendance from outside the function would be by invitation only. This invitation must be either by the SPOC or a line manager within the function. Attendance by invitation may be extended to external consultants.

\(^2\) SPOC: Discussions with our customers in the project teams revealed a distinct need for a 'Single Point of Contact' to relay issues as well as decisions/advice between the scientific/medical expert group and the drug project teams in order to simplify communication.
9. The SPOC must propose appropriate members for the given board meeting (e.g. per previous involvement in a discussion on the forum) and publicise the intended meeting membership with reasonable notice.

10. A minimum of 3 members with reasonable expertise in the subject under discussion must attend the meeting in order to have a formal session. This would be in addition to the SPOC on the project being discussed.

This consultation board was the successor of the previous Medicine and Science meetings so the second pilot process effectively replaced the first as the new group effectively absorbed parts of the original department. Again, a discussion forum was installed to enable the offline preparation of the board meetings as discussed above. This second pilot system continues to be used at the time of writing this thesis.

In fact, there is no significant difference between the second process and the previous process – both have group reasoning meetings that result in the capture of explicated and consolidated group knowledge and opinion. Both are ideally preceded by a discussion on a forum but can also run without, even though a pre-discussion was found more efficient (see Section 4.5). Furthermore, both meetings usually dealt with one or two issues given the time allowance of about 1.5 hours. In the case when they deal with more than one issue, the outcome is captured separately.

4.3.3 Comparison of the Two Pilot Process Implementations and Reflections on Knowledge Codification

Because of the high similarity of the group reasoning processes, they are discussed together in this chapter, even though the focus of the discussions changed towards decision capture as discussed below. The significant evolution of the information model, however, warrants separate treatment in Chapters 5, 6 and 7.
As stated above, the two pilot processes were separated by more than one year and during this time the information model had evolved significantly. The first pilot process discussed in Section 4.3.1 utilised an information model known as KNO v1 (see Chapter 5) and later KNO v2 (see Chapter 6), whereas the second pilot process, discussed in Section 4.3.2, used KNO v3 which is the subject of Chapter 7. Therefore, the knowledge objects were not carried forward from the first pilot to the second because their different structure. The old knowledge objects could still be accessed by the group, but they were not merged into the same knowledge base.

In terms of knowledge management strategies, the literature makes a distinction between codification and personalisation strategies (Hansen et al 1999). Like the pharmaceutical R&D, business consulting is a similarly knowledge intensive industry. Amongst other organisations, Anderson Consulting and Ernst & Young have adopted codification strategies. Codification strategies are largely based on technology and use huge databases where codified knowledge can be stored. The rationale of a codification strategy is to achieve ‘scale in knowledge reuse’. This is very much a reflection of the case based reasoning paradigm discussed in Chapter 2. Other consultants such as Bain or McKinsey tend to favour knowledge management focused on ‘personalisation’ strategies as discussed by Jashapara (2004). These strategies are more people centered Bain and McKinsey are more interested in developing their employees through brainstorming exercises and face-to-face communication in order to gain deeper insights into problems, and formal knowledge capture is less in focus (Jashapara, 2004). The former approach provides access to robust and proven solutions to similar problems as well as excellent means for knowledge retrieval and reuse, whereas the latter is a more adaptive approach which is especially useful in the fast changing pharmaceutical environment.

It was decided to introduce a mixture of a personalisation approach (group digest and reasoning) and codification (‘formal knowledge capture’) in the author's
research in order to get the best of these two worlds. The strength and benefits of using a combination of different KM strategies has already been considered beneficial by other authors, such as Wlig (1999), despite a lack of acceptance in the consulting industry (Jashapara 2004).

4.4 Evaluation of the New Decision Making Process

Face-to-face meeting time is precious at AstraZeneca Clinical Development and the preparation of such a group reasoning meeting by a threaded message forum was found to greatly improve meeting efficiency as rated by group members during the meetings. All participants agreed that the requirement to contribute their own opinion offline and to familiarize themselves with other opinion prior to the face-to-face enabled the meeting itself to focus on the discussion and decision making process rather than on lengthy introductions to the subject or on reiterations of each individual perspective.

The implemented novel methodology is, in fact, applying knowledge management at the level of the knowledge worker, getting them into a dialog. It is new in the respect that it uses mostly existing intranet technology for both innovative thinking (divergent thinking – on the threaded discussion forum) and decision making (convergent thinking – at the digest and summarisation meeting) which, according to a review by Jashapara (2004), is often said to be difficult to bring together. This is the counterintuitive aspect of this approach, where technology is actually enhancing rather than reducing the level of thinking. The proposed methodology is furthermore supported by research findings by von Ghyczy (2003), in that it enables time and space independent contribution of ideas and facts. Von Ghyczy states that this is an important prerequisite to enable the application of cognitive metaphors\(^3\) stimulated by a different environment in order to support innovative problem solving.

\(^3\) Physical distance and time independence often enables the application of cognitive metaphors stimulated by the different environment – Kekule's dream illustrates this nicely. Whilst at home, he was staring at the fireplace and fell asleep. But then in his dream, the pattern of glowing coal...
The restriction of the divergent thinking to a textual medium or representation is not seen as a limitation because the group is mainly using textual documents as input and usually supplies the result of the reasoning again in a textual representation. To what extent the inclusion of further media would increase innovation in thinking in a similar setting is an interesting question and could be addressed with dedicated research. The use of whiteboards during face to face meetings to collect people's opinion was abandoned after the introduction of the threaded discussion forum, but tools such as problem rephrasing and problem / solution inversion (Sloane, 2003) or Ideawriting (Moore, 1987) have also been used successfully in our group reasoning meetings.

Limitations of the threaded discussion forum were expressed by the user group in a review meeting 12 months after the start of the first pilot implementation and attended by all 14 members of the user group. The meeting particularly commented on the inability to cluster related discussions automatically. This shortcoming makes it difficult for the staff to identify similar previous discussions because they are difficult to locate and tend to get scattered as the forum gets more and more populated.

Other limitations became overt as well. Those limitations were not grounded in technology or its deficiencies, but in human or social factors. During the roll-out of the methodology described in Section 4.3, it became evident that the group's behaviour could be divided into about 30% early adopters (they used both discussion forum and group reasoning consistently from the introduction), 50% slow adopters (used either one from the introduction) and about 20% more reluctant staff (didn't use either one). Whilst this issue was relatively straightforward to address in that rather small group of 14 staff of the Medicine and Science group by intensified influencing and training of individuals, the inspired him to think of hexagonal arrangements, thus solving the mystery of the benzene structure he was after for so long. Interestingly, he could not solve the problem whilst working in his laboratory.
The author is concerned that this may well be a significant hurdle for an intended wider roll-out of the methodology within AstraZeneca. This finding is well in line with research by Malhotra (2002), Barth (2002) and Sarnoff and Wimmer (2003). Apart from the fascination and power of technology-enabled knowledge management (KM), these authors found it important to address the cultural aspects of KM (awareness, rewards and recognition and the involvement of HR) with the same drive and effort as the technological aspects. The papers by Malhotra (2002), Barth (2002) and Sarnoff and Wimmer (2003) analysed failed cases of knowledge management introduction. It is apparent from these findings that the reason for many KM failures was that organisations did not adequately address cultural and social aspects and the fact that successful KM initiatives need to be embedded in people's daily work processes.

Early consultations with AZ Human Resources and senior management were initiated to focus on these important cultural aspects, but the details are outside of the scope of this thesis and are subject to ongoing research and collaboration with Loughborough University. Results will be reported elsewhere. In the meantime, the decision making process developed as part of this research, continues to be successfully used in the second pilot environment of the Clinical Pharmacology group at AstraZeneca.

While there is still some development work on the cultural aspects around the use of the decision making process for use in the wider company context, the introduction of a different group reasoning process has nevertheless to be considered an improvement over the previous situation, by at least 80% of staff involved (fast and slow adopters), who now used it regularly.

After the initial improvements of group reasoning as reported above, the research is now focusing on improvements of the information capture and information storage model, which will be described in the next chapters.

The overall evaluation of the new decision support framework will be done in Chapter 7 when all components have been implemented.
4.5 Summary of Chapter 4

A review meeting was carried out 12 months after the start of the first pilot implementation and was attended by the author and all 14 members of the user group. In a round table review, users have reported benefits and limitations of the novel process as described in Section 4.4. The unanimous opinion of the user group was that the new process was superior to previous working practice in their group reasoning meetings and expressed their interest to work with the author on refinements. The overall evaluation of the new decision support framework will be done in Chapter 7 when all components have been implemented.

The combination of two collaborative mediums, namely an asynchronous discussion forum together with a synchronous medium represented by the digesting and summarisation meetings, was also found to allow a greater depth and clarity of knowledge generation than would be possible by simply adopting one of these techniques by Veerman and Veldhuis-Diermanse (2001).

The process described in this chapter already considers or implements several of the ‘ten guiding principles of knowledge management’ identified by Davenport (1996) and listed below:

1. Knowledge management is expensive (but so is stupidity!)
2. Effective management of knowledge requires hybrid solutions of people & technology
3. Knowledge management is highly political
4. Knowledge management requires knowledge managers
5. Knowledge management benefits more from maps than models, more from markets than from hierarchies
6. Sharing & using knowledge are often unnatural acts
7. Knowledge management means improving knowledge work processes

-79-
8. Knowledge access is only the beginning
9. Knowledge management never ends
10. Knowledge management requires a knowledge contract

The action research methodology was used to investigate and develop the anticipated decision capture methodology and the related toolset (see the review of research methodologies in Chapter 3). The procedures around action research align very well with the 'results driven incremental technique' as proposed for the development of information systems by Fichman and Moses (1999). This methodology follows a bottom up process by designing small pilot systems and evaluating and refining them as experience has grown. The first iterative cycle of this knowledge management implementation at AstraZeneca Clinical Development used a threaded discussion forum to prepare decision making meetings to save meeting time and an information model to capture and disseminate the knowledge in a structured manner for improved future re-use.

Chapter 5 will now discuss the implementation and testing of the first information model (KNO v1).
Chapter 5 – RDF/XML Knowledge Objects with Metadata

5.1 Scope

The first part of chapter 5 introduces a novel decision capture format, KNO v1, as already mentioned in the previous chapter. The second part evaluates this novel storage format in order to identify the benefits and also the shortcomings when used in practice from the internal point of view of the user group.

Research methodologies employed in this Chapter are brainstorming and prototyping, which are used to justify action intervention prior to each iterative prototyping and to identify and prioritise areas for improvement. They also provide a reflective learning on the shortcomings of the previous prototype. Brainstorming sessions are usually performed as 3 hr sessions, with mixed audience (details given in Sections 5.2, 5.3, and Section 3.6).

5.2 Implementation of a New Decision Capture Format in AZ Clinical

As pointed out by Tiwana (2000), one of the most important differences between an information repository and a knowledge repository is that the knowledge entities within a knowledge repository are annotated with context. According to him, this context is required by the definition of the word 'knowledge'. Contextual aspects could be declarative knowledge such as:

- the business environment,
- assumptions, procedural knowledge such as sequence of events that happened
and, when it comes to decisions:
- causal knowledge such as rationale for decisions,
The richness of the knowledge entity should enable subsequent users to recall precisely what happened, why it happened and why things were done the way they have been done. It is this richness that puts a future user into the position to understand a previous case and to learn by abstraction from a case represented by a given knowledge entity and relate this to his or her own situation. The understanding of a previous situation and the learnings derived may however be complicated if there is a considerable difference between the 'front version' and the 'back version' (Goffman, 1959) of a previous decision context, particularly if the front version only is captured. It is therefore important that the knowledge manager is aware of this issue and aims to reflect the 'whole truth' and 'nothing but the truth' as best as he can, otherwise the value of the capture will be much reduced or can even be misleading at future reviews.

The insights from the literature review as well as the observed shortcomings of current company documents to provide an accessible and understandable repository of previously created knowledge and decisions, led to the creation of the first version of information entities introduced by the author. These entities are referred to as knowledge objects (KNO) in the remainder of this thesis. The name was chosen in analogy to the learning objects proposed by Parchoma (2002). This first version of knowledge objects was used as the storage format in the first pilot decision capture processes described in Section 5.3.1.

Having established the suitability of XML in the literature review, the implementation of a new information model was developed with XML files that use metadata to annotate the knowledge content. The use of Dublin Core metadata is supported by the literature review (see Section 2.4.3). This novel model was developed to facilitate the capture and dissemination of knowledge/decisions generated in a more structured manner. A similar approach and justification for supporting the knowledge lifecycle with metadata annotated
knowledge entities was proposed by Uelpenich, and Bodendorf (2003). These authors called the metadata they are suggesting "Attributes of Explicit Knowledge"

The author sought advice from information experts within AZ early on in the design of the information model, which provided invaluable help in its construction¹. These discussions helped the author to understand the use of XML in the context of a big company, which facilitated the acceptance and implementation by the corporate Information Systems function. In accordance with the insights from the literature review, RDF/XML was ultimately chosen in order to provide a framework that is able to represent semantic meaning and interdependencies of the metadata. As discussed already in Section 2.4.3, this semantic interrelationship of metadata should provide an additional, independent machine reasoning layer within the case based reasoning paradigm.

According to Wess, Althoff and Richter (1993), a case base representation can be flat where all cases have the same hierarchical level, or a hierarchical order. The latter is suitable for taxonomical tasks (e.g. to identify an animal based on features), the former is suitable for the anticipated decision capture as the decisions to be captured are usually at the same "level", i.e. they are all made in the context of individual development projects and not above or below this level. It was therefore decided to start the case base with a flat file structure containing knowledge object instances in the form of single xml documents. A provision to link related KNOs to each other is nonetheless made through the introduction of a dc:relation element (see below).

¹ The author is particularly grateful to Kerstin Forsberg in Information Strategy, Clinical Information Science, AstraZeneca, Sweden, for intense discussions on the practical use of XML, RDF/XML and metadata for the aims and objectives of this research.
The author decided to start with a low level of granularity with each KNO having one sub-level of attributes as shown in Figure 5.01 and to implement a higher granularity as needed and driven by ongoing research rather than making too many upfront assumptions about the appropriate level of granularity.

An overview of the first information model developed in the current research (KNO v1) is depicted in Figure 5.01. The KNO v1 implements Dublin Core metadata (see Chapter 2) as well as proprietary metadata under the azkno namespace. Most of the metadata are self explanatory but a few deserve a more detailed discussion:
• The azkno:issue element is not part of the Dublin Core namespace but was introduced by the author within its proprietary namespace in order to capture 'issues' that could not be resolved in the discussions that led to the creation of this knowledge object, but that the group wanted to follow.

• The dc:subject element provides one or more keywords or key phrases (one per element) that give contextual information about the subject under discussion.

• The azkno:category element provides one or more categories (see below) for the creator of the KNO to include. This is aimed at enabling more relevant search and retrieval. This element is introduced again in the proprietary namespace "azkno".

• The dcterms:valid elements contains an expiry date that can be specified by the creator at creation of the KNO. The aim was here to flag possible knowledge, information or decisions that may be invalidated by an upcoming event.

• The dc:relation element optionally provides links to relevant resources, references or other related KNOs. The latter could enable the creation of a 'KNO network'.

• The dc:terms:abstract element was chosen to contain the content of the KNO. This content is usually textual information in natural language and contains the issue under discussion as well as possible solutions / recommendations.

A set of categories was agreed in a brainstorming session involving all 14 staff of the user group in the first pilot process. This involved a meeting of about three quarters of an hour convened specifically for this purpose. The discussion was moderated by the author to ensure all participants had their say and suggestions were put with stickers on a whiteboard for all to see. The discussions continued with a clustering of related topics until all participants reached a consensus. Then the following categories were assigned to the clusters by the group:
• Safety
• Pharmacodynamics / Biomarker
• Pharmacokinetics
• Modelling
• Simulation
• Patents
• Project
• Guidelines
• Methodology
• Other

Figure 5.2 shows a screenshot of the KNO browser application, a support tool developed by the author and implemented as an Active Server Pages (ASP) application to be called through the web browser on the client machines. Available KNOs are available for edit only to their creator (and to the system administrator).

Figure 5.3 shows a screenshot of the KNO as rendered in HTML through the application of an XSL stylesheet. This is the view the user gets on the XML KNO when clicking on a particular KNO within the KNO browser application window.
Available Knowledge Objects

- The icon 'new' indicates Knowledge Objects that are less than 2 months old
- The edit button enables to re-edit certain aspects of a Knowledge Object (creator only)

<table>
<thead>
<tr>
<th>Title</th>
<th>Creator</th>
<th>Date Created</th>
<th>Edit</th>
</tr>
</thead>
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<td><strong>Category Safety</strong></td>
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<td></td>
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<td>2004-08-25</td>
<td>edit</td>
</tr>
<tr>
<td>Eclysis digital ECG - lessons learned</td>
<td>newbold_p</td>
<td>2003-12-17</td>
<td>edit</td>
</tr>
<tr>
<td>how to assess host-defense issues with investigational drugs</td>
<td>adelmann_h</td>
<td>2003-06-24</td>
<td>edit</td>
</tr>
<tr>
<td>ICH_E14_comments</td>
<td>adelmann_h</td>
<td>2004-08-03</td>
<td>edit</td>
</tr>
<tr>
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<td>adelmann_h</td>
<td>2003-05-16</td>
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<tr>
<td>MCT1 and heart adverse effects</td>
<td>mclean_l</td>
<td>2002-07-30</td>
<td>edit</td>
</tr>
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<td>edit</td>
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<tr>
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<td></td>
<td></td>
</tr>
<tr>
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</tr>
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<tr>
<td>combination patents in rheumatoid arthritis</td>
<td>adelmann_h</td>
<td>2003-06-16</td>
<td>edit</td>
</tr>
<tr>
<td>Combination respiratory patents</td>
<td>snell_n</td>
<td>2003-02-17</td>
<td>edit</td>
</tr>
<tr>
<td>COPD basics</td>
<td>newbold_p</td>
<td>2002-07-10</td>
<td>edit</td>
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<tr>
<td>Strategy for ventricular fibrillation issues of MCT drug candidates</td>
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<td>MCT1 and heart adverse effects</td>
<td>mclean_l</td>
<td>2002-07-30</td>
<td>edit</td>
</tr>
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</table>

... more categories in between ...

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<td>2003-03-05</td>
<td>edit</td>
</tr>
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<td>2003-12-19</td>
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<td>2003-05-23</td>
<td>edit</td>
</tr>
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<td>Challenge Agents - GMP MSU manufacture, lessons learnt</td>
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<td>2003-08-21</td>
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</tr>
<tr>
<td><strong>Category Other</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paediatric Regulatory Issues</td>
<td>mula_h</td>
<td>2004-02-24</td>
<td>edit</td>
</tr>
<tr>
<td>Investigator Panel to provide RA patients</td>
<td>corfield_j</td>
<td>2003-04-02</td>
<td>edit</td>
</tr>
</tbody>
</table>

Fig. 5.02: KNO Browser screenshot.
### Knowledge Object

**Title**: Food restrictions guidance document for FTM studies  
**Identifier**: foodrestrictions03  
**Creator**: John H  
**Creation Date**: 2003-03-06  
**Expiry Date**: 2005-03-06  
**Category**: Methodology  
**Category**: ME  

#### Summary

<table>
<thead>
<tr>
<th>Title</th>
<th>Food restrictions guidance document for FTM studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifier</td>
<td>foodrestrictions03</td>
</tr>
<tr>
<td>Creator</td>
<td>John H</td>
</tr>
<tr>
<td>Creation Date</td>
<td>2003-03-06</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>2005-03-06</td>
</tr>
<tr>
<td>Category</td>
<td>Methodology</td>
</tr>
<tr>
<td>Category</td>
<td>ME</td>
</tr>
</tbody>
</table>

#### Subject

- Subject reflects keywords (unlimited number) for the context the item has been discussed in. These keywords can be used e.g. for linking this Knowledge Object to others.

<table>
<thead>
<tr>
<th>Subject</th>
<th>food</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>restrictions</td>
</tr>
<tr>
<td>Subject</td>
<td>inhibitors</td>
</tr>
<tr>
<td>Subject</td>
<td>inducers</td>
</tr>
</tbody>
</table>

#### Future Issues

- Future Issue reflects aspects (unlimited number) of the item that have not been resolved within the discussion that created this Knowledge Object thus indicating further work/research. These issues usually should give rise to further discussions down the current thread.

<table>
<thead>
<tr>
<th>Future Issue</th>
<th>Need to consider professional dietary advice about what is considered a moderate caffeine diet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Future Issue</td>
<td>Confirm the potency of red wine as an inhibitor of CYP450 enzymes</td>
</tr>
<tr>
<td>Future Issue</td>
<td>Judges and Havosh need to take up the issue of getting enzymeology data from DDMR earlier in the development package to aid in prediction of interactions by CYP inhibition (eg SimCYP) and to aid in Clearance predictions (SimCYP)</td>
</tr>
<tr>
<td>Future Issue</td>
<td>Need to review restrictions as the phase 1 programme progresses</td>
</tr>
</tbody>
</table>

#### Solution

- Solution reflects URLs to resources (unlimited number - documents, other knowledge objects, external/internet sites etc.) that are linked to this Knowledge Object.

| Solution | Internal Document |

#### Description

- Description represents the context of the Knowledge Object.

Many thanks for the comments regarding food restrictions in FTM studies. The discussion mainly centered around the policy for inclusion/exclusion caffeine and smokers in the studies, as well as agreeing the restriction periods that were to be enforced for a number of other foods.

**Caffeine restrictions**

- It was discussed at length whether to restrict caffeine in the volunteers. Caffeine is known to have CNS and cardiovascular effects however these are minimal in individuals who are moderate drinkers of caffeine. In addition withdrawal symptoms include headache, drowsiness, fatigue and anxiety in subjects who only consume low levels of caffeine. It was therefore discussed that the major withdrawal symptoms were associated in subjects who were heavy caffeine drinkers and that the limits of moderate caffeine drinking should be between 100 and 200 mg per day. Therefore unrestricted intake is thought to be safe provided that caffeine intake is less than 200 mg per day. Further commented that in the...

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**Fig. 5.03: KNO HTML rendition.**
5.3 Evaluation of the Novel Storage Format (KNO v1)

The KNO v1 was used to capture group decisions and consensus for about one year by the Medicine and Science group. During that time, 21 knowledge objects were produced in that format, almost all of them during a group reasoning meeting, following a pre-discussion on the threaded discussion forum.

In a review meeting with the user group 12 months into the use of KNO v1, several benefits of the novel information model and the supporting browser tool were named. The benefits of the tool included a structured and harmonised rendition of the XML into human readable HTML so that the information contained in the knowledge object was easy to recognise and to navigate by staff.

The fact that metadata were present enabled an improved categorisation and thereby helped retrieval through the KNO browser application. It was, however, stated by the users that the fixed set of categories, chosen in early 2003 when the KNO browser application was developed, may become quite limiting for future use as the function developed further. Any new development would have to be reflected in the category set. A valid criticism was that there would be an ongoing need to review and eventually amend this category list and to even change some that already exist. This would have consequences for any existing KNO entities, because they contain hard coded categories (see the azkno:category element in Figure 5.01). It was agreed that there was a need for a more elegant way of categorisation. The research was extended accordingly, because of the significance of this finding. The implementations and results of the research into a more flexible means of categorisation are discussed in Chapter 8.

A review and classification of the 21 KNOs created in the v1 template revealed that the majority (13) were actually capturing a decision process, two of them
were 'lessons learnt' documents and the remaining six were document reviews with harmonised group comments, guidance documents and methodology descriptions.

Overall, several shortcomings of this first KNO version were identified:

- The presence of static categories hard coded into the KNOs: This has limitations in terms of extensibility as discussed above.
- A lack of compliance with the case based reasoning paradigm with very few attribute-value pairs (e.g. unclear problem-solution, or problem-decision mapping): The KNO content was rather verbose, consisting of unstructured natural language text.
- A lack of further content sub-structure: This was mostly verbose natural language text without the ability to easily perform machine exploitation.
- Metadata not expressive enough for decision capture when compared to the decision attributes the literature review had already suggested: The metadata were mainly focused on document properties (name, title, author, categories, creation and expiry date, publisher, domain, format, relations etc.) rather than on decision properties. The only metadata implemented thus far that were related to decision properties were context and issue.

In accordance with the textual case based reasoning paradigm, the knowledge objects, which, represent instantiations of the information model, were highly specific, natural language, knowledge representations where case authoring was done manually through domain experts. As there was no application available to produce the XML, the group members were supported by the author with regards to manual XML file editing. Although this manual editing was found to be doable after some days of training, the time taken meant it was only practical to limit the task to just a few individuals. This was clearly identified as another issue to be addressed in later development phases.
5.4 Summary of Chapter 5

The action research methodology was used to investigate and develop the anticipated information model and toolset (see the review of research methodologies in Chapter 3). A first information model (KNO v1) was designed to capture and disseminate generated knowledge in a structured manner for improved future re-use.

A review of KNO v1 identified some shortcomings, and this prompted the author to carry out an extended brainstorming with experts, both within AZ (end users as well as IS staff) and from the Loughborough University Computer Science and Information Science departments. This next step of the KNO evolution, reported in Chapter 6, aimed to refine the information model and then re-evaluate its success.
Chapter 6 – RDF Knowledge Objects with Decision Attributes

6.1 Scope

The previous chapter described a new information model for knowledge capture and sharing (KNO v1). The review of 21 KNOs created in that format provided another validation of the aims and objectives of this thesis as it revealed that, in most of the cases, the Medical Science group was aiming to map a collective decision process. Chapter 5 also concluded with the identification of shortcomings of the knowledge object version 1, particularly its lack of compliance with the case based reasoning (CBR) paradigm with few attribute-value pairs (except Dublin Core document metadata), the lack of a sub-structure within the often verbose natural language content and, most importantly, metadata that were unlikely to be expressive enough to map a decision making process.

This chapter reports the next refinement of the KNO information model, according to the aims and objectives of this thesis and the concepts around decision mapping and case based reasoning as reviewed in Chapter 2. It begins with a description of the process the author has adopted for his action research approach for an incremental improvement of the KNO information model.

The next part of this chapter discusses improved metadata that are derived from the review of the literature in Chapter 2, the analysis of the 21 KNOs created by the Medical Science group in the version 1 template and during brainstorming with both internal and external experts.

Section 4 of Chapter 6 describes the new information model KNO v2 and how this gives a better fit with the aims and objectives of the author’s research.
The final section evaluates the novel KNO v2 information model to assess the improvement over KNO v1. However, this section also discusses remaining shortcomings that became overt during daily work in the Medical Science group.

Research methodologies employed in this Chapter are brainstorming and prototyping, which are used to justify action intervention prior to each iterative prototyping and to identify and prioritise areas for improvement. They also provide a reflective learning on the shortcomings of the previous prototype. Brainstorming sessions are usually performed as 3 hr sessions, with mixed audience (details given in Sections 6.2, and Section 3.6).

6.2 Brainstorming and Results Driven Incremental Technique as part of the Action Research approach

After a thorough review of the 21 KNOs created with KNO v1, the author invited experts from both AstraZeneca (AZ) and Loughborough University to brainstorming sessions on how to improve the KNO v1 template in alignment with the aims and objective of the author’s research.

According to Kock et al (1997), Fetterman (2002), and Howard and Eckhardt (2005), brainstorming fits in well with action research. It also aligns well with the ‘results driven incremental technique’ for the development of information systems as proposed by Fichman and Moses (1999). Other process models for systems engineering under evaluation by the author were the quite similar, iterative ‘spiral model’ (Boehm, 1985), the ‘waterfall model’ (Royce, 1970), and the ‘Vee model’ (Wason, 2006). The ‘waterfall model’ was de-prioritised by the author because of the one-dimensional nature of the analyse-design-code-test paradigm; It was felt impossible in the current setting of ongoing research for the optimal system design that all requirements for the system can be correctly and completely stated in the beginning. The ‘Vee model’ was also rejected as its main aspect is a
decomposition of the project into smaller and smaller pieces in order to manage system development risk, which again requires a large amount of pre-planning and pre-consideration which is considered appropriate in the current research as point out above. Hence a stepwise, iterative approach was deemed appropriate in the current setting and the 'results-driven incremental strategy' was chosen which is in fact a derivative of the Boehm 'spiral' model.

The results-driven incremental strategy was developed as a consequence of observed pitfalls of more traditional all-at-once implementations. The traditional implementation strategy, together with the results-driven incremental strategy, are depicted graphically in Figure 6.01. The horizontal axis represents time and, according to Fichman and Moses, may also be viewed as a rough proxy for implementation cost. The vertical axis represents the amount of business benefit enabled by the implementation. The traditional approach not only delays the arrival of business benefits until the end of the project, but has other important issues as well. It allows, and in fact encourages, implementers to focus on technology itself instead of the corresponding organizational changes required to actually derive value from their implementation. In addition, the absence of clear linkages to the user community invites "over-engineering," that is implementing functions that may never be used or adding features that are not necessary to achieve desired business value.
The most obvious advantage of the results-driven incremental approach is simply that the stream of business benefits arrives much sooner (area A in Figure 6.01). Implementation steps frequently involve the target user group and increase both quality and acceptance of the implementation. According to Fichman and Moses (1999), implementers following the results-driven incremental approach have found that it not only compresses the time to getting some benefit, but it dramatically shortens the time to complete the entire initial implementation and increases the overall level of project benefits. These additional benefits (represented by area B in Figure 6.01) arise from combining incrementalism with a strong focus on the end user and the anticipated business results.

The action research cycle proposed by Howard and Eckhardt (2005) was implemented within the author's research as follows: The author invited staff from AZ Medical Science (part of the KNO user community), from AZ Information...
Systems (informaticians and librarians), and from the Computer Science and Information Science departments of Loughborough University for several brainstorming sessions.

Brainstorming sessions were held 4 times during the year in which KNO v2 was in development. On average 4 AZ staff and 2 Loughborough University staff attended. These meetings were scheduled three hours each. People were selected by the author with regards to the problem to be addressed at each meeting. No pre-meeting literature was distributed but the agenda was communicated in order for the participants to prepare.

Each brainstorming session started with an initial problem / ideas presentation by the author (30 minutes maximum). The author moderated the following course of the meeting and consolidated the ideas brought forward from time to time summarising the evolution of the ideas presented so far, and giving a reminder of outstanding issues that needed further discussion if necessary. During this phase he used Mind Mapping as proposed by Buzan and Buzan (1996) to capture and cluster topics as they were mentioned. The allowance for the free brainstorming was usually 2 hours. The last 30 minutes were spent on consolidation of topics and agreement of consequences.

These brainstorming sessions:

1. Analysed the previously generated knowledge objects, the underlying information model and the shortcomings discovered when creating the KNOs in practice, with the author also contributing important concepts revealed during his literature review.

2. Discussed and suggested improvements to the implementation of the knowledge objects and underlying information model.
After each iteration of implementation changes to the information model, the end user community, i.e. Medical Science staff, were asked to provide reflections on the implementation steps with regards to usability of the KNO information models. The dissemination of each new iteration concept and the gathering of the views of the Medical Science group were significantly aided by 2-3 staff of the Medical Science group also being part of the multi-disciplinary brainstorming group. Figure 6.02 depicts the action research cycle of action, implementation and reflection as outlined by Howard and Eckhardt (2005).

![Action Research Cycle](image)

**Figure 6.02: Action Research Cycle after Howard and Eckhardt (2005)**

### 6.3 Identification of Attributes to Map a Decision Process

The literature reviewed in Chapter 2 discusses several decision aspects or 'descriptors' of a decision process from several different domains and, through the author, this literature became an input to the brainstorming sessions. The suspicion, reported in Chapter 4, that the metadata model of KNO v1 lacked the expressiveness necessary to capture a human decision process was confirmed during the brainstorming sessions. From these sessions, a set of generalized descriptors was derived that should warrant further investigation for their usefulness to describe a decision making process in its genuine richness within the current domain and to make the decisions transparent for other (non-involved) readers. At the same time, the level of abstraction of these descriptors aimed to make the model applicable to any decision making process in the
pharmaceutical business in order to facilitate any later broadening of application through AZ, should the information model prove to be successful.

<table>
<thead>
<tr>
<th>Decision Attributes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Context</strong></td>
<td>Business context the decision was made or needed in</td>
</tr>
<tr>
<td><strong>Sequence of events</strong></td>
<td>A sequence of events that triggered an issue</td>
</tr>
<tr>
<td><strong>Definitions</strong></td>
<td>Some useful definitions used in the documentation of the context, issue and/or decision, e.g. acronym resolution, sense disambiguation etc. to facilitate both human and computer 'understanding' of the matter.</td>
</tr>
<tr>
<td><strong>Issue</strong></td>
<td>A crisp description what the issue was</td>
</tr>
<tr>
<td><strong>Assumptions</strong></td>
<td>Underlying assumptions that are preconditions for the decisions</td>
</tr>
<tr>
<td><strong>Decision</strong></td>
<td>A crisp description on what the decision was</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td>Links to documents, web resources etc. that were used in the decision making and may help a reviewer to gain more insight</td>
</tr>
</tbody>
</table>

Table 6.01 Decision attributes derived from the brainstorming sessions

Consensus was obtained in the brainstorming group and the descriptors listed in Table 6.01 were chosen to be used in the next phase of the research. For ease of reference they are from now on called decision attributes. According to the metadata discussion in Chapter 2, these decision attributes are to be regarded as specific metadata.

6.4 The Implementation of the Knowledge Object Information Model v2

KNO v2 is based on the metadata already implemented in v1. Further metadata were added, mainly to support an optimised decision mapping as discussed in Section 6.3. Some metadata elements changed their meaning or were dropped.
The brainstorming suggested that the "issue" element in KNO v1 which was intended to keep issues that are not resolved at the creation of the respective KNO should not be used as such but should instead capture the issue that prompted the decision process captured in the KNO as this is would align the KNO much more with the decision making process in general where a decision is preceded by an issue to solve.

The brainstorming suggested, furthermore, that the information model should provide for more than one decision to be captured with each issue, as there may be more than one solution to any given issue. Interestingly, this was actually confirmed by the review of the 21 existing KNOs (v1), where the Medical Science group had already come up with different possible options to one subject in five of the 21 KNOs. The implementation should, therefore, take into account the multiple possible decision attributes for one given issue.

Four additional brainstorming sessions, conducted in a similar style to those discussed in Section 6.3 but consisting of only Medical Science group members (on average 3 representatives) were concerned with the implementation of the information model considering real life usability. These sessions with the end users indicated, furthermore, that there would be a need to capture options that were considered but finally rejected as they are usually not captured in meeting minutes. In fact, not a single AZ standard document that was reviewed, as described in Chapter, 4 had captured an option that was discussed but finally rejected. Only the final agreed decisions were captured. In a following discussion in a meeting of the whole Medical Science group, this was not believed to reflect the real life decision process as the discussions usually consider several options from the beginning as nearly all Medical Science group members recalled, but obviously only the agreed outcome seemed to be captured by default.

Everyone in the Medical Science group indicated, however, that capturing non-adopted options together with their reason for rejection would provide an
excellent contribution to the understanding of the decision process. This is supported by the findings of Cooper et al (2005) who discuss the impact of an organisational learning tool in NASA’s Jet Propulsion Laboratory (JPL): “The system does, however, provide a means of reinforcing previous learning for repeat visitors, and can help new employees begin the acculturation process. Even the obsolete questions serve a purpose by capturing a snapshot of the organization and key personnel ... ”. As a consequence, a “rejected” attribute was implemented that could have zero or many occurrences in each KNO.

The review of the 21 existing KNOs (v1) revealed, furthermore, that some KNOs represented decisions that were made sequentially and thus are somehow linked. The Medical Science group found that knowing about this linkage was very useful as it enabled them to track a complex, multi-step decision process / progress. Some simple visual decision mapping tools discussed in the literature are also designed to capture multi-step decision processes, for example the IBIS Map (Kuntz and Rittel, 1970; Conklin and Begeman, 1989). A brainstorming of the multi-disciplinary group around this subject finally led to the implementation of triggers and outcome attributes, with the linkage of related KNOs accommodated in the sequence of events attribute that is mentioned in Table 6.01.

Because of the ongoing nature of decisions, the multi-disciplinary brainstorming group felt that it would be necessary to have some time constraint on the KNO in order to avoid it being an open ended container. This led to the introduction of the concept of a pending issue, together with an issue due date and a responsible person to track an anticipated timeline by which an issue is expected to be resolved.

The v1 expiry date was dropped because, upon a review of the 21 existing v1 KNOs, an expiry date was found to be more suitable for the ‘guidance’ type KNOs because they may represent advice that is subject to review because of changing regulatory requirements in the drug development industry. The Medical
Science group agreed that as the focus of research was clearly on decision KNOs which represent the current thinking at the time they are created (including the assumptions, etc., at that time), they therefore represent a valid snapshot in time and so would not need an expiry date.

Because of the complexity of the outlined new KNO structure, the multidisciplinary brainstorming group felt it would be useful to add a summary attribute which would enable a human reader to gather quickly what each KNO is about. This led to the implementation of an *abstract* attribute.

The Medical Science group came to the conclusion that the static categorization introduced by the azkno·category element in KNO v1 had the disadvantage of an immense maintenance effort. The Medical Science group recognised that after two years of operation, two new categories already warranted their inclusion, namely *disease* and *regulatory concerns*. As a consequence, all existing KNOs would need to be reviewed for a possible inclusion of these newly added categories. Furthermore, the KNO Browser application (see Chapter 5) would also have required some code change, as it expected certain categories which were hard-wired into the software. It was decided to drop the category element in KNO v2. A brainstorming was done instead, again involving experts from AZ Information Systems and the Loughborough University Department of Computer Science, in order find some means of ‘dynamic categorisation’ that would be flexible with regards to category extensions and would not imply any changes to the source documents (KNOs). This brainstorming initiated the development of a much improved categorisation and search concept which was developed in parallel of the KNO version 2 and is, therefore, reported and discussed in another part of this thesis (see Chapter 8).

Having constructed the new decision mapping structure of KNO v2 the multidisciplinary brainstorming group decided to drop the “subject” element used in KNO v1 to capture keywords and keyphrases to give contextual information, as
this information is now more suitably allocated to the azkno:context tag which is a child element to the azkno:issue tag.

The discussions reported above finally gave rise to the second version of the KNO information model (KNO v2), which is depicted in Figure 6.03.
Fig. 6.03: KNO information model version 2 (KNO v2)
Figures 6.04 and 6.05 show an excerpt on how the mapping of sequential decisions was performed with the KNO v2 architecture. Figure 6.04 depicts a visual map fragment drawn from the KNO and Figure 6.05 represents the corresponding RDF/XML fragment.

Note that the decision in the top left corner as well as the rejection (bottom left) have triggers from outside the decision tree, whereas the other two decisions are triggered by outcomes within the decision tree. Decisions and rejection have associated assumptions.

**Fig. 6.04: Excerpt from a decision mapping done with KNO v2 – Visual Map**
Note that, because of space limitations, not all elements are fully expanded. Decisions 6 and 7 and the rejection have their triggers expanded whereas decision 8 has assumptions expanded.

Fig. 6.05: Excerpt from a decision mapping done with KNO v2 – XML.
6.5 Evaluation of the Knowledge Object Information Model v2

Because of the complexity of the new information model as compared to KNO v1, evaluation of KNO v2 was done through user group debriefing after creation of each of the new version 2 KNOs. These debriefing sessions took the form of a short meeting of the staff involved in the creation of each KNO, chaired by the author, in which all participants were invited to describe their experiences and opinions of the process. The KNO template v2 was used to generate only two knowledge objects, the reasons are given below. Both KNOs were created with hindsight in order to map sequences of decisions made previously. The Medical Science group found that a capture of a whole sequence of decisions in one KNO is rather too complex to be applied in daily work. The biggest perceived drawback, however, was the fact that KNO v2 was found to be mainly suitable for post-hoc capture. The issues with the practical use of KNO v2 as collected by the author during the debriefing sessions were:

- The focus of information model v2 was more on decision linking than on actual decision support. This became overt in the fact that the presentation of decisions captured with KNO v2 to uninvolved members of staff still exposed weaknesses in decision transparency and therefore understanding. The user group felt that each individual decision could possibly be described in a richer manner using more decision attributes in order to improve the portrayal of individual decisions.

- The issue due date in KNO v2 was found of limited use in real life because the anticipated ‘issue is supposed to be solved’ time had to be revised once for each of the KNOs created, because it was estimated too optimistically on both occasions.

- The notion that the KNO itself is not a finalized entity with regards to the decisions captured until the issue due date has expired, was found irritating. When should that process of adding more decisions into one KNO end, given the fact that the issue due time could be extended?
The notion of a 'responsible person' is likely to create a 'cultural issue' and acceptance problems for the system as people were not happy to be responsible for something that is an effort of the whole Medical Science group.

The distinction between decisions and 'rejected decisions' or rejections was found unnatural. The Medical Science group felt that both represent options that were discussed but received different acceptance and there should be a better means of capturing that outcome. A proposal was to separate actual capture and outcome annotation – both physically within the information model architecture as well as in time - which would also have the advantage of making the KNO an entity which is more linked to activities in the present.

The process of KNO v2 authoring was still regarded as time consuming, given the fact that the information within the KNO had greatly expanded over v1 and there was no application to prevent the user from being exposed to plain XML editing.

Even though the KNO v2 information model had quite a few issues as discussed above, several beneficial aspects of the second refinement were recognised whilst applying the KNO v2 template in real life or in the user group debriefing thereafter. These benefits include:

- The implementation of decision attributes such as triggers and assumptions as specific metadata over and above the document type metadata of KNO v1 was perceived as a step forward.
- The ability to link decisions in order to map a 'decision tree' was considered useful compared to KNO v1 where the relation element was used for both related source documents and KNOs.
- A separation of decision capture in one instance of time and some outcome annotation in a second instance was felt worth pursuing by the Medical Science group in a next refinement. This is well in line with recent findings by Mackenzie et al (2006) as they claim that, given the dynamic...
nature of decision-making teams and the long-term consequences of
decisions, there would also be a need for decision support systems to
allow decisions to be recorded, revisited and changed. This propagated
decision life cycle support is much in line with the aims and objectives of
the author's research in order to provide a means for decision re-visiting
and organisational learning as outlined in Section 1.4.

6.6 Summary of Chapter 6

The second step in the iterative development of an information model for
decision support was generally perceived as useful by the user community. The
most significant advancements were the beginning of an implementation of more
decision specific metadata, more advanced concepts around decision linking and
the proposed separation of decision capture and outcome annotation. The most
significant drawback of KNO v2, as perceived by the user community, was the
difficulty in using that Information model for forward planning. Therefore it was
decided to make an early move to the next refinement stage.

The action research approach adopted for the development of KNOs with multi-
disciplinary and subject-specific brainstorming sessions, architecture refinements
and subsequent testing by the user community under real life conditions fully
implemented the Action Research Cycle described by Howard & Eckhardt
(2005), as discussed in section 6.2 and depicted in Figure 6.02.

The involvement of experts, again both from within AZ (end users as well as IS
staff) and the Loughborough University Computer Science and Information
Science departments, has once again proven useful. The next incremental
development, reported in Chapter 7, aimed to refine the information model once
again implementing the lessons learnt and then evaluating its success.
Chapter 7 – RDF Knowledge Objects with Decision Attributes, Scenarios and Risk Management Features

7.1 Scope

Chapters 5 and 6 introduced and described the implementation of information models for knowledge or decision capture. In KNO v1 (Chapter 5), the emphasis was largely on the establishment of an RDF/XML information model to provide, firstly, the appropriate framework for metadata accommodation, and secondly, the introduction of a first set of metadata for the purpose of decision capture. These metadata were considered more or less ‘unspecific’ to any particular problem domain but provided valuable help in document classification and identification. The most significant advancements introduced with KNO v2 (Chapter 6) were the implementation of more decision-specific metadata, more advanced concepts around decision linking, and a clear separation of decision capture from outcome annotation. KNO v2 had only a short life span as it introduced novel decision capture features that were perceived as significant enough to warrant early further development, given the shortcomings that actually limited the day-to-day use of KNO v2. In order to further improve the information model aligned with the aims and objectives of this research, particularly in support of ongoing decision making, more brainstorming with additional internal and external experts was done. In addition, extended customer feedback was acquired in order to align the capabilities with the requirements of project customers external to Medical Science.

The first sections of Chapter 7 describe the extended brainstorming that was started about three months after the implementation and subsequent evaluation of KNO v2, and a survey about Medical Science customer service - looking from both the internal and customer viewpoints - by an external, independent consultant. This survey was initiated totally independently from the author's research as the Medical Science leadership team wanted to have an
independent review of Medical Science performance. It was undertaken in parallel to the brainstorming exercises and refinements that lead to KNO v3 and is reported here simply because it was interestingly able to provide another independent support of the aims and objectives of this research project.

The next section discusses the outcomes of the above and their implications for the current information model (KNO v2). This section is then followed by a section on the actual implementation of an extended information model (KNO v3). The implementation of KNO v3 was paralleled by the re-organisation of AZ Clinical Development and was taken as an opportunity to extend the group reasoning process that worked well in its first pilot implementation (see Section 4.3.1) into the newly created departmental structure as discussed in Section 4.3.2. Finally, Chapter 7 is concluded with an evaluation of KNO v3.

Research methodologies employed in this Chapter are brainstorming and prototyping, which are used to justify action intervention prior to each iterative prototyping and to identify and prioritise areas for improvement. They also provide a reflective learning on the shortcomings of the previous prototype. Brainstorming sessions are usually performed as 3 hr sessions, with mixed audience. A formal questionnaire with open questions is used to gather feedback after the implementation of the EPISTEME framework, which provides an overall evaluation of the combination of personalisation and codification strategies as intended in this research. (details given in Sections 7.2.1 and 7.3.2, 7.5.1, and Section 3.6).
7.2 Further Action Research Activities

7.2.1 Extended Brainstorming

Continuing with the Action Research approach, the multi-disciplinary brainstorming group described in the last chapters was extended by inclusion of more internal and external experts in order to work on the shortcomings identified in KNO v2. The company librarians used to do annotations of digital media were identified as suitable experts to address annotation questions as suggested by Nichols et al (2002). An AZ content management expert as well as an experienced AZ librarian was brought in to discuss and identify the optimal backend for the anticipated knowledge base with regards to the anticipated linkage of KNOs and transaction issues. Brainstorming was carried out on the improvement of features around accepted and rejected options, as proposed already in KNO v2. This revealed immediately, that these discussions touch the domain of risk management which is a skill set developed in project management as pointed out by Haimes (1998), Huchzermeier and Loch (2001), and more recently by Sandøy, Aven and Ford (2005). AZ project management (PM) expertise was therefore sought and provided by the Medical Science knowledge manager (see Section 4.3.1) who had previously worked in PM at AZ.

Brainstorming sessions were held as described in Section 6.2. Briefly, such meetings were held four times during the year in which KNO v3 was in development. On average four AZ staff and two Loughborough University staff attended. Again, these meetings were scheduled three hours each. People were selected by the author with regards to the problem to be addressed at each meeting. No pre-meeting literature was distributed but the agenda was communicated in order for the participants to prepare.
As outlined already in Section 6.2, each brainstorming session started with an initial problem / ideas presentation by the author (30 minutes maximum). The author moderated the following course of the meeting and consolidated the ideas brought forward from time to time summarising the evolution of the ideas presented so far, and giving a reminder of outstanding issues that needed further discussion if necessary. During this phase he used Mind Mapping as proposed by Buzan and Buzan (1996) to capture and cluster topics as they were mentioned. The allowance for the free brainstorming was usually two hours. The last 30 minutes were spent on consolidation of topics and agreement of consequences.

These brainstorming sessions:

1. Analysed the previously generated knowledge object v2, the underlying information model and the shortcomings discovered when creating the KNOs in practice, with the author also contributing important concepts revealed during his literature review.

2. Discussed and suggested improvements to the implementation of the knowledge objects and underlying information model.

After every iteration of implementation changes to the information model, the end user community, i.e. Medical Science staff, were asked to provide reflections on the implementation steps with regards to usability of the KNO information models. The dissemination of each new iteration concept and the gathering of the views of the Medical Science group were significantly aided by two or three staff of the Medical Science group also being part of the multi-disciplinary brainstorming group.
7.2.2 An Externally Performed Customer Service Survey

The Medical Science leadership team approached Bernard Marr from the Centre for Business Performance of Cranfield University School of Management in order to undertake an independent Medical Science performance review. Interestingly, this coincided with the author's research on decision support. Marr's research interests centre on the analysis of organisational value creation mapping and the identification of key success drivers and their interplay, which are largely intangible assets such as knowledge, expertise and communication (Marr et al, 2004a). Marr evaluated intangible asset management and value creation in different industries such as BP, Royal Dutch Shell, Novo Nordisk, The Home Office, Fujitsu, DHL and Thomas Miller (Marr, 2006). Whilst conducting the survey and undertaking the interviews, Marr became interested in the author's research as it was targeting the management of intangible assets such as knowledge and decision making in an R&D environment (see also Pike et al 2005).

The author convinced Marr that an external, independent evaluation of project customer needs, the business support given by Medical Science and its related communication skills would be of immense value to the author's research on decision support as well. Opportunities were seen that Marr's Value Creation Mapping (Marr et al, 2004b) could provide another validation of the author's aims and objectives. It would also provide an evaluation of the direction and progress of the author's research. This assumption is further supported by Ittner and Larcker (2003). Their research found that companies in increasing numbers are measuring customer loyalty, employee satisfaction, and other nonfinancial areas of performance that they believe affect profitability but that they've failed to relate these measures to their strategic goals or establish a connection between activities undertaken and financial outcomes achieved. They argue that the companies they've studied can't demonstrate that improvements in nonfinancial
measures actually affect their financial results. The authors recommend to first, develop a model (the 'value creation model') that proposes a causal relationship between the chosen nonfinancial drivers of strategic success and specific outcomes and then to use established statistical methods for validating the assumed relationships and continue to test the model as market conditions evolve. In another paper, Ittner et al (2003) found that understanding the value creation modelling and analysing it can yield powerful insights that can be used as the basis for better decision-making in an enterprise. Their research indicated that 23% of the companies built and verified their causal value creation models and, in turn, had a 2.95% higher Return on Assets (ROA) and 5.14% higher Return on Equity (ROE) compared to companies that didn't use causal models. Figure 7.01 depicts the Value Creation Map by Marr (2004b).

Fig. 7.01: Value Creation Map. Template overview (Marr, 2004b)
At an initial meeting between Cranfield University Centre for Business Performance and AZ Medical Science management in 2005, agreement was reached and the assessment started by the creation of a structured interview set by Medical Science and Cranfield staff. The interview set covered the following topics and questions:

1. Value Proposition
   a) Why does AstraZeneca Medical Science exist?
   b) What are AstraZeneca Medical Science offering to their customers?
   c) How are AstraZeneca Medical Science adding value to their customers?

2. Value Drivers
   a) What does AstraZeneca Medical Science have to do to deliver [the above]?
   b) What must therefore be AstraZeneca Medical Science capabilities? What competencies / capabilities give AstraZeneca Medical Science a competitive advantage?
   c) What underlies these competencies / capabilities? What are the building blocks of the competitive advantage? What resources underlie these capabilities? What are the resources (tangible and especially intangible) that are the basis for any advantage?
   d) What about Human Resources, i.e. what skills, knowledge, competencies are important?
   e) What about Relationships, i.e. what are the critical relationships (internal and external) that are important to deliver [the above]?
   f) What about Structural Resources, i.e. what are the critical processes/routines? What is the organisational culture needed? What is the leadership model? Is there any intellectual property (IP)?
g) What about Physical Resources, i.e. what critical infrastructure (e.g. IT) is needed to deliver [the above]?

h) What ranking would you assign for the resources and capabilities in order of importance?

3. Sustainability

a) How easy would it be for your competitor to copy your competencies / capabilities?

b) How easy would it be for your competitor to copy the underlying resources?

c) What makes them difficult to copy?

d) Could they be substituted with other resources?

e) What would happen if you take away one resource?

4. Dynamic Capabilities

a) How do you ensure that AstraZeneca Medical Science builds the right capabilities and competencies for the future?

b) How could measures be used to help in this process?

Medical Science and Cranfield then identified 20 staff, ten Medical Science members (five Section Directors, five group members), and ten project customers (five Global Product Directors, five Clinical Project Team Leaders). Interviews were then conducted by Cranfield staff over a four week period; each interview took about 45-60 minutes. The evaluation of the interviews and the subsequent identification of Medical Science UK output deliverables, core competencies and the delineation and mapping of value drivers were performed as outlined by Marr et al (2004b) and briefly sketched in Figure 7.02.
7.3 Outlines for Possible Improvements of the Information Model

7.3.1 Lessons Learnt from the Cranfield Survey

Marr was able to extract a very reasonable Medical Science value proposition (red box in Figure 7.03) as well as its core competencies ‘Sound Advice’ and “Effective Communication” (yellow boxes in Figure 7.03) from his interviews. This resonated well when being presented to the Medical Science management.

In order to understand the delivery of the Medical Science value proposition through the two core competencies, Marr investigated the underlying Value Drivers (blue bubbles in Figure 7.03) and their interplay. This value map was
generated by Marr using the results from the interview questions around Value Proposition, Value Drivers, Sustainability and Dynamic Capabilities as stated in Section 7.2.2. The visualisation used in Figure 7.03 is using the outline of a cognitive map as introduced by Axelrod (1976). The usefulness of cognitive maps in the process of organizational optimisation and renewal was confirmed in a large number of papers, e.g. Barr et al (1992).

Fig. 7.03: AZ Medical Science Value Creation Map. Causative Relationships between Value Drivers (Marr, 2006).

The outlining of the Value Creation Map revealed interesting stakeholder priorities that closely matched the Medical Science team experiences as discussed in the next section. It became evident that the Cranfield survey and Value Creation Mapping identified both important business processes such as:

- Peer reviews
- Presentation of advice
• Training and development efforts

and several **weaknesses and important issues** with the Medical Science communication core competence, for example:

• Medics were not "always good at bringing their ideas across in an understandable format".

• People in Medical Science were "sometimes not able to put their views across in a structured way without being aggressive or sulky".

• Processes need improvement (peer review, presentation)

When considered together – both the important business processes identified and the communication weaknesses revealed – these findings validate the aims and objectives of this research project concerning the provision of an improved means of knowledge management for both Medical Science and the drug project teams. This is particularly the case after the re-organisation of AZ Clinical Development at the end of 2004. It became evident that an optimisation of advice (ie. the provision of knowledge) consolidation and communication is crucial for the success of Medical Science and also the drug projects.

### 7.3.2 Observations and Feedback from Project Team Interactions

The experience of the Medical Science staff concerning the advice given to their customers, the drug project teams, was captured in Medical Science group debriefing sessions in April and August 2005, where staff reported their interactions with the project teams (the 'internal' view) These were held as anonymous individual de-briefs and took about 30 min each. The respondents underwent an individual structured interview with the author. Respondent frequency was calculated on a dual scale (tend to agree / tend to disagree) for each of the questions below. In addition, the author held short feedback sessions
(usually 20 min. teleconferences or face-to-face) with key project representatives throughout April to August 2005. Aim was to get two independent reads from each of the 13 teams that MS supported, using the same interview methodology as above. These project representatives were either the Project Manager or the Project Medical Director (as available) and contributed the 'external' view.

The following questions were asked:

Clarity of advice given

- The MS advice was immediately clear to the project
- No major discussion was needed at the meeting
- Significant discussions, but were finished at end of meeting
- Decision had to be postponed to another meeting

Usefulness of advice

- MS staff is often told that their advice cannot be used because of other project constraints
- MS staff is frequently asked if they considered other solutions

Communication

- MS rep is respected as single point of MS contact
- MS reps struggle to get their points across

Results:

In 54% of the internal replies and 45% of the external replies, the MS advice was rated to be immediately clear to the project and no major discussion was needed at the meeting. In 27% of the internal and 36% of the external replies, significant discussions took place, but were finished at end of the meeting. Only in 18% of the internal and the external replies, the decision had to be postponed to another meeting.
In 36% of the internal and external replies, MS staff was told that their advice cannot be used because of other project constraints. In 81% of the internal and external replies, MS staff was asked if they considered other solutions.

In 81% of the internal and external replies, MS reps were seen as being respected as single point of MS contact. In 36% of the internal and 45% of the external replies, MS reps struggled to get their points across.

Interestingly, a difference between the internal view and external view was absent in many of the responses, maybe because the interviews were conducted in an anonymous fashion and the answers were honest. Slight deviations were generally ‘in favor’ of the internal view and may be attributable to a slight overconfidence bias (Lichtenstein et al, 1982).

Project customers also mentioned during the short feedback calls that they get key advice in all sorts of formats, for example Word documents, email or even verbally over the phone. Both internal and external respondents expressed their frustrations about the current situation during the interviews.

The findings described in Section 7.3.2 are generally congruent with those from the independent Cranfield survey presented in Section 7.3.1.

7.3.3 Scenarios and Risk Management

The findings discussed in Sections 7.3.1 and 7.3.2 indicate the difficulty and often rejection of ‘monolithic’ proposals. The author therefore proposed that Medical Science staff should provide customers with strategic choices or ‘scenarios’ rather than just one solution that is a ‘favorite’ from the Medical Science point of view. This acknowledges that project teams may have other circumstances and constraints to consider. A use of scenarios is usually connected with an assessment of risk and benefit of the options (Kaplan and Garrick, 1981). According to Miller and Wailer (2003), scenario planning gained prominence in the 1970s as a strategic management tool and scenario planning
encouraged managers to envisage plausible future states of the world and allowed them to consider how to take advantage of opportunities and avoid potential threats. They discriminate between two key tools for facilitating decision making under uncertainty, namely

- Scenario Analysis & Planning and
- Real Option Analysis.

Miller and Waller (2003) state, furthermore, that scenario planning has a long history in strategic management research and practice. Its development was closely associated with the rise of strategic planning and, more generally, the emergence of the field of strategic management. Scenario planning is a qualitative method. During a scenario planning process, participants discuss current trends and future prospects arising in a firm’s external environment. They create coherent stories about possible futures. Managers exercise their judgment by distilling the myriad of possible future states of the world to the most plausible few. Through scenario planning, the contingencies, uncertainties, trends, and opportunities that are often unanticipated can be identified, evaluated and acted upon.

Real option analysis, on the other hand, has its roots in finance research and only recently has begun to influence management practice. Real option analysis takes a quantitative approach focusing on specific investment projects available to a firm. Analysts apply option valuation models to determine the potential for value creation from maintaining flexibility under uncertainty. By framing real investment decisions in terms analogous to financial options, real option theory argues that valuable risk reduction can result from breaking large investments into series of smaller decisions. Spreading investments over time lets managers respond to unfolding contingencies. By investing in flexibility, managers can take advantage of upside (gain) outcomes and avoid downside (loss) outcomes.

Mun (2002) makes an attempt to position decision tools such as Scenario Analysis, Real Option Analysis and Monte Carlo Analysis based on properties
such as organizational scale and quantitative vs qualitative nature. They argue that Scenario analysis and planning and Real Option are two of the most diffused tools for evaluating projects and developing decisions when faced with uncertainty. From their review, the author concludes that Monte Carlo Analysis as well as Real Option Analysis are depending on quantitative numerical data and would hence not be useful in the current research. Scenario Analysis was positioned in the qualitative field and the author would agree with that. However, Mun (2002) positioned Scenario Analysis as decision tool however on the Macro Level, i.e. for decision with enterprise wide impact. The applicability on a project level is however confirmed through work by Lankila (2004) in computer science, by Karta et al (2004) in greenhouse gas mitigation, and by Villiger and Bogdan (2004) in pharmaceutical research & development.

Scenario planning has regained interest in the field of strategic management and in this process scenarios are built on existing data, participant beliefs, tacit and explicit knowledge (Miller and Waller, 2003). From a broad (almost infinite) variety of possible futures, the most likely are selected and thoughtfully studied. Difficulties in the quantification of scenarios can be addressed by the adoption of the argumentation technique, where arguments are being brought forward that are "for" or "against" propositions and being presented to the user together with a conclusion in the form of a linguistically expressed statement of risk (see Section 2.3.3). These aspects make the concept of Scenario Analysis and Planning particularly attractive for application in the author's research. It was seen as a credible approach to overcome the weaknesses of the previous concept as discussed in Sections 7.3.1 and 7.3.2. The adoption of Scenario Planning formed the rational for the inclusion of metadata elements related to scenario planning and risk management in the information model as discussed in Section 7.4.1. This proposal was discussed and subsequently agreed by the brainstorming group. This novel approach and its implications for the Medical Science / Project Team interaction are depicted in Figure 7.04.
The consequence of this proposed novel scenario approach to advising immediately resolved issues around the distinction between 'decisions' and 'rejections' as implemented in KNO v2 and discussed in Sections 6.4 and 6.5. This is because rejections are, in the novel model, part of the alternatives, expressed as different scenarios. Dropping the distinction between decisions and rejections at the scenario element level is also in line with the revised aim of KNO v3 as opposed to KNO v2, namely to support actual decision making and not the post-hoc capture of decisions already made as discussed earlier in this chapter. This would enable the separation of concerns held by the Medical Science advisors with regard to proposed options (scenarios) and the subsequent adoption / rejection decision by the project team. As a consequence, the post-
annotation features, some of which have been first introduced in KNO v2 needed re-consideration, as is discussed in the next section.

7.3.4 Post-Assessment / Outcome annotation

The separation of concerns with regard to proposed options (scenarios) and the subsequent adoption / rejection by the project team and the implications for enhanced annotation capability of the knowledge object was described in Section 7.3.3. This separation followed a suggestion from the user group made during the evaluation of KNO v2. The user group proposed to introduce some post-assessment annotation capability to enable a review of the outcome and impact to be recorded at a later stage when an evaluation could be made, e.g. whether it indeed led to a desired outcome, providing a ‘solution’ in case-based reasoning terms.

During the refinement of these ideas (see Section 7.2.1 for the brainstorming sessions that led to KNO v3) it became obvious that the implementations of scenarios plus the post-annotation would also capture non-adopted proposals together with their assumptions, etc. so that this valuable information would not be lost.

In fact, the scenarios elaborated by the Medical Science experts enable the project teams to make an informed decision. This decision is subsequently captured in the same KNO in the form of an annotation and this is where the learning loop closes. This approach is in line with the thinking of Aamod and Plaza (1994), and is also described in Jashapara’s book on Knowledge Management (2004 – Chapter 9), where the preconditions and implications of a learning organisation are discussed.

It was also thought by the brainstorming group to be a better replacement for the pending issue flag of KNO v2. However, the brainstorming suggested the
implementation of some timing element in the next generation KNO (v3), which finally led to the implementation of a scheduled date when the annotation could be expected as well as some means to control this expiry. In contrast to the data in the KNO v1, it was now the annotation that could expire, not the knowledge itself. Figures 7.05a and 7.05b illustrate how the outcome annotation fits into the case-based reasoning paradigm.

![Diagram of Case-Based Reasoning](image)

Fig. 7.05a: The Dynamics of Case-Based Reasoning (modified from Kolodner, 1993)
7.3.5 Decision Linkage / KNO Networks

Resource link elements (dc:relation) were already introduced as part of KNO v1, where they had a dual role:

- Links to related source documents
- Links to other related KNOs

In KNO v2, a distinction between source documents and other KNOs was introduced by separating these two aspects into different XML elements:

- The dc:relation element was kept to contain links to related source documents only

Fig. 7.05b: Extension of the Case-Based Reasoning concept with outcome annotation as implemented in this research
The `azkno:trigger` element was introduced to state the condition that triggered the creation of the particular decision in which context this element appears.

As KNO v2 was mainly used to capture a *series of decisions*, the trigger of a particular decision could also refer to a *previous* decision that triggered a new one. As discussed in Chapter 6, the Medical Science group was more interested in supporting actual decisions *to be made*, but was still keen on having a means of linking related decisions / KNOs. Therefore, the aspect of KNO linkage was recognised by the brainstorming group as a key feature to be implemented for the users in the development of KNO v3 as described in this chapter.

The evolution between KNO v2 and KNO v3 with regard to KNO linkage can thus be described as a move from multiple sequential / linked decisions all mapped into one KNO to simultaneous multiple options plus the ability to link related KNOs together to form a KNO network. This evolution was dealt with in several brainstorming sessions and as a consequence, the *trigger* element that was part of the *decision* tag in KNO v2 was moved to the *issue* tag and states the ultimate trigger of the issue. For the purpose of linking related KNOs, `azkno:predecessor` and `azkno:successor` elements were introduced in the RDF/XML (see Figure 7.06a). This still enables the chaining of KNOs in a 'causality chain' but in a better way, because v3 provides dedicated elements for KNO linkage, whereas the trigger is used only as the reason for the issue. The implementation of software that actually displays linked KNOs is beyond the scope of this research, though ideas are given in Chapter 8.
7.4 The Implementation of the Knowledge Object Information Model v3 and the Episteme Application

7.4.1 The Information Model

Document metadata are displayed in Figure 7.03a. They are largely inherited from the previous KNO versions. The `dcterms:abstract` element was finally dropped in KNO v3. That element, in the original KNO v1, kept all the content, but it played only a marginal role in KNO v2 because of the increased structure of the content. In KNO v3, the structure described below is able to handle all the content aspect so the abstract element became completely redundant.

![Structure and Values Table]

Fig. 7.06a: KNO information model version 3 (KNO v3). Document Metadata and KNO linkage elements.
Metadata to map the scenario attributes are displayed in Figure 7.06b. The azkno:assumption tag provides a mapping of the justification for a scenario as a given scenario is always put forward on the basis of underlying assumptions. As pointed out in Section 7.3.3., the use of scenarios is also connected with an assessment of risk and benefit of the options. The azkno:benefit and azkno:benefit elements introduced in the information model address the risk management aspects and the azkno:disadvantage element states obvious or known downsides of a certain scenario. Brainstorming carried out by the extended group discussed whether risk and disadvantage represent different aspects of a scenario that would warrant a separation into two distinct elements and the conclusion of that brainstorming session was that they should be kept separate. The main reason for a separation of concern was that risk would depict something which may or may not happen, whereas a disadvantage could be clearly identified as such and possibly be dealt with beforehand.

Both azkno:risk and azkno:benefit elements have two risk management qualifiers attached, namely azkno:probability and azkno:impact that, according to general risk management procedures (Saaty, 1987) would allow a further risk classification into the four categories

- high probability – high impact
- low probability – high impact
- high probability – low impact
- low probability – low impact

This would allow a more informed risk evaluation by the customer as depicted in Figure 7.0.4.

An azkno:rank element provides a means for expressing a favourite scenario or a scenario ranking from the Medical Science ('internal') point of view.

---

Risk and benefit are both features of risk management as they have to be considered in conjunction. A risk is more 'attractive' to take if at the same time there is a big benefit to be expected.
The `azkno:assumption`, `azkno:risk`, `azkno:benefit` and `azkno:disadvantage` elements furthermore have a `dc:relation` element to them that allows reference of related sources as discussed in Section 7.3.5.

---

**Fig. 7.06b:** KNO Information model version 3 (KNO v3). Decision/Scenario and Risk Management Metadata
KNO v3 metadata to handle the annotation aspect discussed in Section 7.3.4 are displayed in Figure 7.06b and 7.06c. The post assessment can be divided into a mandatory section and an optional section. The mandatory section includes the metadata shown in Figure 7.06. The post assessment flag is set to true if those metadata are completely filled in.

The `azkno:chosen_scenario` element has three attributes to it. The `azkno:chosen_scenario_ID` attribute captures the ID of the scenario that was finally adopted by the customer. It will be 'NONE' if the project adopted a scenario not suggested by Medical Science. The `azkno:chosen_scenario_rank` attribute captures what the original rank assigned by Medical Science was for the adopted scenario. In the case where the project decided on an option not suggested by Medical Science, the rank will be set to '0' (zero). The remaining attribute, `azkno:chosen_scenario_annotation`, is able to capture an additional natural language comment, if one is necessary for explanation.

The `azkno:scenario_outcome` element captures the outcome of the adopted scenario. This element has two attributes to it. The `azkno:desired_outcome` attribute is, in fact, a flag that takes the states 'Yes' or 'No'. The `azkno:desired_outcome_annotation` attribute captures an additional natural language comment, if one is necessary for explanation.

The extended brainstorming group discussed who should do the outcome annotation, particularly the assessment of whether the adopted scenario produced the desired outcome or not. The group felt that, in order to avoid opinion or bias, this should be done by the customer, i.e. the project team, instead of Medical Science. One incentive for the customer is clearly that this would provide them with an additional feedback on functional performance, which is required anyway by AstraZeneca. The initial outcome annotation was done by Medical Science staff (see Chapter 7.5.2), but this aspect will have to be discussed with the project teams in the future.
In addition, the `azkno:assumption`, `azkno:risk`, `azkno:benefit` and `azkno:disadvantage` elements have a post assessment aspect to them which has already been discussed in Section 7.3.4. The latter are optional and can take reflections on the appropriateness of the stated assumptions, risks, benefits and disadvantages.

The annotations are expected to have implications for organisational learning, e.g. if the risk was always considered too high beforehand, the organization gets an opportunity to investigate the reasons and move to a more appropriate risk estimation. On the other hand, frequent desired outcomes with favorable scenarios should enable the building of trust between Medical Science and the project teams.

Fig. 7.06c: KNO information model version 3 (KNO v3). Annotation Metadata (see text)
The integrity of the final KNO V3 RDF architecture was successfully validated with IsaViz (Pietriga, 2002) and showed no disagreement with the RDF syntax rules.

7.4.2 The EPISTEME Application

In order to avoid Medical Science staff being exposed to RDF-XML editing, and also to provide a search capability, a software application, EPISTEME\textsuperscript{2}, was developed in conjunction with AZ corporate Information Systems. EPISTEME was developed according to specifications and use cases elaborated with involvement of an end user, the author, the Medical Science knowledge manager and a corporate IS project manager according to AZ software development guidelines. The application was subsequently tested according to the same guidelines by creating user test scripts that followed the use cases (see Appendix 4) defined at design time. Three selected end users from Medical Science were involved in the test phase. Bugs were fixed until all test scripts passed and all design objectives of EPISTEME had been met.

The application was designed to serve several purposes:

- Create, edit, list and view (HTML rendition) a KNO
- Create a pointer to a PDF file of the HTML rendition of the KNO for referencing purposes
- Search and retrieve existing KNOs in the case base

The PDF rendition is stored in a defined place with a virtual link on the AZ intranet content management system and can thus be referenced in other documents. Fig 7.07 displays the front screen of the Episteme application.

\textsuperscript{2} As distinguished from techne, the Greek word \textit{episteme} (literally, science) is often translated as knowledge (http //en.wikipedia.org/wiki/Episteme)
Fig. 7.07 Front Screen of the Episteme Application

The HTML rendition of the KNO is available in two different views, a customer view and an internal view. The difference is that KNO annotations (see Section 7.3.4) are displayed in the internal view only. Fig. 7.08 displays the HTML rendition of a KNO in the customer view which - at the moment - does not show post-assessment annotations.
### AstraZeneca Medical Science UK Knowledge Object

**Title:** The optimal study design - new or rotating cohorts  
**Identifier:** AZD2914_optimal_study_design.xml  
**Creator:** Helen Spray@astrazeneca.com  
**Creation Date:** 2005-07-06

---

### Context

**study design, fixed cohorts, rotating cohorts**

**Issues**  
AZD2914 - What is the recommended study design - New cohorts or rotating cohorts

---

### Scenario A Rank 1  
**Rotating Cohorts**

<table>
<thead>
<tr>
<th>Assumption</th>
<th>Benefit</th>
<th>Risk</th>
<th>Disadvantage</th>
</tr>
</thead>
</table>
| * Drop-out rate is not considered to be a problem Evidence level: [ ] [ ] [ ] | * Inter-occasion variability Evidence level: [ ] [ ] [ ]  
  * Inter-subject variability Evidence level: [ ] [ ] [ ]  
  * Can include comparator lab e.g. food/Formulation Evidence level: [ ] [ ] [ ] | * Study comes out inconclusive because of too many aspects and too few subjects exposed for all treatments despite increase in complexity Evidence level: [ ] [ ] [ ] | * May need larger cohorts to account for drop-outs Evidence level: [ ] [ ] [ ]  
  * May need more reserves Evidence level: [ ] [ ] [ ]  
  * Fewer subjects exposed overall Evidence level: [ ] [ ] [ ] |

---

... cont. on next page ...
In this research, an improvement over simple full text matching has already been implemented within the EPISTEME application. The author was inspired by the concepts around Dynamic Categorisation (Johnstone, 1998), which enabled the search engine AltaVista to introduce a new search paradigm that uses statistical analysis to group results into related categories without the interaction of a user. Wollersheim and Rahayu, (2005), have published a similar approach to a dynamic query expansion for information retrieval of imprecise medical queries. The approach implemented by the author so far is using a taxonomy of drug development terms or ‘concepts’ (at the time of this writing, about 900 concepts and their dependencies have been included). This taxonomy was developed by the author using the KAON framework (Gabel, Sure and Voelker, 2004). A snapshot of the taxonomy (at a high level) within the KAON user interface is depicted in Figure 7.09. Some concepts have multiple inheritances (e.g. the concept ‘patient’ as depicted). This has not caused issues.
in the search process so far but the author is conscious of the relevant literature on this topic, e.g. Doerr (2001).

![KAON Workbench](image)

**Fig. 7.09:** Example view of the top level of the drug development taxonomy in the KAON workbench view (see text)

This taxonomy forms the heart of the semantic query expansion engine introduced by the author. At the moment, creation and maintenance of the taxonomy is done manually as an automated creation of a taxonomy or ontology is still a challenge for a computer system (Modica et al., 2001; Gomez-Perez et al., 2003). A computer may suggest relationships of concepts based on the analysis of huge amount of texts but knowledge extraction from text itself
requires a domain specific ontology (Alani et al, 2003). The manual creation of a taxonomy or ontology by domain experts was considered more adequate if the number of source documents to learn from is small, as it is the case in this research.

The taxonomy itself is furthermore supported by an English dictionary, WordNet (Miller, 1995). The schematic of the taxonomy-WordNet interaction is sketched in Figure 7.10. For this kind of interaction between a taxonomy and a dictionary, the author has used the term 'semantic query expansion'. Both WordNet and taxonomy access APIs are implemented as web services in order to improve interoperability.

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![Diagram](image.png)

**Fig. 7.10:** Principle of the Semantic Query Expansion as implemented in the current EPISTEME version
7.5 Evaluation of the Knowledge Object Information Model

Version 3

7.5.1 User Survey

After the implementation of the KNO information model v3 (see Section 7.4.1) and the Episteme application (see Section 7.4.1) the user group applied the novel tools to support actual decision making. As of this writing, 28 KNOs have already been created with the v3 template.

A first short and semi-structured survey was undertaken by sending the questions below to the staff via email, in order to gather results from those seventeen Medical Science users who've created the 28 recent knowledge objects. The seventeen creators of the 28 KNOs were asked to answer several questions with regard to the novel decision support process as well as the EPISTEME application:

- What do you consider to be the main benefits of this approach to decision making?
- Do you think the process and application makes decision making more focused, visible and also available for future reference? (Respondents were instructed that they could agree with only part of the question, but this was not observed)
- Can you envisage any drawbacks in the process?
- What did you like about the application (taking into consideration it is a pilot)?
- What didn't you like about the application?
- Do you have any other comments you think are appropriate?

All 17 of the KNO creators responded to the survey. Apart from question 2, open questions were used at that early stage as these have the advantage that the
freedom they give to the respondents can elicit unexpected, thus very valuable results. This is further justified by the fact that the low total number of respondents currently precludes quantitative statistical analysis anyway.

The results are presented as follows, clustered by common themes:

![Bar charts showing user survey results](image)

**Fig. 7.11a User survey results (cont.)**
Fig. 7.11b User survey results

Note that the term ‘clunky’ groups comments around the effort necessary to enter the KNO information, ‘terminology’ groups those around the names of the fields and controls of the application. ‘Screen design’ groups comments about the placement of controls on the application screens and the navigation between the screens.

Overall, the early feedback was positive, given the fact that the current application design was the first pilot. The application was seen by the users to focus the decision making process by structuring the arguments, and enable them to see the bigger picture. Issues were clearly seen on the application design as well as training required to achieve a wider adoption of both process and application.

7.5.2 KNO Post-Assessments

An evaluation of the knowledge base was made when 25 KNOs were available in order to look for post-assessments of the KNO (see Appendix 5). At that time, four KNOs were ‘completed’ wrt post-assessment, 17 KNOs were still ‘pending’ and 4 were ‘unable to assess’ because the project in which it was used was terminated before a decision outcome was reached.
In all four completed KNOs, the scenario initially flagged as 'recommended' was finally chosen and the chosen scenario produced the desired outcome as well. At the time of writing, in 75% of the eight KNOs, where some discussion had already taken place in the project team and a scenario choice had been made, the initially proposed scenario was chosen. In only two instances (25%), the proposed scenario was not chosen - unfortunately both of the latter were still pending wrt the desired outcome at the time of writing so the consequences could not be reported in this thesis.

Even though the absolute number of completed KNOs is still small, there is a clear indication that in most of the cases, the project team adopted the initial proposal provided by the KNO author and, so far, this has always produced the desired outcome. There are two conclusions that can be derived from this preliminary finding:

- It seems that the clear scenario mapping helped the KNO author to get his recommendation across to his customer
- The preliminary positive outcome assessment of all recommendations so far helps to build trust between the KNO author and the customer

7.5.3 Quotations received from outside of Medical Science

Further to the first user survey, quotes were gathered from other AZ departments that were involved in the development and evaluation of the novel decision support methodology and the EPISTEME application. In particular the corporate Information Systems department and Legal Affairs were consulted to give their perspective of the novel decision support tools. Quotes are listed in Table 7.01.
Table 7.01 Quotes from departments external to Medical Science

<table>
<thead>
<tr>
<th>AZ Corporate Information Systems</th>
<th>AZ Legal Affairs</th>
</tr>
</thead>
<tbody>
<tr>
<td>The way knowledge is shared in a company like AZ is an interesting area and provides us with a great challenge. I was impressed with the way knowledge was captured and made available for exploitation.</td>
<td>Episteme will enhance corporate governance compliance as the frame-work and the application will provoke the users and customers (project teams) to think of the down-stream consequences.</td>
</tr>
<tr>
<td>Although the system might need a relatively small effort to make it more &quot;production ready&quot;, I could see a usage in other areas to capture and share knowledge.</td>
<td>Such an approach will help focus the employee on facts and has the potential to reduce or avoid opinion and guesswork thus is supposed to have very beneficial effects on AZ corporate governance.</td>
</tr>
</tbody>
</table>

7.6 Summary of Chapter 7

An initial survey within AZ, both internal and external to Medical Science, indicated the usefulness of the KNO v3 architecture for decision support. As no immediate need for a change or refinement of the KNO information model in version 3 originated from the first user feedback, the Medical Science leadership team announced to all Medical Science staff at a yearly face-to-face staff communication event in March 2006 that this is the way the leadership team wants staff to prepare and propose important strategic advice to project teams and that a re-evaluation of the concept and tools will take place in a year’s time. This planned internal review will also be paralleled by a second business review of Medical Science value generation similar to that discussed in Section 7.2.2. This independent review is, again, expected to deliver as part of its remit an important independent evaluation of the success of the novel decision support paradigm introduced by the author.
The final chapter will conclude the work by a review of the research with respect to the aims and objectives and also in the light of very recent literature. It will furthermore summarize the achievements, provide a first assessment of limitations and will give recommendations for further research in this area.
Chapter 8 – Conclusion and Outlook

8.1 A short review of Decision Support Paradigms and a Re-Evaluation of the Aims and Objectives

In the light of literature that has emerged during the course of this research project, a re-evaluation of the aims and objectives is in order. In a recent paper, Mackenzie et al (2006) discuss the opportunities for novel decision support processes and associated software that aim to provide extended support for decision making. They put their proposal into the context of different decision support paradigms such as substantive decision support and procedural decision support.

According to them, substantive decision support refers to approaches that attempt to provide knowledge based expertise to address particular decisions. Such a decision support system (DSS) would provide its detailed support from established knowledge held in a knowledge base and could be of great use in, for example, bridge design in civil engineering. However, this form of DSS is suited only to decisions in which the aims of the work are known and agreed, where it is obvious what to do but not the best way to do it. They argue furthermore that in procedural decision support, adding a distinct knowledge base is not enough, since it will not be clear what knowledge is required when it is even unclear what to do. A procedural decision support tool should support people in addressing the “why” and “what” questions, rather than just helping them to think about how an objective should be achieved.

Mackenzie et al (2006) point out that conventional DSSs are very useful when used to support decision making in situations that are well defined, but less useful when problematic situations are ill defined and, in particular, when there is debate about what should be done rather than how it should be done. These
authors argue furthermore that, in the latter situations, there is a need for methods and tools that support ongoing decision-making processes and help teams of people to find their way through such messy situations. This is exactly the situation that the author is facing with his expert group at AstraZeneca and *procedural decision support* is therefore of paramount interest to this research project.

According to Mackenzie et al (2006), procedural decision support involves techniques such as cognitive mapping or dialog mapping. The approach chosen in this research is that of a dialog mapping and can be considered as a refined and extended version of the IBIS Map (Issue Based Information Systems) which was originally suggested by Kuntz and Rittel (1970) and its notation is more formal than that employed in cognitive mapping. IBIS constrains nodes to three types that, according to Kuntz and Rittel (1970), support the "identification, structuring and settling of issues raised by problem solving groups." The IBIS map implements some basic decision attributes such as:

- **Questions**: that state an issue in question form
- **Ideas**: that propose an option or possible resolution to the question and
- **Arguments** (pro or con): which state an opinion or judgement that either supports or objects to one or more ideas.

The knowledge objects in the KNO case base are therefore not recipes for problem solution but should stimulate the thought process around a new problem. The author argues that the derived mapping of previous decisions together with their assumptions, benefits risks and disadvantages provides an ideal support base for solutions to new problems.

An approach similar to the work presented in this thesis has recently been published. Norheim and Fjellheim, (2006), developed 'AKSIO', a very similar knowledge management application for the oil drilling domain. Similarities include the aim for decision support, a case base and an outcome annotation. The fact
that these aspects are useful components for a knowledge management application, irrespective of the knowledge domain, agrees with the approach presented in this thesis.

The mix of a personalisation and codification strategy for knowledge management introduced by the author of the current thesis had however various successes amongst different industries as already pointed out in Section 4.3.3. Had the concept presented in this thesis failed, further research would have been necessary to identify as to whether flaws in the current research setup are responsible for the failure or if certain roadblocks within the pharmaceutical R&D setting could be identified, which would be a very interesting research in itself.

8.2 Evaluation of Achievements

8.2.1 The EPISTEME framework

The system described in this research is called the EPISTEME framework which includes

- a process (see Chapter 4),
- an information model (see Chapters 5 to 7) and
- an IS tool (the EPISTEME application, see Chapter 7).
The first user survey, as presented in Chapter 7, provided a justification of the aims and objectives of this research as it became evident that a rich problem and decision explication and structuring process was found useful in itself. The knowledge worker who generates the decision mapping as provided by the novel process will think more deeply about all facets of the problem and decision which will improve the decision quality. The scenario approach introduced has been validated by an assessment carried out by Cranfield University Management School who concluded that customers wanted strategic options (see Chapter 7). Capture, search and re-use aspects were additional benefits delivered through an IS application support and a suitable information model.

The EPISTEME framework continues to address main AstraZeneca business concerns and priorities as is depicted in Figure 8.02 which shows an excerpt from a very recent business communication. The author has annotated the slide to show how EPISTEME links in with core business priorities.
Enhancing Product Delivery Output

- 22 recommendations that, if rigorously implemented, will enable us to reduce critical path cycle time by over 2 years
- Main Themes
  - Planning/Decision making
  - Strategy and Prioritisation
  - Operating Model/Decision making
  - Continuity of experience/ Best practice
  - Documentation
- Moving from planning into action

This is fully endorsed by RDLT, SET and Board

Fig. 8.02: Episteme framework ties in with 2006 AZ core business priorities

This framework was developed within a narrow drug development project context involving scientific and medical experts. Also, the search taxonomy developed is domain specific. A large body of literature shows that expertise and decision making are closely linked within one knowledge domain.

However, the mapping of the decision process onto the chosen attributes appears to be generic and warrants further research to explore its usability in other knowledge domains within a pharmaceutical company or even with completely unrelated businesses. This assumption is currently subject to ongoing further research at AstraZeneca and should also be performed elsewhere.
8.2.2 An AstraZeneca Business Case for the EPISTEME Framework

AstraZeneca Global Clinical Development has a process for the evaluation and handling of improvement project candidates in place (Processes and Enabling Solutions = PES). The author prepared a short business case according to the first step of the PES process\(^1\) outlined in Appendix 1.

Following this process was important as it represents company policy to get an appropriate justification for a comprehensive pilot implementation of his research project within the AstraZeneca business processes.

8.2.3 The Achievements in the Light of the Aims & Objectives

This thesis had two aims:

1. To improve the way that knowledge around decisions made in a drug development environment is produced, captured and stored so that it can be re-used and re-visited for organisational learning
2. To deliver a framework and an information model to form a basis for a usable decision capture / storage application that can be adopted and used by the wider AZ business

The research by the author produced and tested a framework (EPISTEME, Sections 7.4.2 and 8.2.1) as well as an information model (KNO v3, Section 7.4.1) that was found to improve the way knowledge around decisions made in a drug development environment is produced, captured and stored. The resulting framework was tested and accepted\(^2\) by its users (Section 7.5) as well as adopted by the AZ business for a wider use in the company (Section 8.2.2) by

\(^1\) Details of the PES process will not be given as it represents confidential intellectual property
\(^2\) The Results Driven Incremental Technique explained in Section 6.2 ensured that the users were brought in all along the way of systems design and testing to avoid a rejection of the end product as experienced by Richman and Moses (1999) with traditional implementations

- 151 -
approval through a strict selection and prioritisation process for improvement projects at AZ.

The individual objectives that were achieved towards these aims were as follows:

1. To identify from the literature, best practice on individual and group decision making and to determine possible decision storing formats to be used with the capture process in a format superior to plain text files such as .doc or .pdf files.

The literature review (Chapter 2) provided the basis for understanding of the most important determinants of human decision making and of appropriate information systems to support these in order to make an appropriate decision on the technology to be employed in this research.

Main concepts of human cognition and psychology relevant to decision making as well as key concepts of knowledge management were reviewed in Section 2.2. Important IS paradigms that are known to support human cognitive processes such as genetic algorithms, neural networks (model based reasoning), rule based systems (rule based reasoning) and case based reasoning were reviewed and evaluated for their significance for the author's research in Section 2.3. The following Sections 2.4 and 2.5 evaluate the usefulness of novel information structures and paradigms for the author's research.

2. To implement a process whereby decisions made in meetings can be captured as a group digest and summary.

Chapter 4 introduced and tested a novel process to improve group reasoning and decision making at AZ Clinical Development that formed the foundation of the decision support framework to be built.

3. To evaluate the process and storage format to detect shortcomings when used in practice from an internal company point of view.
4. To identify experts in KM and Information Systems (IS) and use brainstorming
techniques to derive a better information model.
5. To evaluate the improved model by involving customer input to determine
shortcomings as perceived from an external customer's point of view.
6. To further improve the information model by more brainstorming with further
experts taking into account the external customer needs.

The action research paradigm was identified in Chapter 3 as most suitable for the
this research and Chapters 5 to 7 used iterative procedures in order to improve
and re-test the framework under development.

7. To test the final framework with independent expert opinion from internal and
external sources.

Important validation for the key aspects of the framework was provided by an
independent evaluation by the Centre for Business Performance of Cranfield
University School of Management. The final framework was evaluated from both
the users and the AZ management, was found useful and was approved for
further development and wider implementation within the company.

8.3 Identification of Limitations

The maintenance of the knowledge base will be an ongoing activity for many
years and, hence, is beyond the scope of this project. However, as the
information model captures scenarios along with the date and time, it should be
possible for future analysts to judge the relevance of the captured data for any
future decision making, no matter how much later this occurs.

A preliminary assessment of limitations from the survey presented in Chapter 7
revealed issues around business process integration, training, and deficits of the
IS application ("Needs selling", "Needs a better user interface"). Limitations will
furthermore originate from the adoption of the methodology (fast-, slow-, non-
adopters). However, as the framework is being adopted by AZ as working
practice it should eventually become an ingrained part of every-day working procedures. This means that even the slowest adopters should all take part in the end. In order to achieve this, a governance process for the wider use of EPISTEME has to be outlined and implemented further to the introduction of the final system.

The current analysis has shown a lot of potential for this decision support approach. Ongoing utilisation of the EPISTEME framework will deliver a richer set of data for an analysis and publication at a later date.

8.4 Outlook and Recommendation for Further Research

8.4.1 Recommendations for an Extension to this Research to Develop the Novel Decision Support Process Further

During the preparation of the PES business case in September and October 2006, consultations with the user group (4 people) as well as with the brainstorming group (6 people) happened on two instances. During these discussions, several modifications and extensions to the current process have been discussed and captured. They are listed here in no particular order and could give rise to a multitude of further research activities spinning off from the author's research.

1. The customer could take a more active part in both formally inputting the context and issue as well as doing the post-assessment himself which could possibly reduce user bias.
2. The post-assessment of scenarios not taken forward could be considered as another aspect of research.
3. Online capturing during group reasoning meetings with background search of the case base could potentially flag up already captured knowledge related to the issue under discussion. This just-in-time knowledge approach is also
regarded to be very useful by Davenport and Glaser (2002) because the trigger is coming from within the KM application itself and it doesn’t require anyone to look for pre-existing related knowledge proactively.

4. The decision attributes introduced are intended to be generic so that the approach proposed in this research should be fairly domain independent. A proof of this hypothesis could be done at AZ (for example the roll-out and study of the framework in the IS department, Human resources or Finance), or in a completely different setting such as in another company, government or academia. In these cases, the semantic query expansion of EPISTEME would just need a different domain taxonomy.

5. Further and more formal integration of the KNO generation into AZ business processes could be investigated, such as in the generation of Clinical Development Plans, Target Product Profiles and other high-level and regulatory documents.

6. In addition to the KNO author, other staff that attended a group reasoning meeting that led to a certain KNO may be captured in the KNO. See Section 8 4.2.3 on knowledge network creation.

7. An evaluation of the case base (knowledge base) over time may lead to the identification of ‘knowledge-rich’ or ‘knowledge-poor’ areas. This may, for example, be invaluable for the identification of a strategic direction (or lack of direction) of a department. This may consequently trigger the need to acquire new / different skills.

8. Finally, a whole set of metrics around the KNO may be considered such as the number of references to a certain knowledge object requested by others, appropriateness of the preferred scenario, assumption, risk, benefit etc. These metrics could help to build trust between the staff involved in decision making, or be included in individual as well as corporate performance management. All these aspects could give rise to significant and beneficial research topics around the EPISTEME decision support framework.
Of the above, items 3, 4, 5, 7 and 8 are regarded the most promising in terms of their potential benefits, items 1 and 6 would be relatively straightforward to achieve and items 2, 5 and 8 would present more work and possibly difficulties in implementation.

In terms of the social aspects of KM, it has been observed during all iterations of the KNO evolution that there was always a subgroup of fast/early adopters and another subgroup of staff that was more reluctant to adopt these new processes. This will be subject to further research with Loughborough University in order to be much clearer about enablers and inhibitors of the framework introduced by the author. This already ongoing research aims to facilitate the wider roll-out in AZ Clinical Development and beyond.

8.4.2 Recommendations for an Extension to this Research in order to Develop the EPISTEME Application Further

8.4.2.1 Improvement of Knowledge Object generation

The author agrees with Sowa (2002), that natural language simplification and the use of controlled vocabularies are important factors for successful information retrieval as this will improve the ability of search algorithms to read and comprehend the meaning of the natural language text in the KNO.

In a first step, it is proposed to establish a link to the recently introduced XML version of the AstraZeneca dictionary of terms and abbreviations in order to map and hopefully standardise terms and abbreviations already at the KNO input stage. This dictionary is already available electronically in an AZ proprietary XML format which would make it readily accessible for the existing EPISTEME software. Whether more elaborate natural language simplification can be
employed (semi-) automatically by the system or is completely subject to user training requires additional research.

8.4.2.2 Linking of Knowledge Objects

Decisions are rarely made in isolation. There is often a preceding incident or decision as well as one that follows on from the current one. It would possibly provide additional insight into the wider decision making process if such decision series could be linked and such dependencies could be discovered later. The current information model v3 architecture already provides a means for that as discussed in Section 7.3.5.

Figure 8.03 displays how these dependencies may be visualised. This prototype view has been created manually, further research is necessary to implement algorithms that are able to parse the KNO chain automatically in order to create these KNO dependencies dynamically. Example given in the figure: A click on KNO1 reveals that KNO1 is part of a 'network' of related decisions.
Fig. 8.03: Principle of KNO linking using the azkno:predecessor and azkno:successor elements of KNO v3 (see Section 7.3.5). Pilot implementation with TGLinkBrowser (A test version can be found under http://www.compendiumdev.co.uk/touchgraph/TGLinkBrowser.html).

8.4.2.3 Knowledge and Expert Networks

Another useful aspect to be followed on by additional research is the creation of knowledge or expert networks. This can be enabled by the discussion and creation of KNOs in a peer group process (see Chapter 4), technically supported by including the names of the peer group into the KNO, not just its (main) author, the creator, which, according to Dublin Core, (McClelland, 2003) is "an entity primarily responsible for making the content of the resource".
In analogy to the creator, accommodation of other names that contributed to the creation of a specific KNO can be accomplished by adding another metadata tag from the Dublin Core catalogue, dc:contributor, to the KNO. This tag is defined as "an entity responsible for making contributions to the content of the resource" (Dublin Core, 2005).

In a similar way to a search on concepts within the KNO, this tag could be used to link people that have contributed to the creation of a particular content or topic hence supporting expertise and expert network discovery. However, this is beyond the remit of this research project.

8.4.2.4 Improved Case Search and Retrieval

A refinement of the novel semantic search paradigm implemented within the EPISTEME application as outlined in section 7.4.2 and an evaluation of benefits and limits compared to other search techniques is beyond the scope of the research reported in this thesis, but is a very promising start to extended research and development within EPISTEME.

After the initial search has been performed as proposed above, the retrieval may be refined further by using a technique which is known from the internet as Tag Clouds (Hassan-Montero and Herrero-Solana, 2006; Kaser and Lemire, 2007). The principle is that Tag Clouds represent a frequency of terms analysis of a document where an increased occurrence of a term is represented as increased size/boldness. This allows a very quick visual scan and analysis of the document content (see Figure 8.04).
Furthermore, a taxonomy-based tagging of terms within natural language KNOs could provide a 2nd 'perspective' within the case base that would allow additional machine inference and reasoning (strict logical reasoning) in addition to the CBR paradigm of 'similarity', as proposed by Bergmann and Schaaf (2003). Complementation of the similarity-based case-matching approach of CBR by strict logical reasoning could improve CBR’s ability to retrieve matching cases (Chen and Wu, 2003). Tags may be derived from the domain taxonomy or from concepts outside of the domain taxonomy such as temporal patterns. A detection of, for example, terms like 'before', 'after', 'followed by' could improve retrieval of strategic information around the timing of decisions or events. Alternatively, the domain taxonomy may be extended to accommodate those terms.

The question whether genetic algorithms (see Chapter 2) may be able to provide completely new solutions based on an evolutionary processing of existing cases is an interesting question for further research, but clearly beyond the scope of this thesis.
8.5 Summary of Chapter 8

The embedding of KM methodologies into business processes is crucial for sustainable success: There are concerns that many KM initiatives can add considerable time and effort to an individual's daily workload rather than being embedded into tasks and the daily workflow (Davenport and Glaser, 2002).

The results of the first user survey reported in Chapter 7 and the commitment for the full development of EPISTEME by AstraZeneca is an indicator that the framework adds value to the users and the enterprise. Further verification of the usefulness needs to be obtained when more KNOs have been created and a substantial number have been annotated as well as re-used in later decision making.

The author's research has used a combination of pilot studies, brainstorming sessions, review meetings and surveys combined with actual working practice in an iterative manner, which has been proven useful to address the specific aims and objectives. As described in Section 8.2.3, all the aims and objectives set at the outset of this research have been achieved.

AstraZeneca top management has also recently used the EPISTEME decision support framework successfully to assess the impact of restructuring scenarios. This and the endorsement and adoption of the final information model and decision support framework by the AstraZeneca company, means that this research project can now be tested in a variety of areas within the company, and can also now provide the basis for many further research projects on related topics at AstraZeneca and elsewhere.

A major contribution to academic research is that a combination of personalisation and codification strategies for knowledge management worked well together in the current setting within pharmaceutical research & development.
Appendix 1 - PES process

**PES Process Description**
The EPISTEME business case for PES was prepared from September to October 2006 with the assistance of corporate Information Systems staff who were used to the corporate process. The business case was submitted to PES in November 2006. Some excerpts from the EPISTEME business case (the full business case is in Appendix 2 of this thesis) follow below.

**Project Identification**
Productionalisation of "EPISTEME" knowledge management application.
Episteme is a knowledge management application for Medical Science that is currently in pilot.
This business case details what would be required in order to put the pilot application into production as a web-based application. The intended user base is initially Medical Science, but the underlying principles are equally applicable across AZ to support a knowledge base for information reuse and decision capture.

**Scenarios**
- Note that the potential scope for use of Episteme is very high. As it would prove useful across many areas of the business, to avoid over-generality for the purpose of this document two very specific examples are detailed.

**Benefits**
- Improved consistency and presentation of clinical information to project teams
- Retention and opportunity to reuse clinical information – protects corporate intelligence.
- Built-in feedback process to measure and evaluate advice given so far to project teams, giving the opportunity to improve based on feedback
- Concise, consistent and verified clinical scientific information will be provided to relevant customers in a standard scenario-based format
Appendix 1 - PES process

- All scenario-presented advice is risk and evidence rated to improve and shorten the decision making process by drug project teams
- In the event of any inspection or audit, all advice is clearly and transparently available for impartial review in a single screen
- Will allow definition and measurement of KPIs\(^1\) within MS, as it will provide data detailing level of reuse of information, feedback on outcomes etc. This will bring advantages in creating metrics that did not previously exist, as MS mainly provide qualitative data on their performance rather than quantitative.

Benefits market

- Medical Science: more efficient working and reuse of information
- Drug project teams: quicker advice in standard format, knowledge base of previous medical and scientific expertise made available.

The cost/benefit analysis is a significant part of the PES evaluation. Therefore, considerable thinking went into the compilation of this information which has been done with the help from corporate IS staff during September and October 2006 and is detailed in Appendix 3a (Cost Benefit Analysis for EPISTEME) and Appendix 3b (Benefits map).

In the presentation at the November PES meeting emphasis was given on the aspects of decision support that EPISTEME would provide for project teams, as they represent the most valuable assets for AZ in terms of value generation.

After the PES presentation of the aspects of EPISTEME and the results from the pilot implementation, senior management unanimously agreed the business case and requested that the EPISTEME framework receives priority for further development at AZ with the intention of wider roll-out and use.

\(^1\) KPI = Key Performance Indicator
Appendix 1 - PES process

PES Process Outline

Initiation of improvement projects

- Potential improvement projects must be sponsored by a functional leader/representative sitting on PES (or another senior level in AZ)
- The Business Area Leader (who is accountable for ensuring the governance of the processes and enabling solutions/tools within a defined business area) will ensure any proposal addresses both process and technological aspects of the business area and must agree the proposal with the Global Lead of the owning Department. If there is no relevant business area readily identifiable or the proposal relates to the creation of a new business area, the initiator agrees on the proposal with the Departmental Global Lead.
- Effects of the proposed improvement project on other business areas (processes and enabling solutions/tools) are mapped out with input from Development IS (IS Solution Leader) and P&PM (Process Advisor)
- Alignment with the Clinical Development strategy is confirmed within the department
- The short business case template is filled in, with a brief benefits analysis attached.
- For drug project related improvement project requests, the Therapy Area Vice President should submit a short business case to the PES Chairman.
- Global Lead of the initiating department (for Therapy Area projects: the PES Chairman) sends the short business case to the PES coordinator, who circulates it among the PES members.
- If a complete short business case is received at least 10 working days before the next PES meeting, the PES coordinator enters the improvement project initiative on the PES agenda (where a set amount of time is allocated for new business cases), otherwise includes it on a subsequent PES meeting agenda. Incomplete business cases will not be reviewed.
Appendix 1 - PES process

- If the improvement project initiative is under USD 200K (fully costed), the project is put on the PES agenda for information. If the improvement project initiative is above USD 200K (fully costed), the project is put on the agenda for decision.
- The sponsoring PES member presents the improvement project initiative to PES.
- The short business case must contain sufficient information to enable PES to answer the following questions:
  - Are the benefits of the proposed improvement project in line with the Clinical Development strategy, including alignment with the Clinical KPI benefit graph?
  - Is there a potential for payback?

Based on the short business case, PES either rejects the improvement project or endorses the start of the project justification stage and the development of a full business case. PES may waive the development of the full business case, if, based on the information in the short business case, the cost-benefit ratio of the development of a full business case does not justify this activity.

DevIS and P&PM provide input into the completion of the full business case, as needed. The full business case must contain a detailed benefits analysis.

- The complete full business case must be received by PES at least 10 working days before the next PES meeting in order to be discussed on that meeting.
- The full business case must contain sufficient information to enable PES to answer the following questions:
  - Is the project worth its cost?
  - Is this project more important than other projects?
  - If the improvement project initiative has a cost above USD 1 million (fully costed), the PES chair submits the PES approved business case for analysis and approval to the Development Improvement Board.
Appendix 1 - PES process

Communicating PES decisions

- PES documents its decisions in the PES minutes and the PES sponsor of the project communicates PES decisions to affected staff.

Managing approved improvement projects and reporting progress

- PES appoints the business project leader based on the recommendation of the sponsoring PES member. If applicable, an IS project manager will also be appointed by the DevlS PES representative.
- Improvement projects must adhere to the AstraZeneca Project Management Framework and follow the methodology of the IS Project Management Model. Projects without an IS component must follow the same process, however, should disregard IS specific steps.
- All improvement projects must be entered into Matrix, with forecasts made for both FTEs and dollars. For new improvement projects, the business project leader must request an N-code and inform all participants in the project about the N-code they are expected to record their time spent on the project. Improvement projects under the cut-off point (USD 200K) should use the N5287000000 code created for such projects.
- All improvement projects must have an MS Project Plan filed in the Clinical Development Improvement Projects eRoom. It is the project leader's accountability to ensure that the MS Project Plan is available and is updated by the 4th working day every month. For access to the Improvement Projects eRoom, contact the PES Coordinator. The MS Project Plan template is available on the PES infospace.

Improvement project leaders must submit a monthly status report on the standard template to the Improvement Projects eRoom. The monthly status report must be submitted no later than the 4th working day of every month. However, if deviations from the agreed project plan are anticipated, immediate notification of PES via the Project Sponsor is necessary. The status report template is available on the PES infospace.
Appendix 1 - PES process

- Following the approval to start the Justify phase of a project, the project leader must obtain approval before a new phase of the project may start. Resources are released for the project at these points. The project leader must fill in a stage approval report and submit it to the PES Coordinator and the project's PES Sponsor. Decision points 2 and 3 are delegated to the project's PES Sponsor; however, the stage approval reports for these decision points must be on file at PES. The stage approval reports are available on the PES infospace in the 'PES Forms' portlet.

Closing of improvement projects
Stage approval reports 4 (end of Execute stage) and 5 (end of Close stage) are circulated to all PES members who may raise questions on the submitted information. At the end of the 'Close' stage a final Project Status Report must be submitted, briefly describing why the project is closed (completion, premature termination). Once the Close stage is complete, the project leader must summarise the project learning points on the end-of-project learning template (available on the PES infospace) and submit the information to the PES coordinator. In case of prematurely terminated projects, the project's PES sponsor decides if an end-of-project summary is necessary.
## IMPROVEMENT PROJECTS SHORT BUSINESS CASE DP0

**Version 231**

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<th>Project Name</th>
<th>Productionalisation of &quot;Episteme&quot; Knowledge Management</th>
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<td>Function</td>
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<tr>
<td>Project PES Sponsor</td>
<td>Rick Sax</td>
</tr>
<tr>
<td>Project Leader</td>
<td>Holger Adelmann</td>
</tr>
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</table>

### Description of the project

**Short description of Project**

Pilot developed under x-dev Q4 2005/Q1 2006 to implement knowledge management application for decision capture. This has shown its value to the business and this business case proposes putting it into production across Medical Science. Episteme facilitates a timely and structured approach to issue management to resolve drug development issues and reduce iterations, it provides a knowledge base to allow individuals to research previous MS data and reduce rework, it develops, protects and retains corporate intelligence and it reduces risk by improving corporate governance in the decision making process.

### Deliverables

- Web application with following characteristics:
  1. Provides repository of medical strategic information presented by MS to project teams
  2. Provides searchable tool to capture scientific discussions/decision making processes within MS
  3. Ensures corporate knowledge protected and available for future reference
  4. Provides knowledge base that captures key data to provide business metrics to assess performance of MS and identify areas for improvement
  5. Provides MS with industry-leading tool to develop strategies for best drug development programmes in most cost/resource efficient way
  6. Runs as web application using standard AZ tools combined with free/open source components
  7. Post implementation review of impact, improvements to working processes and feedback from stakeholders.

### Project<200 kUSD or comb. DP0/DPI requested

- Yes

### Dependencies

- None

### Overall timing

- 1 year

### Length of Justify stage

- 3

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Appendix 2 – EPISTEME PES Business Case

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<tr>
<td>Project timing (months)</td>
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**Benefits and link to strategy**

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<td>R&amp;D Drivers</td>
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- Quality
- Volume
- Cost
- Time

Strategic fit to KPIs
Lower cost, increase shareholder value, shorter lead times for submissions.

Main Benefits
- Improves cost/resource efficiencies within MS
- Improves corporate governance by providing formal mechanism for capturing decision making process
- Provides easily searchable knowledge base for MS of previous scientific discussions and decision making, reducing rework and allowing key personnel to spend more time in high-value roles rather than in re-justifying decisions
- Low cost, high impact and high potential across MS globally via web interface

Proposed benefit metrics

Proposed benefit owners

**Economic feasibility**

**Estimated benefit market**
The scope of the application is not limited to Medical Science but will directly support drug development through CPT and GPT. Episteme will also directly affect AZ's ability to defend in litigation, and will significantly benefit usability in all areas of decision making. The benefit market can easily be estimated in the multiple millions of dollars range.

**Expected benefit value**

**Estimated project cost**
GDD IS: 3.1 IS FTE for one year, Clinical: 2.85FTE for one year. No significant capital costs: server infrastructure to be provided by IS O&BS. No licence costs. Spend estimated at 6FTE for 1 year. There will be some ongoing S&M costs to support the platform, estimated at 0.3FTE/year.

**Man power for Justify stage**
GDD IS: 0.1 FTE year   Clinical: 0.1 FTE year

**Financial cost for Justify stage**
IS O&BS providing infrastructure and using existing licences: no other anticipated costs

**Specific information for Global Clinical Development**

<table>
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- 169 -
Appendix 2 – EPISTEME PES Business Case

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Appendices and Administrative information

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<tr>
<th>Add/Update SBA report</th>
<th>Short Benefit Analysis Report</th>
<th>Benefit Graph</th>
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This form was completed by: Ric Harris/Holger Adelmann/Kevin Nairn

Completion date: 02/07/2006


Business case reviewed in PES on Nov 2006

PES Decision Approved
# Project Model Assumptions

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<th>Value</th>
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<td>12 minutes per day</td>
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<tr>
<td>Increase confidence in chosen strategies</td>
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<td>hr/week/person</td>
<td></td>
<td>12 minutes per day</td>
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<tr>
<td>Reduce number of repeat mistakes</td>
<td>2</td>
<td>hr/month/person</td>
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<tr>
<td>Improve and shorten the decision making process by project teams</td>
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<td>hr/month/person</td>
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<td>2 issues per month per person</td>
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<td>Simple integration of advice into high level business documentation and process plans</td>
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<tr>
<td>Easier to improve our business processes</td>
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<td>hr/month/person</td>
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<td>Also time saved for leadership team</td>
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<tr>
<td>Improved ability to respond to external queries and challenges as decision presented chronologically</td>
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<td>wk/year</td>
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Appendix 3a – EPISTEME Cost Benefit Analysis

EPISTEME
All financial amounts in kUSD ()

1. Scenario Assumptions

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2. Benefits

Financial benefits

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</tr>
</thead>
<tbody>
<tr>
<td>Shorten the drug project’s critical line by 1 day (one project)</td>
<td>Business</td>
<td>0</td>
<td>0</td>
<td>1,000</td>
</tr>
<tr>
<td>Less risk of losing a positive corporate reputation</td>
<td></td>
<td></td>
<td></td>
<td>3,000</td>
</tr>
</tbody>
</table>

Total Financial Benefits

<table>
<thead>
<tr>
<th>Category</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>1,000</td>
</tr>
</tbody>
</table>

Manpower Benefits (expressed as FTE years)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Category</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work time saved in information searching and retrieval</td>
<td>Business</td>
<td>0.90</td>
<td>3.66</td>
<td>11.00</td>
</tr>
<tr>
<td>Increase confidence in chosen strategies</td>
<td>Business</td>
<td>0.90</td>
<td>3.66</td>
<td>11.00</td>
</tr>
<tr>
<td>Reduce number of repeat mistakes</td>
<td>Business</td>
<td>0.45</td>
<td>1.87</td>
<td>5.60</td>
</tr>
<tr>
<td>Improve and shorten the decision making process by project teams</td>
<td>Business</td>
<td>0.45</td>
<td>1.87</td>
<td>5.60</td>
</tr>
<tr>
<td>Simple integration of advice into high level business documentation and process plans</td>
<td>Business</td>
<td>0.45</td>
<td>1.87</td>
<td>5.60</td>
</tr>
<tr>
<td>Easier to improve our business processes</td>
<td>Business</td>
<td>0.25</td>
<td>0.99</td>
<td>2.97</td>
</tr>
</tbody>
</table>
Appendix 3a - EPISTEME Cost Benefit Analysis

| Improved ability to respond to external queries and challenges as decision presented chronologically | Business |
|---|---|---|---|---|
| | 0.23 | 0.93 | 2.80 |

| Easier for people to switch and get up to speed in new projects | Business |
|---|---|---|---|---|
| | 0.07 | 0.29 | 0.86 |

Total Business Manpower Benefits (FTE years) | 3.70 | 15.14 | 45.43 |
Total IS Manpower Benefits (FTE years) | 0.00 | 0.00 | 0.00 |
Total Benefits | 7.40 | 3.028 | 10.086 |

3. Initial Investment / Project Costs

<table>
<thead>
<tr>
<th>Manpower (FTE years)</th>
<th>Category</th>
<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>Delete</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Business Lead</td>
<td>Business</td>
<td>0.20</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>Knowledge Management</td>
<td>Business</td>
<td>1.95</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Acceptance Testers</td>
<td>Business</td>
<td>0.40</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Training</td>
<td>Business</td>
<td>0.40</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>IS Project Manager</td>
<td>IS</td>
<td>0.15</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>SD&amp;I</td>
<td>IS</td>
<td>0.15</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>Quality Manager</td>
<td>IS</td>
<td>0.15</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>Architect</td>
<td>IS</td>
<td>0.10</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Developer</td>
<td>IS</td>
<td>0.20</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Test Manager</td>
<td>IS</td>
<td>0.10</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Project Analyst</td>
<td>IS</td>
<td>0.20</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Project Support</td>
<td>IS</td>
<td>0.15</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Total business manpower (FTE years) | 2.95 | 0.01 | 0.00 |
Total IS manpower (FTE years) | 1.20 | 0.03 | 0.00 |

Revenue costs

<table>
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<tr>
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</thead>
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<tr>
<td>Category</td>
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## Appendix 3a – EPISTEME Cost Benefit Analysis

### License costs for Autonomy, WordNet, KAON2

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<tr>
<th></th>
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<th>2008</th>
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</thead>
<tbody>
<tr>
<td>Revenue Costs</td>
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</tr>
<tr>
<td>Total Revenue Costs (linked to investment or project)</td>
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<td>0</td>
<td>0</td>
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### Capital Expenses

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<th>2009</th>
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<tbody>
<tr>
<td>Oracle servers, Prod and Dev/Pre-prod</td>
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<td>15</td>
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### Total Capital Expenses

<table>
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<tr>
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<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>15</td>
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<td>0</td>
</tr>
</tbody>
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### Depreciation & Amortization According to Plan

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<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oracle servers, Prod and Dev/Pre-prod</td>
<td>5</td>
<td>5</td>
<td>5</td>
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### Total Depreciation & Amortization (acc. to plan)

<table>
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<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
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<td>5</td>
<td>5</td>
</tr>
</tbody>
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### Total Project Costs

<p>| | | | |</p>
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<th></th>
<th></th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Total</td>
<td>779</td>
<td>6</td>
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### 4. Operating Costs (Ongoing)

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<th>2009</th>
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</thead>
<tbody>
<tr>
<td>Business System Owner</td>
<td>0.02</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Business Superusers</td>
<td>0.07</td>
<td>0.15</td>
<td>0.15</td>
</tr>
<tr>
<td>ASM</td>
<td>0.05</td>
<td>0.10</td>
<td>0.10</td>
</tr>
<tr>
<td>IS Quality Manager</td>
<td>0.02</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Application Architect</td>
<td>0.05</td>
<td>0.10</td>
<td>0.10</td>
</tr>
</tbody>
</table>
Appendix 3a – EPISTEME Cost Benefit Analysis

Total Business Manpower (FTE years)  0.09  0.20  0.20
Total IS Manpower (FTE years)  0.12  0.25  0.25

Revenue Costs

<table>
<thead>
<tr>
<th>Category</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance costs for KAON2, WordNet, Autonomy IS</td>
<td>0</td>
<td>3</td>
<td>3</td>
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Total Revenue Costs (linked to operating costs)

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3</td>
<td>3</td>
<td></td>
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5. Net Earnings

Net Earnings (kUSD)

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Profit</td>
<td>-33</td>
<td>2,944</td>
<td>10,008</td>
</tr>
<tr>
<td>Taxes</td>
<td>-9</td>
<td>824</td>
<td>2,802</td>
</tr>
<tr>
<td>Net Earnings (for the year)</td>
<td>-24</td>
<td>2,120</td>
<td>7,206</td>
</tr>
<tr>
<td>Accumulated Net Earnings</td>
<td>-24</td>
<td>2,096</td>
<td>9,302</td>
</tr>
</tbody>
</table>

6. Cash Flow

<table>
<thead>
<tr>
<th>Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Benefit</td>
<td>-33</td>
<td>2,944</td>
<td>10,008</td>
</tr>
<tr>
<td>Reversal of Depreciation &amp; Amortization Acc. to Plan</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>This Year’s Capital Expenses</td>
<td>-15</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Taxes</td>
<td>9</td>
<td>-824</td>
<td>-2,802</td>
</tr>
<tr>
<td>Cash Flow (for the year)</td>
<td>-34</td>
<td>2,125</td>
<td>7,211</td>
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</tbody>
</table>

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### 7. Key Indicators

**Net Present Value, Internal Rate of Return, and Payback Period**

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
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<tbody>
<tr>
<td>Discount Rate</td>
<td>10.0%</td>
</tr>
<tr>
<td>Net Present Value (NPV)</td>
<td>7,858</td>
</tr>
<tr>
<td>Internal Rate of Return (IRR)</td>
<td>6560.5%</td>
</tr>
<tr>
<td>Payback Year</td>
<td>2008</td>
</tr>
<tr>
<td>Payback Period (years)</td>
<td>0.0</td>
</tr>
</tbody>
</table>
# EPISTEME Cost Benefit Analysis

All financial amounts in kUSD

## 1. Benefits

<table>
<thead>
<tr>
<th></th>
<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Financial Benefits</strong></td>
<td>0</td>
<td>0</td>
<td>1,000</td>
</tr>
<tr>
<td><strong>Total Business Manpower Benefits (FTE years)</strong></td>
<td>3.70</td>
<td>15.14</td>
<td>45.43</td>
</tr>
<tr>
<td><strong>Total IS Manpower Benefits (FTE years)</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Benefits</strong></td>
<td>740</td>
<td>3,028</td>
<td>10,086</td>
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</table>

## 3. Initial Investment / Project Costs

<table>
<thead>
<tr>
<th></th>
<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total business manpower (FTE years)</strong></td>
<td>2.95</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Total IS manpower (FTE years)</strong></td>
<td>1.20</td>
<td>0.03</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Total Revenue Costs (linked to investment or project)</strong></td>
<td>30</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Capital Expenses</strong></td>
<td>15</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Depreciation &amp; Amortization (acc to plan)</strong></td>
<td>5</td>
<td>5</td>
<td>5</td>
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## 4. Operating Costs (Ongoing)

<table>
<thead>
<tr>
<th></th>
<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
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<tbody>
<tr>
<td><strong>Total Business Manpower (FTE years)</strong></td>
<td>0.09</td>
<td>0.20</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Total Revenue Costs (linked to operating costs)</strong></td>
<td>0</td>
<td>3</td>
<td>3</td>
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## Cost Summary for Business Case

<table>
<thead>
<tr>
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<th>Year 0</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Financial cost (business)</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Financial cost (IS)</strong></td>
<td>5</td>
<td>8</td>
<td>8</td>
</tr>
</tbody>
</table>

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Appendix 3a – EPISTEME Cost Benefit Analysis

<table>
<thead>
<tr>
<th></th>
<th>Total Manpower cost for Business (FTE years)</th>
<th>Total Manpower cost for IS (FTE years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.04</td>
<td>1.32</td>
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5. Net Earnings

<table>
<thead>
<tr>
<th></th>
<th>Net Earnings (for the year)</th>
<th>Accumulated Net Earnings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-24</td>
<td>2,120</td>
</tr>
<tr>
<td></td>
<td>2,096</td>
<td>9,302</td>
</tr>
</tbody>
</table>

6. Cash Flow

<table>
<thead>
<tr>
<th></th>
<th>Cash Flow (for the year)</th>
<th>Net Cash Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-34</td>
<td>2,125</td>
</tr>
<tr>
<td></td>
<td>2,091</td>
<td>9,302</td>
</tr>
</tbody>
</table>

7. Key Indicators

**Net Present Value, Internal Rate of Return, and Payback Period**

<table>
<thead>
<tr>
<th>Net Present Value (NPV) at 10%</th>
<th>7,858</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Rate of Return (IRR)</td>
<td>6560 5%</td>
</tr>
<tr>
<td>Payback Year</td>
<td>2008</td>
</tr>
<tr>
<td>Payback Period (years)</td>
<td>0 0</td>
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</table>
Appendix 3a - EPISTEME Cost Benefit Analysis

Net Earnings and Cash Flow (for the year)

Accumulated Net Earnings and Net Cash Flow
Appendix 3b – EPISTEME Benefits Map

<table>
<thead>
<tr>
<th>Benefits Market</th>
<th>Lead time reduction benefits</th>
<th>Risk reduction benefits</th>
<th>High-potential benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dollar-valued benefits</td>
<td>Structured and fully reasoned approach to all key decisions (Time)</td>
<td>Faster, more efficient decision to define clinical plans (Time)</td>
<td>Single location for all strategic direction (Time, Resource and Cost)</td>
</tr>
<tr>
<td></td>
<td>Creation of a single knowledge base stored in one location (reduced complexity)</td>
<td>Faster, more efficient decisions when faced with emerging issues during development (Time)</td>
<td>Knowledge management capability with respect to the decision making process and identification of prior experience and networks of experts (Resource)</td>
</tr>
<tr>
<td></td>
<td>Better deployment of key strategic resources that focus on resolution of scientific issues and deliver projects as efforts are focused on strategy rather than protracted information seeking (Resource)</td>
<td>Evaluate and apply experience to resolve new issues (Time, Resource and Cost)</td>
<td>Visually identify who has been involved in defining the strategic direction of the project over time - who and who has not been involved (Time and Resource)</td>
</tr>
<tr>
<td></td>
<td>Shorter duration of timelines as the clinical plans become more focused and we build the knowledge base (Time)</td>
<td></td>
<td>The strategic direction is linked directly to the supporting expert advice (Resource)</td>
</tr>
<tr>
<td></td>
<td>More efficient and better designed Clinical strategies therefore less $$ (Cost)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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## Appendix 3b – EPISTEME Benefits Map

<table>
<thead>
<tr>
<th>Dollar-valued benefits</th>
<th>Lead time reduction benefits</th>
<th>Risk reduction benefits</th>
<th>High-potential benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less resource intensive for MS - therefore more resource can be offered to projects or split across project teams (Time)</td>
<td>No need to re-invent the wheel (Time and Resource)</td>
<td>Advice presented with strategic options rather than a single option (Time)</td>
<td>Minimise the loss of intellectual property if people leave the company - Protection of corporate assets (Cost)</td>
</tr>
<tr>
<td>Trusted brand - improved reputation and feedback from PT (Time)</td>
<td>Better shorter and more focused group reasoning targeted at issue resolution (Time)</td>
<td>Advice presented with A, B, R, D and associated supporting evidence (Time)</td>
<td>Identification and reward of experts easily (Volume)</td>
</tr>
<tr>
<td>Standard consist message to project teams will improve their ability to interpret the advice (Time)</td>
<td>Increased confidence based on trusted brand leads to reduced recycling of issues and thereby decreases time (Time)</td>
<td>Knowledge stored in a single location that can link to most other applications (Time and Resource)</td>
<td>Improve knowledge sharing (Time and Resource)</td>
</tr>
<tr>
<td>Identification of knowledge rich and knowledge poor areas to assist in resourcing (Resource)</td>
<td></td>
<td>Advice created from groups of experts input rather than a single opinion (Resource)</td>
<td>Linking strategic direction to decision making process enables people to visualise the strategic direction (Resource)</td>
</tr>
<tr>
<td>Generate metrics to enable MS to identify improvement targets - Improve MS contribution to drug development strategies (Resource)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Easier for people to get up to speed on new projects as the strategic direction is easily traced (Time)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Better advice leads to better more efficient development programs (Time and Resource)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| creation | searching |
Appendix 4 - EPISTEME Use Case Analysis

AstraZeneca GDD IS
Global Drug Development Specification

Use Case Analysis for Knowledge Mgt Pilot Application

Internal Information

Author/Owner: Mitesh Patel
Document Id: N5321000000
Document Ref. Name: Use Case Analysis for Knowledge Mgt Pilot Application
Version: 0.1
Pages: 1(17)
Document Type: Specification

Review

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<tr>
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<th>Reviewed by role</th>
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<tbody>
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<td>Kevin Nairn</td>
<td></td>
</tr>
<tr>
<td>Review Signature</td>
<td>Date Reviewed</td>
</tr>
<tr>
<td></td>
<td>Recommended</td>
</tr>
<tr>
<td></td>
<td>Not recommended</td>
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Approval

<table>
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<tbody>
<tr>
<td>Holger Adelmann</td>
<td>Director Clinical Pharmacology UK</td>
</tr>
<tr>
<td>Approval Signature</td>
<td>Date Approved</td>
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<td></td>
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</table>

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Appendix 4 - EPISTEME Use Case Analysis

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1. INTRODUCTION

1.1 Purpose
This document details the Use Case Analysis for the Knowledge Management Pilot Application.

1.2 Scope
This project is concerned with implementing a pilot version of the Knowledge Base Application and providing a user-friendly interface to allow users in Medical Science UK to input, view, search and export to PDF "Knowledge Objects" to the application.

1.3 References
N5321000000 - Project Charter for Knowledge Base Pilot Application
N5321000000 - Xdev Knowledge Base Feasibility Study – version 1.0
Architectural Assessment Report

1.4 Definitions

<table>
<thead>
<tr>
<th>KNO - Knowledge Object</th>
<th>A distinct piece of information regarding a particular discussion, question or opinion which can be input to the application – the application facilitates and enables the user to create the advice based on Scenario's that will benefit AstraZeneca</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario based advice</td>
<td>Advice given to project teams/TA etc…outlining the suggested scenarios – each scenario has a preference, risk and evidence rating provided by Medical Science UK</td>
</tr>
</tbody>
</table>

2. USE CASE ANALYSIS

2.1 Background
For more information please see Project Charter and Feasibility Study

2.2 Use Case Diagram
The diagram below describes the major piece of functionality that the Application must be able to deliver.
Appendix 4 - EPISTEME Use Case Analysis

2.3 Use Case Description – Create KNO

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Create Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>The main scenario outlines the steps to Create a Knowledge Object in the system</td>
</tr>
<tr>
<td>Role(s)/Actor(s)</td>
<td>Any valid System User who has User or Knowledge Manager privileges</td>
</tr>
<tr>
<td>Security Requirements</td>
<td>The System will pick up the user privileges once the user accesses the system</td>
</tr>
<tr>
<td>Triggers</td>
<td>1. Knowledge Capture Event</td>
</tr>
<tr>
<td>Pre-Conditions</td>
<td>Relevant Knowledge to Capture as a KNO</td>
</tr>
<tr>
<td>Success Post-Conditions</td>
<td>Knowledge Object Created in System and a PDF is generated and stored.</td>
</tr>
<tr>
<td>Failure Post-Conditions</td>
<td>The system throws an error message to the user, and also informs the Knowledge Manager/system administrator, even though input is captured.</td>
</tr>
</tbody>
</table>
### Appendix 4 - EPISTEME Use Case Analysis

#### Main Scenario – User Creates a Knowledge Object

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> The user adds a descriptive Title for the Knowledge Object</td>
<td>Based on the Descriptive Title, the system will fix inconstancies within the title and produce by default a unique descriptive Filename, which the User can choose to modify but needs to be revalidated by the system. The system will automatically populate the User Name, which will be non-editable. The System will automatically populate the Creation Date, which will be non editable. Post Annotation Date proposed by system as default 1 year from current date, however this date can be amended according to when the advice is expected to deliver its final outcome (positive/negative).</td>
</tr>
<tr>
<td><strong>2</strong> The user enters into the Context Field some descriptive text or related terminology for the Knowledge Object</td>
<td>The System will capture the text the User enters for the Context.</td>
</tr>
<tr>
<td><strong>3</strong> The user chooses to add definitions for terms used within the Knowledge Object</td>
<td>The system will check them against the controlled vocabulary. The system will check the structure: Item (Acronym) = description</td>
</tr>
<tr>
<td><strong>4</strong> The user enters the reasons for Knowledge Object Creation into the Trigger Field.</td>
<td>The system will provide a list of all Triggers (TA, EXPT, Clinical, Study Team, External, Clinical Project Team, Medical Science, others)</td>
</tr>
<tr>
<td><strong>5</strong> The user enters text that describes the Issue that needs to be addressed this forms the basis of the Knowledge Object.</td>
<td>The System will automatically prompt the user to input the first scenario</td>
</tr>
<tr>
<td><strong>6</strong> The user enters a description for the scenario</td>
<td>The system captures the free text entered by the user</td>
</tr>
<tr>
<td><strong>7</strong> The user enters an Assumption for the scenario</td>
<td>The System will capture as many Assumptions as the user decides to enter.</td>
</tr>
<tr>
<td>- The user can enter more than one assumption by pressing the + button</td>
<td></td>
</tr>
<tr>
<td>- The user can add a link(s) to a document(s) or web pages in the Relation tag. Relation defines pointers to resources that are related to this Knowledge object e.g. detailing evidence</td>
<td>The System provides hyperlinks to the document or related articles e.g. website</td>
</tr>
<tr>
<td>- The System will link as many related Items as the user wishes to refer to</td>
<td></td>
</tr>
</tbody>
</table>

*At creation stage the system should make use of a controlled vocabulary where appropriate.*
## Appendix 4 - EPISTEME Use Case Analysis

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Create Knowledge Object</th>
</tr>
</thead>
</table>
| **8** - The user selects an Evidence level for the Assumption | - The System will provide options for the evidence level of the statement - "Low", "Medium" & "High", "None", which the user can select.  
- If User selects "None" the system will prompt the user with "Are you sure evidence level cannot be assigned?" |
| **9** - The user enters a benefit for the scenario.  
- The user can enter more than one benefit for the scenario and complete steps 10-12. | - The System will capture as many benefits as the user decides to enter |
| **10** - The user selects an Evidence level for the Benefit | - The System will provide options for the evidence level of the statement - "Low", "Medium" & "High", "None", which the user can select.  
- If User selects "None" the system will prompt the user with "Are you sure evidence level cannot be assigned?" |
| **11** - The user enters a risk for the scenario.  
- The user can enter more than one risk for the scenario and complete steps 14-16.  
- The user can add a link(s) to a document(s) or web pages in the Relation tag. Relation defines pointers to resources that are related to this Knowledge object e.g. detailing evidence. | - The System will capture as many risks as the user decides to enter  
- The System provides hyperlinks to the document or related articles e.g. website  
- The System will link as many related items as the user wishes to refer to |
| **12** - The user selects an Evidence level for the risk | - The System will provide options for the evidence level of the statement - "Low", "Medium" & "High", "None", which the user can select.  
- If User selects "None" the system will prompt the user with "Are you sure evidence level cannot be assigned?" |
| **13** - The user enters a disadvantage for the scenario.  
- The user can enter more than one disadvantage for the scenario  
- The user can add a link(s) to a | - The System will capture as many disadvantage as the user decides to enter. |
## Appendix 4 - EPISTEME Use Case Analysis

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Create Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>document(s) or web pages in the Relation tag. Relation defines pointers to resources that are related to this Knowledge object e.g. detailing evidence.</td>
<td>- The System provides hyperlinks to the document or related articles e.g. website</td>
</tr>
<tr>
<td></td>
<td>- The System will link as many related items as the user wishes to refer to</td>
</tr>
<tr>
<td>1 - The user selects an Evidence level for the disadvantage.</td>
<td>- The System will provide options for the evidence level of the statement - &quot;Low&quot;, &quot;Medium&quot; &amp; &quot;High&quot;,&quot;None&quot;, which the user can select</td>
</tr>
<tr>
<td></td>
<td>- If User selects &quot;None&quot; the system will prompt the user with &quot; Are you sure evidence level cannot be assigned?&quot;</td>
</tr>
<tr>
<td>1 - The user can add a link(s) to a document(s) or web pages in the Relation tag. Relation defines pointers to resources that are related to this Knowledge object e.g. detailing evidence</td>
<td>- The System provides hyperlinks to the document or related articles e.g. website</td>
</tr>
<tr>
<td></td>
<td>- The System will link as many related items as the user wishes to refer to</td>
</tr>
<tr>
<td>2 - On completion of all scenarios the user is prompted to Rank the Scenarios</td>
<td>- The System displays all the scenarios and expects the user to rank them. The System will then display the scenarios in rank order (1 = preferred . x)</td>
</tr>
<tr>
<td></td>
<td>- No 1 being the preferred scenario offered to the project team</td>
</tr>
<tr>
<td></td>
<td>- User may choose not to rank scenario at that time.</td>
</tr>
<tr>
<td>2 - The user saves their Knowledge Object</td>
<td>- The System captures and validates the Knowledge Object, and displays message &quot;Knowledge Object Created Successfully&quot;</td>
</tr>
<tr>
<td></td>
<td>- PDF of Knowledge Object is created and a pointer is sent by email to the user.</td>
</tr>
<tr>
<td></td>
<td>- In case of a validation error the system displays &quot;KNO created but errors need fixing, KM has been informed&quot;</td>
</tr>
<tr>
<td>2 - In the absence of a post assessment the knowledge object is regarded as DRAFT</td>
<td>- The System automatically sets the post assessment flag to 'void'</td>
</tr>
</tbody>
</table>
## 2.4 Use Case Description – Edit KNO

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Edit Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>The main scenario outlines the steps to Edit a Knowledge Object in the system.</td>
</tr>
<tr>
<td><strong>Role(s)/Actor(s)</strong></td>
<td>Any valid System User who has User or Knowledge Manager privileges.</td>
</tr>
<tr>
<td><strong>Security Requirements</strong></td>
<td>To edit the KNO the user must be its Author or a Knowledge Manager</td>
</tr>
</tbody>
</table>
| **Triggers** | 1. Need to complete the KNO e.g. Assumptions, Benefits, Risks  
2. Need to annotate what scenario chosen by project team  
3. Need to annotate with the post Assessment  
4. Adding another scenario |
| **Pre-Conditions** | Knowledge Object available to Edit. |
| **Success Post-Conditions** | Knowledge Object successfully Edited in System  
Validated KNO stored back in the system  
PDF is replaced with the updated version only if editing beyond post annotation has been performed what happens if the user edits something other than the post annotation – should throw an error message |
| **Failure Post-Conditions** | In case of a validation error the system displays "KNO created but errors need fixing, KM has been informed" |

### Main Scenario – User edits a Knowledge Object

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The user selects the Edit Object Button</td>
<td>The system will list all Knowledge objects that the user has access to and is able to edit in date created order</td>
</tr>
<tr>
<td>2 The user selects a Knowledge Object to edit from the list</td>
<td>The system populates the Create Object Form</td>
</tr>
</tbody>
</table>
| 3 The User can edit only the following fields in the Knowledge Object that have not been greyed out. | The System automatically greys out the following fields that are not available to edit  
Available = evidence level(s), relation(s) as well as all post assessment fields  
There is a period of 7 days post creation date for completion of the KNO |
| 4 The Knowledge Manager can edit most of the fields in the Knowledge Object but has full accountability for any changes i.e. consistency with messages | The system allows the KM to amend most of the fields associated with the KNO except Not available = Title, Identifier (filename), Creator, Creation date |
# Appendix 4 - EPISTEME Use Case Analysis

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Edit Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>given to customers previously</td>
<td>The system will capture the information in the Post Assessment Field(s) (free text)</td>
</tr>
<tr>
<td></td>
<td>The system displays message “Approved KNO “</td>
</tr>
<tr>
<td></td>
<td>IF Post assessment is completed on the issue the system automatically sets KNO to ‘Approved” by setting the post assessment flag to true</td>
</tr>
<tr>
<td>The user can enter in the Post Assessment Field(s) the preferred scenario and reasoning behind</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The system saves Knowledge Object displays message “Knowledge Object annotated Successfully”</td>
</tr>
<tr>
<td></td>
<td>A PDF version is created successfully and a pointer is sent by email to the user.</td>
</tr>
<tr>
<td></td>
<td>In case of a validation error the system displays “KNO annotated but errors need fixing, KM has been informed” in which case the post assessment flag is not set to true and the KM will need to update this</td>
</tr>
<tr>
<td>The User saves the Knowledge Object.</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 4 - EPISTEME Use Case Analysis

### 2.5 Use Case Description – Search KNO

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Search Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>The main scenario outlines the steps to Search for a Knowledge Object in the system.</td>
</tr>
<tr>
<td><strong>Role(s)/Actor(s)</strong></td>
<td>Any valid System User</td>
</tr>
<tr>
<td><strong>Security Requirements</strong></td>
<td>Any Valid System User</td>
</tr>
<tr>
<td><strong>Triggers</strong></td>
<td>1. An Issue arises, which the project team seeks guidance. The user searches through the Knowledge Base application to see if a similar issue has been dealt with before and therefore be used again to overcome or help resolve a future issue</td>
</tr>
<tr>
<td><strong>Pre-Conditions</strong></td>
<td>Knowledge Objects available to search</td>
</tr>
<tr>
<td><strong>Success Post-Conditions</strong></td>
<td>Matching Knowledge Object found</td>
</tr>
<tr>
<td><strong>Failure Post-Conditions</strong></td>
<td>Matching Knowledge Object not found</td>
</tr>
</tbody>
</table>

#### Main Scenario – User searches for a Knowledge Object by full text matching only

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The user enters a keyword or Key Phrase</td>
<td>Free text is displayed in the search box according to the users requirements</td>
</tr>
<tr>
<td></td>
<td>The user selects where the search should be performed e.g. issue, scenario, context or all tags</td>
</tr>
<tr>
<td></td>
<td>The user can select AND or OR and enter another Key word, in that case search will be in all tags</td>
</tr>
<tr>
<td>2 The user clicks on Look Up</td>
<td>The system provides a go find button</td>
</tr>
<tr>
<td>3 The User clicks on Go Find</td>
<td>The System displays the Knowledge Objects that match the search criteria</td>
</tr>
</tbody>
</table>

#### Alternate Scenario 2 – User Searches for a Knowledge Object using Semantic Search

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a 1 The User selects the Semantic Search option</td>
<td>The Semantic Search box is ticked</td>
</tr>
<tr>
<td>2b 2 The user enters a keyword or Key Phrase.</td>
<td>Free text is displayed in the search box according to the users requirements</td>
</tr>
<tr>
<td></td>
<td>The user selects where the search should be performed e.g. issue, scenario, context or all tags</td>
</tr>
<tr>
<td></td>
<td>The user can select AND or OR and enter another Key word, in that case search will be in all tags</td>
</tr>
<tr>
<td>3c 3 The user clicks on Look Up</td>
<td>If the term(s) is within the ontology the system provides a go find button</td>
</tr>
<tr>
<td></td>
<td>If its not in the ontology the System will query wordnet and display sense(s) in relation to the Key word or Phrase if wordnet contains the term(s) if not it will throw 'Unable to use term'</td>
</tr>
</tbody>
</table>
## Appendix 4 - EPISTEME Use Case Analysis

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Search Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>for semantic search - default to simple text match and provide a go find button</td>
</tr>
<tr>
<td>The user selects the correct sense if found in wordnet</td>
<td>The system does a wordnet search around the term(s) and matches the retrieval with the ontology and provides a selection of matches if at least one match was found the user is prompted to select a match. The system is doing a search expansion with the help of the ontology into the matching term(s) and provides the user with a go find button.</td>
</tr>
<tr>
<td>The user selects Go Find</td>
<td>The System displays the Knowledge Objects that match the search criteria</td>
</tr>
</tbody>
</table>

### Alternate Scenario 3 – User chooses to List all Knowledge Objects

| 1b. 1. The User clicks on the List KNO button | The System displays all available Knowledge Objects                                     |
### Appendix 4 - EPISTEME Use Case Analysis

#### 2.6 Use Case Description – View KNO

<table>
<thead>
<tr>
<th>Use Case</th>
<th>View Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>The main scenario outlines the steps to View a Knowledge Object in the system.</td>
</tr>
<tr>
<td><strong>Role(s)/Actor(s)</strong></td>
<td>Any valid System User.</td>
</tr>
<tr>
<td><strong>Security Requirements</strong></td>
<td>Any valid System User</td>
</tr>
<tr>
<td><strong>Triggers</strong></td>
<td>1. A user wants to view previous KNO</td>
</tr>
<tr>
<td><strong>Pre-Conditions</strong></td>
<td>Knowledge Objects available to View.</td>
</tr>
<tr>
<td><strong>Success Post-Conditions</strong></td>
<td>Knowledge Object rendered and displayed according to 'internal' or 'customer' style sheet</td>
</tr>
<tr>
<td><strong>Failure Post-Conditions</strong></td>
<td>If the Knowledge Object is not rendered correctly, the system will send an email to the system administrator</td>
</tr>
</tbody>
</table>

**Main Scenario – User views a Knowledge Object – Customer View**

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The user searches for the Knowledge Object that they want to view</td>
</tr>
<tr>
<td>2</td>
<td>The user selects the Knowledge Object that they want to view</td>
</tr>
<tr>
<td>3</td>
<td>The user clicks on Customer View</td>
</tr>
<tr>
<td>4</td>
<td>The user clicks on the View Button</td>
</tr>
</tbody>
</table>

**Alternate Scenario 2 – User Views a Knowledge Object – Internal View**

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 a 1</td>
<td>The user clicks on Internal View</td>
</tr>
<tr>
<td>4 b 2</td>
<td>The user clicks on the View Button</td>
</tr>
</tbody>
</table>

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## Appendix 4 - EPISTEME Use Case Analysis

### 2.7 Use Case Description – Reference KNO

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Export to PDF Knowledge Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>The main scenario outlines the steps to create and send a reference to the PDF version of the Knowledge Object.</td>
</tr>
<tr>
<td>Role(s)/Actor(s)</td>
<td>Any valid System User who has User or Knowledge Manager privileges.</td>
</tr>
<tr>
<td>Security Requirements</td>
<td>The System will pick up the user privileges once the user accesses the system.</td>
</tr>
</tbody>
</table>
| Triggers                | 1. Knowledge Object Created  
                          | 2. Knowledge Object Edited |
| Pre-Conditions          | Valid Knowledge Object available |
| Success Post-Conditions | Knowledge Object pointer to PDF version created successfully and link is sent by email to the user. |
| Failure Post-Conditions | The reference to the PDF Knowledge Object is not created and sent to the user by email |

**Main Scenario – User edits a Knowledge Object**

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The user searches for the Knowledge Object that they want a pointer to the PDF version</td>
<td></td>
</tr>
<tr>
<td>2 The user selects the Knowledge Object that they want to view</td>
<td>The title of the KNO that the user wishes to view is highlighted</td>
</tr>
<tr>
<td>w The user clicks on Reference KNO button</td>
<td>The system sends a reference to the KNO by email</td>
</tr>
</tbody>
</table>

### 2.8 Use Case Description – Index KNO

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Index Knowledge Objects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>The main scenario outlines the steps to Index the Knowledge Objects in the system</td>
</tr>
<tr>
<td>Role(s)/Actor(s)</td>
<td>System Administrator / Knowledge Manager</td>
</tr>
<tr>
<td>Security Requirements</td>
<td>The System will pick up the user privileges once the user accesses the system</td>
</tr>
<tr>
<td>Triggers</td>
<td>1. Change in a knowledge object</td>
</tr>
<tr>
<td>Pre-Conditions</td>
<td>Knowledge object has been amended and validated successfully</td>
</tr>
</tbody>
</table>
## Appendix 4 - EPISTEME Use Case Analysis

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Index Knowledge Objects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Success Post-Conditions</strong></td>
<td>Knowledge Objects re-indexed in the system</td>
</tr>
<tr>
<td><strong>Failure Post-Conditions</strong></td>
<td>System throws a indexing error which needs to be addressed by the system administrator</td>
</tr>
</tbody>
</table>

**Main Scenario – System itself forces a re-index of the KNOs**

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 None</td>
<td>Upon successful validation of a newly created or edited KNO, the system is triggering a automatic re-index of the knowledge base</td>
</tr>
</tbody>
</table>

**Alternative Scenario – System Administrator or Knowledge Manager forces a re-index of the KNOs**

<table>
<thead>
<tr>
<th>User Action</th>
<th>System Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 User manually forces re-indexing by pressing the 'create index files' and 're-index' buttons consecutively. This must be done 10 seconds apart.</td>
<td>The system re-indexes the knowledge base</td>
</tr>
</tbody>
</table>
2.9 Use Case Description – Manage Users

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Manage Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>The main scenario outlines the steps to Manage users in the system</td>
</tr>
<tr>
<td>Role(s)/Actor(s)</td>
<td>System Administrator and Knowledge Manager</td>
</tr>
<tr>
<td>Security Requirements</td>
<td>The System will pick up the user privileges once the user accesses the system</td>
</tr>
<tr>
<td>Triggers</td>
<td>1. New user</td>
</tr>
<tr>
<td></td>
<td>2. Change in users role</td>
</tr>
<tr>
<td>Pre-Conditions</td>
<td>User database which contains the people and their roles</td>
</tr>
<tr>
<td>Success Post-Conditions</td>
<td>Database amended successfully and role updated successfully</td>
</tr>
<tr>
<td>Failure Post-Conditions</td>
<td>Throws an error which needs to be addressed by the system administrator</td>
</tr>
</tbody>
</table>

First Scenario – Administrator adds new user

User Action | System Response
---|---
1. The Administrator identifies a new user. The Administrator completes and defines the roles of the user e.g. trainee or user. The administrator checks that appropriate access has been granted and the new user is able to perform all tasks associated with their access permissions. | The system allows appropriate access to the user.

Second Scenario – Administrator amends the role of a user

User Action | System Response
---|---
1. The administrator identifies a user who needs to have their access permissions amended e.g. user to KM. The administrator checks that appropriate access has been granted and the new user is able to perform all tasks associated with their access permissions. | The system allows appropriate access to the user.

2.10 Design constraints

Please see Architecture Assessment report for more details, which explains what needs to be done in order to fully productionalise the application and meet AZ standards including potential portal integration.
Appendix 4 - EPISTEME Use Case Analysis

2.11 Assumptions and dependencies
This is a Pilot application with a limited shelf life, the application will need to be redeveloped in order to fully productionalise it.

3. OPERATIONAL REQUIREMENTS

3.1 Functional requirements
This will be documented in the Technical Specification

3.2 Data requirements
The Application will store Knowledge Objects and it will be the responsibility of the Medicinal Science department for vetting of these. It is expected that the documents will be stored in PKT and accessed by the application.

3.3 Interface requirements
The Application will need to interface with PKT in order to access Knowledge Objects.

3.4 Performance requirements
The Pilot Application must be available to Medical Science users in the UK.

3.5 System management requirements
The Knowledge Managers will look after the Pilot Application once released to the User Community, therefore no further specifics will be described here. Training will be delivered before releasing to users, the format of which is yet to be agreed.

3.6 Environment requirements
The following environments will be available:
- Production Environment

3.7 Quality characteristics
The Pilot Application must be available until end of Q2 at which point it will be reviewed and a decision made on development of the Final Production Application.

3.8 Control function requirements
These will be documented in the Technical Specification e.g. Error messages and Invalid Entry Checking.
Appendix 4 - EPISTEME Use Case Analysis

3.9 Security requirements

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<thead>
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<th>Use Case</th>
<th>Type of System User</th>
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<tr>
<td></td>
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<td>Manage Users</td>
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3.10 ER/ES requirements
N/A

3.11 Other requirements
N/A

4. REVISION HISTORY

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<td>21st March 2005</td>
<td></td>
<td>1.0</td>
<td>Mitesh Patel</td>
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</table>
Title: AZDxxxx reference formulation

Project halted - unable to close loop

Author: Helen S

Issue: What formulation(s) should be used in a comparative controlled release (CR) study
Scenario A: rank 1
Use both reference arms (Immediate Release - IR and solution)
Scenario B: rank 2
Use the IR tablet as the reference
Scenario C: rank 3
Use the solution as reference

Title: AZDxxxx Regulatory Submission Germany

Project halted - unable to close loop

Author: Helen S

Issue: The issue is around the clarity of safety margins, exposure data, safety monitoring and withdrawal criteria and how and when to approach the regulators and what data to present following a protocol rejection.

Scenario A: rank 1
Arrange a TC with BfArM to discuss the data available and see if it's enough to satisfy their needs
Scenario B: rank 2
Wait until we have all the 40 mg safety/tolerability data and exposure data and then respond
Scenario C: rank 2
Respond with the data we currently have in house as well as the data expected by the end of May 2005
Appendix 5 - KNO Post-assessments

Title: Introduction of phase II AZDxxxx tablet

Pending

Author: Alan S

Issue: The issue is the how to introduce the Phase II tablet into clinical development.

Scenario A: rank 1
Conduct a relative BA study in parallel with use of tablet in clinical studies

Scenario B: rank 2
Conduct a Bioequivalence study (Phase I versus Phase II tablet)

Scenario C: rank 2
Conduct a relative BA study before using the phase II tablet in clinical trials

Scenario D: rank 2
Do not conduct a BA study
Appendix 5 - KNO Post-assessments

Title: The optimal study design - new or rotating cohorts

Pending

Author: Helen Sp

Issue: AZDxxxx - What is the recommended study design - New cohorts or Rotating cohorts

Scenario A: rank 1
Rotating Cohorts
Scenario B: rank 2
New Cohorts

Project moved over to Sweden.

Title: The size, scope and number of doses for an informed PoP

Pending

Author: Helen Sp

Issue: The size, scope and number of doses of AZDxxxx for an informed PoP
Scenario A: rank 1
AZDxxxx PoP study conducted with 2 dose levels (100 mg and 400 mg)
Scenario B: rank 2
AZDxxxx PoP study conducted with a single dose level (400 mg)

Scenario B chosen by the business
Did the scenario produce the desired outcome? Don't know yet. Scenario analysis helped focus the project team as to what the options were and recorded the pros and cons in an organised manner.
KNO provided full information around the different options, and enabled to project team to make an informed decision.

Title: Project Sxxxx early phase 1 study design

Complete

Author: Helen Sp

Issue: What should be the design of the early phase program
Scenario A: rank 2
SAD, MAD studies in healthy volunteers followed by a multiple dose cross-over study in RA patients, followed by a 3 month PoC study in RA patients
Scenario B: rank 1
SAD, MAD studies in healthy volunteers followed by a 3 month PoC study in patients

What scenario was chosen by the business? Scenario B
Did the chosen scenario produce the desired outcome? YES.
Appendix 5 - KNO Post-assessments

This is one of the most successful scenario mapping in the knowledge base to date. The KNO contains a full risk benefit analysis, which enabled the project team to fully assess their options.

**Title:** Scenarios for AZDxxxx PoP study

**Pending**

**Author:** Helen Sp

**Issue:** What should be the design of the PoP study be and what should the exposure criteria be

**Scenario A: rank 2**
Use 1 dose and aim for the lowest dose that will achieve trough concentrations in > 90% subjects above 3 x A2 at CCR3, 1 x A2 at H1 receptor, (based upon population PK predictions), no +ve control

**Scenario B: rank 3**
Use 1 dose and aim to give maximum dose achievable from MAD study (as long as the minimum trough exposure is > 90% subjects above 3 x A2 at CCR3, 1 x A2 at H1 receptor), no +ve control

**Scenario C: rank 1**
Use more than 1 dose in PoP study

**Scenario D: rank 4**
Use 1 dose in the PoP/C study and include a +ve comparator for asthma or COPD

**Scenario E: rank 5**
Use >1 dose in the PoP study and include a +ve comparator for asthma or COPD

What scenario was chosen by the business? D

KNO enabled the project team to consider the options and make an informed decision. Therefore it was a success although the project team didn't use the clin pharm suggestion.
Appendix 5 - KNO Post-assessments

**Title:** PK difference between volunteers and patients for chemokine antagonists in RA

**Pending**

**Author:** Graham B

**Issue:** The issue is whether a PK study in patients with rheumatoid arthritis should be done prior to CCxx POP or whether a different POP design could address that issue.

**Scenario A: rank 1**
Do a PK study in patients based on discussions with Tak, that suggested important PK differences between healthy volunteers and patients with rheumatoid arthritis for CCxx antagonists

**Scenario B: rank 2**
Proceed to POC study without initial PK study in patients

**Scenario C: rank 2**
Proceed to POC study without initial PK study in patients. Include in POC an interim readout from the 1st dose to inform future dose selection in the study.

---

**Title:** Optimal timing of SAD and MAD studies for AZDxxxx

**Pending**

**Author:** Graham B

**Issue:** Timing of SAD and MAD in relation to start of PoP study

**Scenario A: rank 1**
Wait for PK/PD data to be analysed prior to finalising PoP design

**Scenario B: rank 3**
Design PoP and submit CTA and to IRB without analysis of the data from the SAD and MAD studies

**Scenario C: rank 2**
Design PoP study without SAD/MAD and submit CTA and to IRB but plan an additional dose which is incorporated after SAD/MAD analysis

---

**Title:** Timing of urine collection for C2C in AZDxxxx PoP

**Complete**

**Author:** Graham B

**Issue:** Timing of urine sample collection for the C2C biomarker in the AZDxxxx PoP study

**Scenario A: rank 1**
Collection over full 24 hrs

**Scenario B: rank 2**
Collection made during clinical visits (over 6-8 hours)

What scenario was chosen by the business? A
Appendix 5 - KNO Post-assessments

Did the scenario produce the desired outcome? Yes
Team comments - Very useful display of scenarios.
Title: Can we improve on the activity of Axxxxxxx

Pending

Author: P Gh

Issue: Axxxxxxx has been submitted for approval at a high dose as a co-stimulatory mechanism T-cell for Rheumatoid Arthritis treatment. Is the highest dose at the top of the dose response curve. Can we improve on the efficacy of it? The existing published data by BMS was modelled with respect to the dose response relationship. The results of the modelling indicate that the highest dose of axxxxxxx is close to the top of the dose response curve. However, a closer look at the data suggest an initial decrease in efficacy, defined as Disease Activity Score (DAS), at the lower doses which will then start to increase at doses greater or equal to 2 mg/kg.

Scenario A: rank 1
Target the same receptor as Axxxxxxx with a similar mechanism

Scenario B: rank 2
Target a different region of the antigen on T-cells

Scenario C: rank 3
Killing T-cell activation blackage and focusing more on interleukins
Appendix 5 - KNO Post-assessments

**Title:** Which PoM and PoP biomarkers to include into early clinical CCxx antagonist trials

**Pending**

**Author:** Richard K

**Issue:** The issue is which PoM and PoP biomarkers warrant inclusion into early clinical trials of our CCxx antagonist and how will they help us address mechanistic effects and maintained therapeutic efficacy whilst allowing both rapid and high quality decisions to be performed regarding the merit of our compound.

**Scenario A: rank 2**
Perform only the PD PoM in SAD and MAD studies

**Scenario B: rank 2**
Supplement the PD marker with a CCxx micronjection PoM assay

**Scenario C: rank 2**
Supplement the PD marker with analysis of an anti-KLH PoP assay

**Scenario D: rank 1**
Supplement the PoC study with a non-invasive (imaging) analysis of cell homing to the RA joint

**Scenario E: rank 2**
Supplement the PoC study with an invasive analysis of cell homing to the RA joint
Appendix 5 - KNO Post-assessments

Title: Collaborative Image Sharing for Discovery Medicine Histologists and Pathologists

Complete

Post assessment completed

Author: James W

Issue: We need to enable histologists and pathologists to work collaboratively internally.

Scenario A: rank 1
IQbase (using file system)
Scenario B: rank 2
IQbase (using proprietary database)
Scenario C: rank 3
Biomedical Imaging Service
Scenario D: rank 4
Bespoke

What was the chosen scenario (adopted by the business)? A
Did the scenario produce the desired effect? Yes
Are there any comments you wish to make: System not yet in production use (scheduled for May 2007, being handled by Discovery Information). Team Comment: Scenario tool was very useful.

Title: Internal Image Reference Library

Pending

Post assessment again in 6 months

Author: James W

Issue: Need to be able to publish example images to public AZ area, and also search & browse images with context information

Scenario A: rank 1
IQbase with reference area and optional bespoke interface
Scenario B: rank 2
BMI with bespoke interface
Scenario C: rank 3
Bespoke database and interface build

What was the chosen scenario (adopted by the business)? A looks most likely.
Did the scenario produce the desired outcome? Don't know yet.
Are there any comments you wish to make: Even when main system comes into production, it will be some time before this is implemented. Estimate - 2008
Appendix 5 - KNO Post-assessments

Title: Consequences the O'Byrne biomarker MeMo study for CCxx

Pending

Author: Paul N

Issue: What are the potential different outcomes of the biomarker study and their impacts on planning the CCxx PoP study

Scenario A: rank 2
We can conduct a PoP study with the CCxx antagonist where a biomarker is the primary endpoint, which can furthermore be used for stop/go decision making

Scenario B: rank 2
We can conduct a biomarker study with the CCxx antagonist where a biomarker is the primary endpoint, which cannot be used for stop decision making but a favourable result can be used to front load the development programme

Scenario C: rank 2
We can conduct a biomarker study with the CCxx antagonist where a biomarker is the primary endpoint, which will be run in parallel to the clinical asthma study

Scenario D: rank 2
The outcome of the O'Byrne MeMo study shows there is a window and timepoint for investigating drug activity but the variability is so high that it will need large numbers of patients to detect any biological effect

Scenario E: rank 2
Although there is increased CCxx expression in the lung biopsies of the O'Byrne study, there is no obvious timepoint or window for investigating drug activity

Scenario F: rank 2
There is no evidence of increased CCxx expression after allergen challenge-induced increase in lung inflammation in the O'Byrne study
Appendix 5 - KNO Post-assessments

Title: CXxxxx PoM PoP biomarker options
Pending: Too soon to update New KNO

Author: Gillian B

Issue: It may be difficult to establish PoP for RA for this target as germinal cell disruption by this mechanism is likely to take several months. A study in RA may require treatment exposure of between three to six months for a readout on clinical endpoints (ACR, DAS), a maximal effect could take up to one year. If a PoP for germinal cell disruption could be established it could provide confidence for the project team to invest in a RA PoP study of the required duration.

Scenario A: rank 0
Serial synovial biopsy looking for B cell depletion/lymphoid tissue and germinal centre disruption. Incorporate into a 3 month FTIM study in RA.

Scenario B: rank 0
Hypergammaglobulinaemic primary Sjogrens syndrome HGPSS (CXxxxx associated auto-immune disease) as a PoP for lymphoid structure/germinal centre disruption (in salivary glands. 3 month FTIM study in HGPSS

Scenario C: rank 0
Key Hole Limpet haemocyanin test for antibody production and DTH test. Hypothesis: CXxxxx inhibition will disrupt antibody production incorporate in 3 month FTIM study in RA.

Scenario D: rank 0
Radiolabelled B cell trafficking to inflammed joints. Incorporate into a single dose FTIM study in RA.

Scenario E: rank 0
Jo Edwards proposal 3 month PoP study in RA in RF +ve patients, endpoint anti-RF levels at three months
Appendix 5 - KNO Post-assessments

Title: Timing of CYP inducer study in AZDxxxx in relation to the start of Phase II

Ceased development before Phase II

Author: M MacP

Issue: Timing of drug interaction study (CYP inducer) in relation to the start of Phase II in project AZDxxxx

Scenario A: rank 1
Start Phase II and restrict inducers from the protocol

Scenario B: rank 2
Conduct interaction study prior to Phase II

Scenario C: rank 2
Start Phase II and allow inducers into the population
Appendix 5 - KNO Post-assessments

Title: Episteme functionality

Pending

Author: Kevin Nairn

**Issue:** How should we effectively use the information that we collect to translate into knowledge that supports the decision making process?

**Scenario A: rank 1**
Embrace the new knowledge management framework and implement The Knowledge Management Process, The Information Model and the Computer Based Application (EPISTEME) across the business

**Scenario B: rank 2**
Embrace the new knowledge management Process and Model but capture and store the output in another format/application (other than Episteme)

**Scenario C: rank 3**
Do not accept the new knowledge management process (group reasoning) but implement The Model and the Application (EPISTEME) across the business

**Scenario D: rank 4**
Do not accept the new Knowledge Management Framework at all (Process, Model and Application (EPISTEME))
Appendix 5 - KNO Post-assessments

Title: Global imaging support within the oncology TA

Halted

Author: Helen Y

Issue: The issue is how to provide effective and consistent imaging technical support to the Oncology TA in Phase 1 in the USA and across all phases of drug development in China within the context of Discovery Medicine structure. Although focused on provision in the USA and China these scenarios can also be using in the context of the wider question of how to provide effective and consistent technical imaging support to a globalised Oncology TA operating in multiple territories. These two opportunities are therefore considered together.

Scenario A: rank 2
Centralised Alderley Park Imaging capability with expert RCS for each technology based in Alderley Park

Scenario B: rank 4
Establish expert RCS capability locally i.e. structural imaging, functional imaging and nuclear medicine for USA and China.

Scenario C: rank 3 Chosen by business
Establish expert RCS locally for selected technologies (which?) while continuing to support others from Alderley Park

Scenario D: rank 5
Establish local RCS support capable of working across several technology platforms

Scenario E: rank 1
Centralised Alderley Park Imaging capability with expert RCS for each technology based in Alderley Park with ring fenced general DxDxMed RCS (person with capacity to work across all areas at a study delivery level to roll out guidelines, provide local regional input to AP capabilities, act as point of contact etc)

Centralised group, Dedicated RCS USA/China for imaging and tissue – accepted that tissue and imaging require different solutions – options were put on hold due to constraints in budget

Title: Imaging and dose selection strategy for AZDxxxx

Pending

Author: Helen Y

Issue: Should we introduce an imaging biomarker strategy into the current AZD1152 Clinical Development plan to a) demonstrate an early signal (anti-tumour effect) b) aid dose selection. If so, how should this be conducted?

Scenario A: rank 1
Incorporate imaging strategy into the expansion cohorts within the current 3 Phase I studies

Scenario B: rank 2
Conduct a stand alone imaging study at the end of phase I to select the dose for Phase II

Scenario C: rank 3
Do not Introduce an imaging strategy

Scenario A was chosen.
Appendix 5 - KNO Post-assessments

Did the scenario produce the desired outcome? Don't know yet. Full read out 2008. Team Comment: Very useful tool
Title: Patient Reported Outcomes in Phase III

Author: David M

Issue: Should we include patient reported outcomes in Phase III cancer studies and if so, which questionnaires should we use and why

Scenario A: rank 1
Include specific PROs (e.g. FACIT, EQ-5D) in phase III cancer studies

Scenario B: rank 2
Include generic PROs in phase III lung cancer studies

Scenario C: rank 3
Do not include any PROs in phase III lung cancer studies

Scenario A was chosen. Did the scenario produce the desired outcome? Don't know yet.

Comment: Very useful tool
Appendix 5 - KNO Post-assessments

Title: Ring fenced oncology clinical trial capacity in China and US

Complete

Author: Sh M

Issue: How can we best support RCS activities for oncology drug development activities in China and the US. *** The RCS group recommendation is: Scenario D - One of each RCS (imaging & tissue-based) based in each of China & US to be recruited and numbers expanded as workload demands, with responsibility for the implementation of the strategies as defined by the global RCS group lead from AP

Scenario A: rank 5
RCS group at AP to oversee work in China & US (No local RCS expertise)

Scenario B: rank 2
One pan-capability RCS based in each of China & US with responsibility for the implementation of the strategies as defined by the global RCS group lead from AP

Scenario C: rank 4
At least 1 RCS to support each capability (imaging, IHC, biomics, genetics & blood borne markers) is based in each of China & US with responsibility for the implementation of the strategies as defined by the global RCS group lead from AP

Scenario D: rank 1
One of each RCS (imaging & tissue-based) based in each of China & US to be recruited and numbers expanded as workload demands, with responsibility for the implementation of the strategies as defined by the global RCS group lead from AP

Scenario E: rank 3
One Study Delivery Expert (Knowledge Owner) based in each of China & US with responsibility for the implementation of the strategies as defined by the RCS group in AP

What was the chosen scenario (adopted by the business)? Scenario D.
We gave it Rank 1.
Did the scenario produce the desired effect? Yes.
Are there any comments you wish to make? A useful tool for constructive thinking & thought through planning that can be presented in a professional format for decision making.
Appendix 5 - KNO Post-assessments

Title: Txxx early human study designs to optimise PD information and timelines

Pending

Author: Marshall T

Issue: Scenarios for Txxx MAD Study Design to Maximise PD Information and to Minimise Time-Lines

Scenario A: rank 1
Use symptomless atopic asthma subjects in MAD study. Dose for 7 days. Include Sputum induction. Include Segmented Antigen Challenge

Scenario B: rank 2
Use symptomless atopic asthma subjects in MAD study. Dose for 7 days followed by Antigen Challenge. Includes Sputum induction

Scenario C: rank 3
Use symptomless allergic rhinitis subjects in MAD/POP study and dose intranasally for 7 days followed by allergen challenge. Includes Nasal Washings (NW)

Scenario D: rank 4
Use symptomless atopic subjects in MAD/POP study. Dose for 7 days. Includes Sputum induction

Scenario E: rank 5
Use normal subjects in MAD study. Dose for 7 days. Includes Sputum induction

Title: Investigational use of GST in AZDxxxx Project

Pending

Author: Marshall T

Issue: How to use GST to identify early liver damage in project AZDxxxx

Scenario A: rank 1
Investigate GST outside Project then use in SAD, MAD, POP and POC if appropriate

Scenario B: rank 2
Include GST in SAD and use in MAD, POP and POC

Scenario C: rank 3
Include GST in MAD and use in POP and POC

Scenario D: rank 4
Do not use GST
Appendix 5 - KNO Post-assessments

Title: TPD Advice AZDxxxx Tissue Biomarkers

Pending - Too soon to update - New KNO

Author: Jill W

Issue: What strategy is recommended for bio-specimen based biomarker research to support the development of AZDxxxx?

**Scenario A: rank 4**
Scenario 1 None = No exploratory biomarker research is incorporated into the development plans.

**Scenario B: rank 3**
Scenario 2 Prospective = Samples Collected for Prospective Biomarker Analysis with Analysis performed to satisfy inclusion criteria of study

**Scenario C: rank 2**
Scenario 3 Planned Retrospective = Samples Collected for Planned Retrospective Exploratory Biomarker Analysis (Data does not form and inclusion / exclusion criteria for the study)

**Scenario D: rank 1**
Scenario 4 Defensive = Samples Collected for Potential Retrospective Exploratory Biomarker Analysis
Appendix 6 – Decision support interview

Semi-Structured Interview employed in Chapter 4

Question

Information sharing
I mainly share my knowledge and experience by email.
I mainly share my knowledge and experience in group discussions when the subject comes up.
I mainly share my knowledge and experience in dedicated group reasoning meetings on pre-specified topics.

Please give a relevant example from own past experience.

Internal consultation prior to decision making in drug projects
I usually make my decisions without broad regular consultation.
I sometimes consult with my peers before I make decisions.
I usually consult with my peers before I make decisions.

Please give a relevant example from own past experience.

Communication of the decisions
Decisions are usually kept to the team they matter to.
Decisions are usually distributed or posted for my peer group to access them.

Please give a relevant example from own past experience.

Knowledge capture and storage
I usually retrieve previously generated knowledge by looking into dedicated project knowledge stores.
I usually retrieve previously generated knowledge by looking into project meeting minutes.
I usually retrieve previously generated knowledge by talking to a person involved previously.

Please give a relevant example from own past experience.

Knowledge retrieval and reuse
I find the pre-requisites completely sufficient to review and reuse previously generated project knowledge.
I find the pre-requisites OK but still a hurdle to review and reuse previously generated project knowledge.
I find the pre-requisites insufficient to review and reuse previously generated project knowledge.

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Appendix 6 – Decision support interview

Please give a relevant example from own past experience

Knowledge Management support
There is sufficient knowledge management support in my department and I know how to use it
There is some knowledge management support in my department but I struggle to use it
Knowledge management support in my department is completely insufficient
Please give a relevant example from own past experience
Appendix 7 – MS advice feedback pre-scenarios

Semi-Structured Interview employed in Chapter 7

Question

**Clarity of advice given**

The MS advice was immediately clear to the project
No major discussion was needed at the meeting
Significant discussions, but were finished at end of meeting
Decision had to be postponed to another meeting

**Usefulness of advice**

MS staff is often told that their advice cannot be used
because of other project constraints
MS staff is frequently asked if they considered other solutions

**Communication**

MS rep is respected as single point of MS contact
MS reps struggle to get their points across
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