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Approaching Information Valuation
- For clinical research information

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SUMMARY

Information resources hold often one of the main hidden assets in organizations and for that reason, if properly managed and reused, can be a real carrier of value. The purpose of this thesis is to discuss and present a logical method for approaching the valuation of information assets considering risk related aspects of not having the right information, in the right format at the right time when an undesirable event occurs. Consequently, knowing the value of information can prove an important factor when deciding on building IT/IS environment that supports full utilization and business benefits of the information assets. The cases presented in this work are significant to AstraZeneca as well as to the pharmaceutical industry as a whole, portraying the use of clinical research information in relation to risk, supporting the importance of valuing clinical research information and promoting its reusability as a valuable organizational resource.

Given the nature of clinical research (CR) information arriving at a valuation, whether qualitative or quantitative is highly subjective and based on individual or collective assessment. Five reasons for valuing CR information are identified and discussed; *exclusive possession, utility, cost or cost of recreation, potential liability and operational impact,* since information valuation is multidimensional in nature and each reason can represent a potential qualitative and/or quantitative information value. Clinical research information can be said to hold significant value when it comes to supporting risk and issue management. Knowing that CR information is accessible and accurate facilitates the management of issues and minimizes the risk for liability and operational impact as is supported with case studies. The work resulted in a conclusion that the effort to value information is not entirely problem free, although going through the method presented it is possible to approach information value.

The report is written in English.

Keywords: Information, value of information, risk management, clinical research information.

Värdering av information

Utifrån ett kliniskt perspektiv

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SUMMERING

Information kan ofta ses som en viktig men osynlig tillgång inom organisationer och om den är rätt administrerad och återanvänd kan information besitta mycket värde. Syftet med denna uppsats är att diskutera och presentera en logisk metod för att närma sig värdet av informationstillgångar med hänsyn till risk relaterade aspekter av att inte ha rätt information i rätt format vid rätt tidpunkt när en oönskad händelse uppstår. Därför kan det vara viktigt att veta hur värdefull informationen är när beslut tas om att bygga en IS/IT miljö som skall stödja utnyttjandet och affärsmöjligheten av informationstillgångarna. Fallen som presenteras i uppsatsen är viktiga för AstraZeneca men även för läkemedelsbranschen som helhet då dom visar hur klinisk information används i relation till risk. Detta stödjer viktigheten av att värdera klinisk information och återanvända den som en viktig tillgång i organisationen.

På grund av klinisk informations natur är värderingen, kvalitativ eller kvantitativ, väldigt subjektiv och baserad på individuella eller kollektiva bedömningar. Fem andledningar för att värdera klinisk information är introducerade och diskuterade; exclusive possession, utility, cost or cost of recreation, potential liability och operational impact, eftersom värdering av information är multidimensionell i sin natur och varje anledning kan representera ett kvalitativt och/eller kvantitativt värde. Klinisk information kan anses ha signifikant värde när det gäller att stödja risk och ”issue” hantering. Medvetenheten om att klinisk information är tillgänglig och pålitlig understödjer hanteringen av ”issues” och minimerar risken för liability och operational impact, vilket fallstudien visar. Arbetet resulterade bland annat i att värdering av information inte är problemfri, även om det är möjligt att närma sig värdet av information genom att följa den modell som presenteras.

Rapporten är skriven på engelska

Nyckelord: Information, värdet av information, risk management, klinisk information.

Foreword

The work on this thesis was conducted at the department of Medical Informatics at AstraZeneca R&D Mölndal. The work has been very interesting and stimulating, giving us valuable insight into the international pharmaceutical industry as well as related literature to the subject at hand.

We would like to thank everyone at AstraZeneca that took the time to be interviewed, without their help this work could not have been completed. We especially want to thank our academic instructor, Hans Björnson for his invaluable guidance and constructive criticism. We also want to thank our instructors at AstraZeneca, Elof Dimenäs and Kerstin L. Forsberg, for giving us the opportunity to work on this thesis as well as for their help and contribution. We would also like to thank Eva Ekman and Eva-Cathrine Sjöström at the AstraZeneca library for their valuable research assistance and their kindness.

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Table of contents

1 BACKGROUND 1

1.1 INTRODUCTION 1
1.2 PROBLEM DESCRIPTION 1
1.3 PURPOSE AND QUESTION AT ISSUE 3
1.4 DELIMITATION 3
1.5 EXPECTED RESULTS 4
1.6 DISPOSITION 5

2 LITERATURE REVIEW 6

2.1 INFORMATION AS A CONCEPT 6
2.1.1 DATA, INFORMATION, KNOWLEDGE 6
2.1.2 INFORMATION ATTRIBUTES 7
2.2 THE VALUE OF INFORMATION 10
2.2.1 WHAT IS VALUE 10
2.2.2 UTILITY VALUE OF INFORMATION 11
2.2.3 VALUING INFORMATION BASED ON HISTORICAL COST 12
2.3 INCREASING THE VALUE OF INFORMATION 14
2.3.1 MANAGING INFORMATION ASSETS STRATEGICALLY 14
2.3.2 INFORMATION REFINING 15
2.3.3 TAXONOMY OF INFORMATION 15
2.4 RISK 16
2.4.1 WHAT IS RISK 17
2.4.2 VALUING INFORMATION FROM A RISK MANAGEMENT PERSPECTIVE 17
2.5 CONCLUSION 20

3 METHOD 23

3.1 TYPE OF EXAMINATION 23
3.2 POSSIBLE METHODS FOR COLLECTING DATA/INFORMATION 23
3.2.1 LITERATURE STUDIES 24
3.2.2 INTERVIEWS 24
3.2.3 CASE STUDIES 25
3.3 APPROACH 25
3.3.1 INTRODUCTORY DISCUSSION 25
3.3.2 LITERATURE STUDY 26
3.3.3 CASE STUDY 26
3.3.4 DEALING WITH UNCERTAINTIES 27

4 EMPIRICAL STUDY 29

4.1 ASTRAZENECA COMPANY INFORMATION 29
4.1.1 ASTRAZENECA R&D IN MÖLNDAL 29
4.2 CASE INTRODUCTION 30

4.2.1 CASE OVERVIEW 30
4.2.2 KEY FINDINGS 31
4.3 CASE 1: LOSEC (OMEPRAZOL) 31
4.3.1 KEY FINDINGS 34
4.4 CASE 2: PLENDIL (FELODIPINE) 34
4.4.1 KEY FINDINGS 37
4.5 CASE 3: BAYER'S BAYCOL (CERIVASTATIN) 38
4.5.1 KEY FINDINGS 41
4.6 CASE 4: EXANTA (XIMELAGATRAN) AND CONSOLIDATED CLINICAL DATA STORAGE 42
4.6.1 KEY FINDINGS 45

5 ANALYSIS 47

5.1 CASE ANALYSIS FROM A RISK PERSPECTIVE 47
5.2 APPROACHING INFORMATION VALUATION 48
5.2.1 INFORMATION RISK FACTORS 48
5.2.2 REASONS FOR INFORMATION VALUATIONS ACCOUNTING FOR INFORMATION RISK FACTORS BASED ON THE CASE ANALYSIS 49
5.2.3 CLINICAL RESEARCH INFORMATION VALUE INDICATORS 53
5.3 RECOMMENDATIONS 53

6 CONCLUSIONS 56

7 DISCUSSION 58

7.1 REFLECTING ON THE WORK 58
7.2 FURTHER STUDIES 59

Figures and tables

Table 1. Definitions of data, information and knowledge (Stenmark, 2002) 7
Figure 1: Information valuation procedure (Glazer, 1993) 12
Table 2: Ten aspects that add value to information 16
Figure 2: Value to the organization 19
Table 3: Multidimensional information valuation 19
Table 4: Overview of the valuation methods presented 22
Table 5. Interviewees and their role 27
Figure 3: Timeline in the Losec case 32
Figure 4: Timeline in the Plendil case 37
Figure 5: Timeline in the Baycol case 40
Table 6: Multidimensional information valuation for CR information 49
Figure 5: Method for approaching information value 54
Table 7: Information value related to the severity of the issue and the readiness of CR information (liability and/or operational impact) 55

1 Background

The chapter provides a background to the subject and why the study is relevant. It presents the problem statement of the thesis and concludes with the delimitations and expected results of this work.

1.1 Introduction

Few organizations have realized the full potential of their information assets, although most consider their information to be essential to the operation. Information residing in different sources within organizations are most often believed to hold significant value but rarely is there any methodological valuation done. For that reason, it is important to consider the value of information and related risk aspects (not having the right information, in the right format at the right time), as important factors when deciding on building an information environment that supports full exploitation and business benefits of the information assets. Knowing the value of the information assets can lead to having a better understanding of the most and least valuable information in the organization as well as greater awareness of how information is being used, its usability and reliability.

It is suggested that there is a need to maintain a balance between information assets value, risk and the commitment to IT/IS in order to steer and not to over invest in IT/IS. This requires that organizations determine how they approach valuing information and for what reason. However, the task of measuring the value of information has continued to be difficult to a large extent. Although, some success has been achieved in measuring the exchange value of information, whereas its value in trade can be considered to follow the economic laws of supply and demand, but the quantitative value of information in use within an organization has been somewhat intangible.

Therefore the approach of this thesis is to establish information as a concept in order to set the stage for how information is interpreted, valuated, increased in value and finally approach how to account for and minimize risk aspects of clinical research information.

1.2 Problem description

In order to have the ability to determine if an IT project is worth the risk, economical and time consuming effort, a process for valuing the information itself, rather than the frequently applied technology focus, could prove more rewarding to an organization. Therefore the following problems are identified as being relevant in relations to information as an important organizational resource.

Little understanding from management regarding the real value of information and information not fully exploited

The management of information and the underlying data has not been given the highest priority of top management within organizations. This has even been true when it comes to how information and data is managed within the pharmaceutical industry where “paper” documents of valuable information and data, e.g. from clinical

trials, have not been managed as successfully as other parts of the business (Uehling, 2002). Taking into consideration how valuable this information is for reuse and can enhance further discovery, shorten the development time and time to market, it should be regarded as a high priority by top management to focus on improving the information management and exploitation within the organization.

Not a positive relationship between IT investment and financial performance

Although it is widely accepted that information technology has transformed and assisted organizations to reach new heights in performance and productivity it is also accepted that this has been done at perhaps unnecessarily high cost. According to Glazer (1991), Carr (2003), Davenport (1994), Strassmann (2003) et al., there are number of studies suggesting that there is little, if any, relationship between the increase in IT spending and a positive financial performance. Therefore it is suggested by Glazer (1991), Moody and Walsh et al. (1999), that for organizations to successfully implement their IT strategy they should focus on the information and its value rather than on technology, potential benefits and return on investment (ROI) calculations (which are often misleading and done by the project sponsor).

Risk of financial liability due to unavailable information

There is an increasing demand for improving the management of information assets within organizations. This is especially true within the pharmaceutical industry where the driving force for better management of clinical trial information and data comes from the fear of legal liability. Where, the consequences of not acting on information that suggests harmful effects can be deemed as obvious liability issue in a legal action. Furthermore the proactive usage of information can support decision making and increase creativity. Therefore, it can be suggested that better handling and proactive thinking when it comes to managing information and data from clinical trials can assist in earlier detection and resolution of a potential critical situation rising from the effect of a drug. (Uehling, 2002)

Information strategy not in line with information value

Organizations that don't have an information value focus in their IT strategy are missing out on using the information value to guide their IT strategic planning, cost justify IT investments and measure the overall effectiveness of IT (Moody & Walsh, 1999). Once organizations have understanding of the value of information assets, Strassmann (1996) recommends that they establish a strategic framework for the asset governance.

Within AstraZeneca information reuse needs to be addressed

Within the Medical informatics group at AstraZeneca the subject of valuing information has been addressed to some extent. Information has been identified as a resource that is valuable, therefore deserving special attention in order to reach its full potential for the organization. The use and reuse of information assets is considered to be the main indicator for information value when estimating its real business contribution. As an example, a successful drug development process creates considerable value, but actual revenues may take years to materialize. Under the development process there is no registration of value created, only direct cost associations (Bernhut, 2001). Information has all the characteristics of an intangible asset (see 2.1.2) and as such its unique characteristics do not prevent it from being used simultaneously by others in another case. Therefore a method for valuing

information assets can be used within AstraZeneca to support building a better information-sharing environment and promote information reuse.

1.3 Purpose and question at issue

Referring to the discussion in the problem description above, the purpose of this thesis is to discuss and present a logical method for approaching the valuation of information assets considering risk related aspects of not having the right information, in the right format at the right time when an undesirable event occurs. Furthermore the purpose is to explore how information value can be increased in order for the organizations to harness the full potential of their information assets through reuse for e.g. risk reduction, product discovery, etc. Relevant case studies are included in order to establish the link between information valuation and risk aspects.

Although the topics of this thesis have been researched significantly it should not be considered complete or the absolute truth for the subject area.

The **question at issue** for this thesis is:

What is the value of Clinical Research information from a risk analysis perspective at AstraZeneca?

To better understand and make clear the main question the following **underlying questions** will be answered:

- What methods are there for valuing clinical research information?
- How does clinical research information support risk and issue management at AstraZeneca?

1.4 Delimitation

This thesis is delimited to exploring and addressing methods for organizations to value their information assets, considering risk aspects. The theoretical framework will also work as delimitation to this thesis where information value and risk aspects will be discussed and presented (se chapter 2.2 – 2.4).

Since the problem of this thesis is to focus on the intangible assets of information it limits the possibilities of other broader approaches where the focus is on all organizational intangible assets e.g. human and knowledge capital. Most widely known theories and practical methods of valuing intangible assets don't focus on valuing information as an asset of its own. These methods aim to measure the value of e.g. knowledge/intellectual capital to account for in the organizational financial statement (Sveiby, 1997; 2001; Edvinsson & Malone, 1997, Strassmann, 1996), success of knowledge management initiatives (Sveiby, 1997; Kaplan & Norton, 1992; Dhansukhlal & Chaudhry, 2002) and information centers (Skyrme, 2002; Broadbent

& Lofgren, 1993) where information is only considered a small part of a larger context. Furthermore, the first two categories measure the company's performance by indicators that are based on the strategic objectives of the firm making it difficult to isolate the information value.

The purpose of the thesis is not to present an outcome of information value in a monetary value but rather highlight possible approaches to the subject of valuing information. Furthermore, this thesis does not have a focus on finding the value of information from a decision support perspective (Bell, 1991) because of the nature of clinical research information.

1.5 Expected results

The result of this thesis is expected to demonstrate to organizations through examples the importance of information valuation from a risk perspective and that organizations will appreciate the benefits in the valuation process itself rather than a quantitative value of information. The valuation process is expected to lead to greater awareness of information being a valuable asset and playing a key role in the organizations IT strategy. The result of this thesis should give organizations a broader perspective to how information can be valued in different ways as well as being useful to some extent when improving information for reuse and defense purposes.

1.6 Disposition

Chapter 1 – Introduction. The chapter provides a background to the subject and why the study is relevant. It presents the problem statement of the thesis and concludes with the delimitations and expected results of this work.

Chapter 2 – Theoretical framework. The information concept is presented and discussed. Various views on information value and how to add value to information are discussed as well as how risk management relates to information value.

Chapter 3 – Method. The differences between qualitative and quantitative methods are discussed followed by a discussion of possible methods for collecting information that are relevant to this thesis. The chapter argues for the chosen methods that are used in addition to describing the work process for the literature and the case studies. The chapter concludes with a discussion on how to deal with uncertainties.

Chapter 4 – Empirical study. The chapter begins with a short presentation of AstraZeneca as a company followed by a description of the medical informatics department at which the work on this thesis took place. Then the case studies are presented as well as their key finding.

Chapter 5 – Analysis. In this chapter the material from the case studies is analyzed and put in context with the theoretical framework presented in chapter 2. The cases are analyzed from an information value and risk perspective as well as how to approach information valuation based on various reasons.

Chapter 6 – Conclusion. This chapter highlights the findings from the analysis chapter and puts these in context with the question at issue for this thesis.

Chapter 7 – Discussion. In this chapter relevant issues regarding the work on this thesis as well as its conclusions are discussed.

2 Literature review

In this chapter the information concept is presented and discussed. Various views on information value and how to add value to information are presented as well risk related to information value.

2.1 Information as a concept

The definitions of data, information and knowledge are discussed and how they relate to each other. Furthermore, a presentation of information attributes and how they contribute to the uniqueness of information as an asset.

2.1.1 Data, information, knowledge

The relationship between data, information and knowledge has been widely discussed and debated in the literature (table 1). There is some confusion in the use of these terms but most authors agree that knowledge is the definitive result of the capture of data and when context and purpose is applied to data information is produced (Coakes, 2003). By applying one's own terms of reference knowledge is produced within the minds of individuals. Toumi (2000) challenges this view and states that data emerges after information, which in turn emerges after knowledge. According to Stenmark (2002) the three entities influence each other and the value of any of them depends on the purpose for which it is to be used. Stenmark states that knowledge is required to understand both data and information, but at the same time, data and information are important when creating new technologies (knowledge).

When looking at the concept *information* difficulties arise since information has to do with becoming informed and therefore reducing someone's ignorance and uncertainty (Buckland, 1991). It is therefore ironic that the term information is itself vague and used in different ways. The author discusses three different aspects when looking at the term information; information as a thing, information as a process and information as knowledge

Information has to be represented in a physical way, for example in text, so that it can be communicated (Buckland, 1991). *Information as a thing* can have different forms, e.g. text, communication or an object. Therefore information as a thing can impact knowledge or communicate information. With *information as a process* Buckland (1991) means that information is an action, to inform or be informed of something. When a person is informed the knowledge is forwarded in the process. Buckland calls this for *information as knowledge*. He argues that knowledge is what an individual thinks he knows. When an individual is informed the knowledge he possesses changes, but not necessarily in the way that he knows more than before. The message can be against what we previous thought we knew which can cause bigger uncertainty.

Buckland's view on information is one of many seen in the literature. Additional definitions are presented in table 1. Trying to define information in one sentence is too much of a simplification. Although some of the definitions in table 1 are similar to Buckland's definition, his view will be used in this thesis because it is comprehensive and consistent with the view in this thesis.

Author(s)	Data	Information	Knowledge
Wiig	-	Facts organized to describe a situation or a condition	Truths and beliefs, perspectives and concepts, judgments and expectations, methodologies and know-how
Nonaka and Takeuchi	-	A flow of meaningful messages	Commitments and beliefs created from these messages
Spek and Spijkervet	Not yet interpreted symbols	Data with meaning	The ability to assign meaning
Davenport	Simple observations	Data with relevance and purpose	Valuable information from the human mind
Davenport and Prusak	A set of discrete facts	A message meant to change the receiver's perception	Experiences, values, insights and contextual information
Quigley and Debons	Text that does not answer questions to a particular problem	Text that answers the questions who, when, what, or where	Text that answers the questions why and how
Choo *et al*.	Facts and messages	Data vested with meaning	Justified, true beliefs

Table 1. Definitions of data, information and knowledge (Stenmark, 2002)

2.1.2 Information attributes

Information attributes have been highlighted in the literature as being important to the subject of information valuation (Glazer, 1993; Moody & Walsh, 1999). In contrast to more physical products or assets, information can be easily shared between two or more parties because it does not follow the principle of either you have it or I have it, e.g. a car or a computer. One person can have the exact same information as the other at the same time compared to other goods which cannot be accessible to more than one person at a time. Information can be perishable like produce but it's not depletable or scarce as such; in fact information can be seen as self generating where the more it is used the more there seems to be. The more information is used the more valuable it gets can often be seen as the case (Glazer, 1993).

Partly due to these differences in attributes between other assets and information there has been limited success achieved when measuring the exchange value of information, although its value in trade or exchange value can be considered to follow the economic laws of supply and demand, but the value of information in use within an organization has been somewhat elusive.

7 laws of information

An organization has many assets that are of considerable value – information is one such asset which has a value based the benefits of its use and the availability. Moody and Walsh (1999) have identified a number of general principles which can be used as a basis for information valuation.

1. *Information is sharable*. This means that information can be shared between people, organizations and business areas without decreasing in value. This of course is an important quality of information, since sharing information is a vital part in information intensive companies.
2. *The more information is used, the more value it has*. Many resources decrease in value when they are used but information exhibits increasing returns to use. The cost of information lies in acquiring and maintaining it while the costs of using it are almost insignificant. Information that is not used has no value; it becomes valuable when it is used. According to Moody and Walsh (1999) a prerequisite for using information effectively is having knowledge of its existence, knowing where it is located, having access to it and knowing how to use it. According to McGee and Prusak (1993) information must be valued in a context of a specific users and decision makers, therefore information is data in use where use implies a user. They also state that information is infinitely reusable, it does not deteriorate or depreciate and only its user determines its value.
3. *Information is consumable*. Like many other assets information tends to decrease in value over time and according to Moody and Walsh (1999) information has three "lives": an operational shelf life (operational purpose, short lifetime), a decision support shelf life (support decision making, long lifetime) and a statutory shelf life (for legal requirements, very long lifetime).
4. *The value of information increases with accuracy*. The more accurate information is the more useful it is to an organization. Inaccurate information can on the other hand be very costly to an organization in terms of both operational impact and inaccurate decision making. If decision makers know how accurate (or inaccurate) the information is they are working with, they can incorporate a margin for error into their decisions (Haebich, 1998).
5. *The value of information increases when combined with other information*. When information can be compared and combined with other information it generally becomes more valuable. Being able to relate two sets of information together is substantially more valuable from a business viewpoint. Combining information is generally necessary when producing decision support information because it requires consolidating information from different operational systems.
6. *More information is not necessarily better*. In many cases the more resources you have the better you're off (e.g. finances). Information is anything but limited and the biggest problem in companies today is not the lack there of but having easy access to relevant information combined with overload of information. Decision making performance decreases once the amount of information exceeds a certain point but people still seek more information than can be efficiently processed in an effort to avoid mistakes and reduce uncertainty. This may lead to the conclusion that people believe that more information is better without being aware of their own information processing limits.

7. *Information is not depletable*. Most resources are depletable, the more you use the less you have. Information however is self-generating, which means that the more you use it, the more you have (Glazer, 1993). This is because new information is often created as a result of summarizing, analyzing or combining different information sources together. The original information remains and the derived information is added to the existing asset base and this is why information is not a scarce resource.

Measurable information attributes

The value of information is not a function of the information itself, but rather of measurable attributes of the information, according to Thomsen (2001). Thomsen means that the concept of assigning value to information is a substitute for assigning value to the area the information covers. In addition to coverage, the other important measurable information attributes are accuracy and timeliness (or speed).

According to Nichols (1987) there are valuable attributes embedded within the nature of information which are; relevance, timeliness, availability, comparability, objectivity, sensitivity and quality. The relevance of these information attributes is based on the reason for its valuation (Poore, 2000). But, for information to possess value the first three attributes (relevance, availability and timeliness) need to be present but the others can be considered as less important but desirable to some extent (Nichols, 1987). Nichols further states that all information, to be valuable, must possess quality and mentions validity, accuracy and precision as the most important quality attributes.

Information quality attributes

A list of information quality attributes is presented on the Management Information Systems Quarterly website [URL1]. Some or all of these attributes (based on the reason for the valuation) can be considered relevant when measuring information value.

- *Currency of information* – is the information up to date
- *Frequency of use* – how often is the information used
- *Level of aggregation* – origination/compatibility of information
- *Relevance of information* – how relevant to each situation is the information
- *Source of information* – how reliable is the source
- *Information scope* – what is the extensiveness of the information
- *Timeliness of information* - information provided in sufficient time for an action to be accomplished
- *Information structure* - how the content is assembled into one unit
- *Age of information* – what is the age of information when it becomes available to a function or user
- *Reliability of information* – how reliable is the information
- *Accuracy of information* – the correctness of information
- *Utility of information* – what is the usefulness of the information
- *Adequacy of information* – how satisfactory is the information
- *Data integrity* – how reliable is the source data

- *Quantity of information* – how extensive is the information
- *Recency of information* – how recent is the information
- *Value of information* – how valuable is the information (strategic value)
- *Information richness* – how rich is the information (ex. in content, accuracy, timeliness and relevance)

Blumberg and Sparks (1999), mention that the most important information valuation criteria are *reliability* and *objectivity* of the source of information.

Information as an asset
According to Moody and Walsh (1999) information satisfies the definition of an asset much better than employee or customer, although all three are commonly referred to in the literature as intangible assets. Where the company does not own employees and customers but information is owned. Information is an intangible asset with relevant attributes of having service potential and being able to give economic benefits to its owner, but not possessing the physical form of an object.

According to Godfrey et al, Henderson and Peirson (Moody & Walsh, 1999) the essential attributes of an asset are:

1. *Has a service potential or future economic benefit*; something is only an asset from an accounting viewpoint if it is expected to provide future services or economic benefits. The benefits may arise from either the use or sale of the assets. Information satisfies this requirement, because it provides the capability to deliver services and to make effective decisions.
2. *Is controlled by the organization*; control in this sense means the capacity of the organization to benefit from the asset and to deny or regulate the access of others to that benefit. Information also satisfies this requirement - if an organization has information, it alone has access to it unless it sells or grants access to another party.
3. *Is the result of past transactions*; this means that control over the asset has already been obtained as a result of past transactions such as purchases, internal development or discovery. Information also satisfies this requirement. Information is usually collected as the by-product of transactions which have occurred (internal development), or may be the result of a purchase (e.g. a proprietary mailing database) or discovery (e.g. through analysis of data).

2.2 The value of information

This thesis is to a large extent about the value of information and it is therefore important to know how the value term is interpreted when it comes to information. This chapter will shed some light on the meaning of the word and how the valuation of information can be approached.

2.2.1 What is value

The meaning of the word *value* depends on a person's own perception and can be both qualitative and quantitative. Therefore value has various definitions in the literature

and Huatuco et al (2001) has identified five main uses and meanings of the term value. Therefore the value term is used for:

1. *Cost reduction*. This is the traditional view when measuring the value of information, which is preferable due to the quantitative nature of cost and therefore making its measurement objective.
2. *A commodity in the marketplace*. Information value is determined upon the demand and the supply of the information.
3. *Good decision-making*. Information is valuable when it allows good decision making and therefore the value is depended upon the quality of the decisions made based on the information.
4. *Just in time (JIT)*. In the JIT perspective the value of information depends on its fundamental characteristics, namely; information is delivered to the right person, at the right place, at the right time and in the right format
5. *Meeting goals*. The value of information contributes when the organization wants to improve its performance measures and achieve customer satisfaction.

Hyvärinen and Simpson & Prusak (Huatuco et al., 2001), have recognized the difficulty of measuring the value of information. It is only possible to measure the effects of value, which suggests that value can only be measured indirectly (Robinson, 1962). Here, two types of value measurement are defined; indirect and direct.

The indirect type (points 3 and 5) provides the qualitative aspect of the value of information. The indirect type is seen as complementary to its direct counterpart. The direct type can quantify the value of information in terms of cash units (points 1 and 2) or in terms of information characteristics (point 4).

2.2.2 Utility value of information

Information that is useful can be seen as at least as valuable as the use that it is meant for (Poore, 2000). Valuing information based on its utility means to a large extent that the revenue generation based on the information that is used can be attributed to the value of information in part or whole.

Glazer's (1993) methodology for valuing information assets is based on the role of information as a component in the value-add chain. From any given transaction between a firm and its customers or suppliers there are valuable information which describes the transaction that took place or some related information that can be stored within the organizations data repositories. Glazer identifies three components of value that can be derived from these transactions, which are:

- Having information about the transaction can aid in future selling/buying of complementary products i.e. information can be analyzed for greater benefits for the organization.
- Transaction information can contribute to more efficiency in future transactions.
- The transaction information can have an exchange or market value to a third party.

In the same fashion the value of the exchange of information within the organization can be computed, generally from its contribution to the reduction of production or operations cost. According to Glazer, the sum of the information value that can be derived from these exchanges of information gives the total information value for the organization. The value is enabled to large extent by the inclusion of information systems and IT being used within organizations, but keeping in mind that it is the information itself that gives the value not the information technology, which is only an enabler and therefore assumed to be a fixed cost in the process. As information value increases with use the IT cost decreases, which is the assumption of all IT investments.

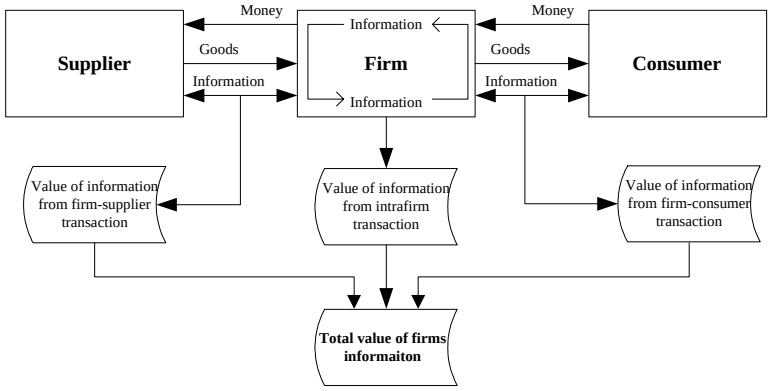

Figure 1: Information valuation procedure (Glazer, 1993)

Glazer recognizes how valuing information resources can contribute to the information and business strategy and assist in deciding what particular focus and commitment to have.

In order to implement the method, Glazer recommends that managers work together in order to arrive at a consensus for the value of transaction or exchange data. He further explains that this is necessary in order to make the tacit knowledge that resides in the head of managers more explicit. This would help in reducing the overall complexity of the valuation problem into a few more manageable problems. Glazer identifies the complexity of arriving at a monetary value of information therefore states, “the process of going through an information-valuation exercise is sometimes as important as the output itself” (p. 106).

One of the key benefits of Glazers methodology is that it can assist companies in identifying information that are valuable but not been exploited for its value, therefore by going through the process and arriving at a value which could motivate an IT investment strategy. The major weakness of this method is that the estimations of the value of information are highly subjective and seem to be time consuming to put together.

2.2.3 Valuing information based on historical cost

The historical cost method is a well established and used accounting method that is defined as “*An accounting principle requiring all financial statement items to be*

based on original cost" [URL2]. When using the historical cost method the asset (e.g. information) is valued based on how much it originally cost to acquire the actual asset (e.g. purchase price or development cost). The underlying principle behind this method is that the value of the asset is estimated based on the cost at the time of the acquisition. According to Moody & Walsh (1999) the assumption is that a firm, under normal circumstances, will only spend money to acquire an asset if it believes it will receive at least the equivalent amount spent in economic benefits. The historical cost method is the traditional cost accounting approach when valuing assets and is still the most widely used method in practice despite many attempts trying to replace it due to its flaws of not representing the correct market value according to Henderson & Peirson (Moody & Walsh, 1999).

When valuing information based on historical cost the information is represented by the costs for capturing, producing or purchasing information (Moody & Walsh, 1999). The advantage of this method is that costs for collecting information can be quantified while benefits tend to be subjective. The disadvantage of the method is that undesirable results can be obtained if the historical cost method is used in its standard form because it supports the creation of more and more information regardless of how (or if) it is used (Moody & Walsh, 1999). They propose several modifications to the method, which are:

- The cost of collecting the information should be used as the baseline for measurement of value for operational information.
- The management of information should be valued based on the cost of the processes used to extract the information from operational systems.
- Information that is collected redundantly should have zero value to avoid "double counting".
- Unused information should be considered to have zero value; this can be determined via usage statistics.
- The value of the information should be multiplied with the number of users and number of accesses to the information. When used for the first time, information will be valued at cost of acquiring. Each subsequent use will add to this value. This means that the historical cost of the information can be modified in the light of its use in practice.
- The value should be depreciated based on the *shelf life* of the information.
- The value should be discounted by its accuracy relative to what is considered to be acceptable. In practice, this would probably have to be done based on perceptions of accuracy, because of the cost of empirically measuring accuracy.

By modifying the historical cost method in this way an encouragement is made to make existing information available to a larger group of people and users instead of simply creating new information. Unused information has no value, just cost. By using this approach for valuing information companies can highlight which information is most valuable (most used) and which information gives the most benefits (cost compared to value).

2.3 Increasing the value of information

Increasing the value of information is an important step for valuing information. In this chapter some approaches to increase the value of information will be presented and discussed.

2.3.1 Managing information assets strategically

Skyrme (1997), in his article on Information Resource Management (IRM), highlights some key aspects that need to be focused on in order to manage information assets strategically and to fulfill the requirement of having "the right information, in the right place, in the right format, at the right time". Skyrme further recommends that organizations should adopt the principles of IRM, typically used for monitoring valuable tangible assets, to intangible assets like information because of the increasing value of information and lack of management in many organizations.

Some of the more important management aspects that need attention according to Skyrme (1997);

- It is important that managers understand the role and impact of information on the organization. Whereas information can add value to products and services as well as improve quality of decision-making and reduce risks.
- Establish a clear assignment of responsibility of an organizational wide Information Resource Management Initiative (IRM). Because the responsibility of developing value from information resources falls often short when governance is not apparent.
- Institute policies for how to utilize information resources throughout its lifecycle. Pay attention to ownership, information sharing and integrity. Make policies consistent with the organizational culture.
- Identify information resources, their users, usage and importance. Further identify the information cost, value and sources. Classify information by key attributes. Classify knowledge and make knowledge maps i.e. inventory over what the organization knows.
- Employ data mining, information refining and knowledge editing methodologies and techniques. Using technologies based on intelligent agents can help in the data mining process, but topic experts are needed to repackage relevant material in a user-friendly format through basic content analysis. Refining information methods techniques are examples of commercial methodologies that are not widely used by organizations, but can be highly valuable.
- Institute an effective information management strategy through the development and implementation of appropriate technological systems. These systems can be e.g. intranets, groupware and collaborative technologies for more widespread sharing and collaborative use of information as well as advanced text retrieval, document and content management and knowledge management expertise systems among others.
- Promote a culture for sharing information through expertise systems and communities.

2.3.2 Information refining

While data is mined with the aid of Data Mining (DM) techniques information can be said to be refined. That is why beyond data mining, information refining and interpretation for corporate wide utilization is what adds value to information [URL3].

According to professor Konsynski (1996) information refining is a computer-based process that converts raw information among others, reports, memos, directories and databases, into electronic form, extracts the content units and recombines them into a new form that can be distributed in a variety of ways. The end product of information refining can take several forms and among them a database, marketing report, electronic publication, paper publication etc. Therefore the most significant aspect of information refining is that it can increase the quality of raw information and in the process increases its value by helping simplifying its use for new use and re-use.

Due to the increasing amount of information and its exponential growth, it can in many cases be impractical for users to pull useful data from useless information. With the aid of computer based technologies that support information refining and business intelligence that assist users the value of information can be increased significantly as well as information re-use.

Organizations where presented as being *information refineries* by Clippinger and Konsynski (1989) where the information processing infrastructure is represented in a well thought out flow. This flow of information has been identified as being comprised by the following stages where information refining is the major value adding process in the infrastructure; discovery, acquisition, refining, storage/retrieval, delivery and presentation/use [URL4]. A closer look at the information refining step reveals; standardization, categorization, analysis, integration, interpretation and combination that are all value adding attributes (Clippinger and Konsynski, 1989).

A repository of information is created from *raw* data or information that is discovered, acquired and refined before being included in the repository. This refinement process can be manual (e.g., keyed in from paper) or computer automated (e.g., standardized form, less errors, with indexing and integration with analysis, etc.). A properly constructed information repository can be used as a platform for supporting products or product families and can allow for continuous discovery of new products with lower cost due to the reuse of the information resources. (Zack and Meyer, 1995)

Stokke et.al., (1996) stated that: "Intellectual capital is information that has been formalized, captured and *refined* to produce or manufacture a higher valued industrial product" (p.2), further he recognizes information as being the major industrial and corporate asset today.

2.3.3 Taxonomy of information

Taxonomy is a scheme for categorizing and describing different views of information. The taxonomy describes the structure, handling, access and intended audience of existing information within an organization so it can be accessed, used and reused. For an organization to be successful it is essential that it has the ability to collect, manage and exploit high quality information. Gaining access to the right information

at the right time creates an opportunity for drawing conclusions and making decisions that are optimal for the organization. [URL5]

In order to gain access to the right information at the right time it is important to increase the value of the information by increasing its accessibility and suitability for use and reuse. Skyrme (1994) presents ten aspects that add value to information that are presented in table 2.

1. Timeliness	Shelf life of information
2. Accessibility	Easy to find and retrieve
3. Usability	Ease of use
4. Utility	Is suited and usable for multiple applications
5. Quality	Accurate, reliable, credible, validated
6. Customized	Filtered, targeted, appropriate style and format
7. Medium	Appropriate for portability and ongoing use
8. Repackaging	Reformatted to match onward use
9. Flexibility	Easy to process (can be used in different ways)
10. Reusability	Can be reused

Table 2: Ten aspects that add value to information, (Skyrme, 1994)

The aspects presented in the table refer to increasing the user experience and usefulness of the information needed. These ten aspects are consistent with various information quality frameworks as well as information refining methods and taxonomy procedures that can increase information value through e.g. reuse.

Information can be found in different areas of an organization's environment; in different databases, formats and physical locations. It is a big assignment for an organization to gather, collect and reuse this information and it requires an enterprise wide plan to describe, manage and distribute the information and the information environment. This means that companies must analyze and build an information infrastructure that represent full value of information. Full value is experienced when the information consumer can get consistent, updated and correct information concerning their business domain, at the right time. The way information is accessed, used and presented must be taken into account when the taxonomy is created. [URL5]

Many companies are surprised to see to what extent a taxonomy analysis is actually a business analysis. Since taxonomy is created in order to describe information so that the information can be utilized and acted upon it must reflect the business needs of the organization. In the end the design and development of the taxonomy should be done with the aim of meeting these specific business needs. [URL5]

2.4 Risk

Risk is an extensive subject area covering several organizational areas, e.g. insurance, legal, financial and information management (security risk). The purpose of this chapter is not to cover risk through its extensive organizational impact e.g. drug development and clinical research but rather define the concept of risk and set the stage for its narrow scope presented in this thesis, which is highlighting risk elements that can affect information value.

2.4.1 What is risk

- *Risk is* – "the chance or likelihood of an undesirable event occurring and causing loss or harm. The key element of risk is uncertainty, without which, there is no risk".
- *Risk Analysis is* – **"**the process of gathering and analyzing risk-related information in the preparation of a risk assessment".
- *Risk Assessment is* – "a detailed articulation of the risks associated with the information assets and supporting Information Technology and communication (IT&C) resources at risk, threats that could adversely impact those assets and vulnerabilities that could allow those threats to occur with greater frequency or impact".

Ozier, (2003)

Risk management is defined by Caelli et al. (Finne, 2000) as having the aim of protecting an organization from incurring financial harm by "identifying, measuring and controlling uncertain events" at the lowest possible cost to the organization. Blake (2003) means that risk can be divided into basically two types, pure - and speculative risk.

- *Pure risk:* where loss is certain
- *Speculative risk:* the degree of loss varies

Further Blake explains that these risks usually take the form of some or all of the following:

- Economical (market changes)
- Legal (liability)
- Social (public relations)
- Political (government interpretations)
- Juridical (jury decisions)
- Physical (property)

Risk management issues are not stationary by its nature with constantly changing circumstances, both inside and outside of the organization, forces organizations to look at risk from a broad spectrum. The trend to look at risk management with this broad perspective has proved necessary since organizations are constantly exposed to risks that can be both pure and speculative (Blake, 2003).

2.4.2 Valuing information from a risk management perspective

Valuing information can prove useful when making decision on investment in technology for risk evasion. Having a balanced view of the cost of information control and the information value from a risk management perspective is the main message of the valuation methodology presented by Poore (2000).

Poore mentions that valuing information depends to a large extent on the purpose of the valuation therefore as such information can have several values. The author rejects the cost based valuation method as well as other methods relying solely on subjective opinions because they do not consider the risk management perspectives. Valuing information from a risk perspective differs from other valuation methodologies in Poore´s view where one or more of the following conditions are most likely the motivating factors for the valuation:

- *Exclusive possession* - Having exclusive possession of some information can be valuable for an organization. If the information is no longer exclusive then its value is diminished and if the organization is not aware of the loss of exclusivity it can lead to potential risk.
- *Utility* - Useful information can be seen as having a minimum value of the use it relates to in the organization. At the same time having information that cannot be used to its full potential can have negative value (maintenance cost, liability etc.).
- *Cost of creation or re-creation* - Valuation is based on how much it did cost the organization to acquire the information. From a risk management perspective if the information can be re-attainable for approximately the same cost the valuation can be useful. However if the process for recreating the information cannot be repeated then this valuation is not useful. If it is known that the recreation of the information is possible but for a higher cost that valuation could prove to be more relevant.
- *Liability* - Organizations may have liability concerns associated with information, for example be liable according to law, safety or third party interest. The organization may choose to value the information according to the ramification if a trust is breached. Poore means that liability issues can arise from issues of confidentiality, availability or integrity. Recognizing the difficulty in making a forward looking or hypothetical case resulting in liability damages, Poore suggests this valuation principle should best be used based on a historical case or previous occurrences.
- *Convertibility* - When information is representative for value, that is convertible to other assets, the information should be valued to at least the conversion value. The information value should be derived from the security risk assessment for unauthorized use or change to the information, which could occur and be undetected or unrecoverable.
- *Operational impact* - Information valuation can be based on the impact the absence of the information and/or data could have on the organization. If a timely access to pertinent and correct information is not available how would that affect the operations? Therefore quantifying the impact can give the value of information from a risk management perspective.

Quantifying information assets

If information is accurate, timely, permitted, useful and rare it can be seen to have a positive value and if the contrary is true it can be a liability, meaning having a negative value. Poore suggests that the value of information from a risk management perspective can be presented on an interval where the scale of positive (value) and negative (liability) information value would represent the total value of the information to the organization.

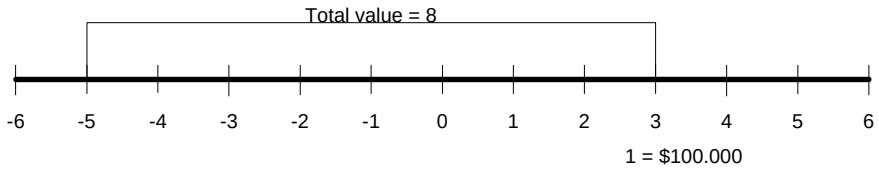

Figure 2: Value to the organization, (Poore, 2000)

Example: If the information value is 3 and the liability related to the same information is -5 then the total value of the information to the organization is 8.

Information valuation techniques

As mentioned before different techniques for valuing information are required in different situations all depending on the source of value the information has to the organization. Poore provides short examples of techniques for valuing information assets, but not in any detail. As a reference for further exploration of techniques for valuing information assets, Poore suggests a publication from the Information Systems Security Association (ISSA) called *Guidelines for information valuation* published in 1993. (The authors of this thesis where unable to obtain a copy of the document which is under revision, planned to be republished in the first quarter of 2004)

Multidimensional value of information

According to Poore the aforementioned categories of information valuations can be viewed as multidimensional in the sense that they can be affected independently by security elements such as confidentiality, reliability and availability. The affects the security elements have on the information valuation are mapped in table 3. Poore suggests that when performing the valuation the focus should be on the security elements most directly affecting the purpose of the valuation and a special attention should be on how they are categorized and dealt with for risk evasion.

Sec. element / **Inf. value**	Confidentiality	Availability	Integrity
Exclusive possession	x		
Utility		x	
Original cost or cost of re-creation			x
Potential liability	x	x	x
Convertibility	x	x	x
Operational impact		x	x

Table 3: Multidimensional information valuation, (Poore, 2000)

- *Confidentiality:* information being secret or private within a predetermined group. Sensitive information is protected from unauthorized or premature disclosure.
- *Availability:* information being accessible and usable within a reasonable time when it is required by the administrative organization.
- *Integrity / quality:* information being correct and sound representation of authorized administrative and business processes.

(Finne, 2000)

Qualitative value of information
Poore gives examples of qualitative valuation of information when a quantitative valuation is not practical. He recommends a rank ordering of risk valuations that have been identified through a risk assessment process. A simple rank ordering from least to most damaging risk is suggested since the process of going through the risk assessment provides management with sufficient information for informed decision making.

2.5 Conclusion

The conclusion from the *information as a concept* chapter is that the value of information is more difficult to measure than other assets, which can to some extent be related to the difference in their attributes. One of which is the fact that information can be indefinitely shared between two or more parties at the same time unlike e.g. car, computer and factory. Information value increases with use, accuracy and the more accessible it is to users. Therefore, information can be valued with regards to information attributes like accuracy, timeliness, content etc., which are closely related to information quality aiming to increase the availability and usefulness of the information.

The conclusions drawn from *the value of information* chapter is that the meaning of the word *value* usually depends on a persons own perception which can be expressed both qualitatively and quantitatively and that a value can only be measured by its benefits e.g. cost reduction, decision making, commodity in the marketplace. Therefore information can be viewed to be at least as valuable as the use it is put to. Two perspectives for valuing information are presented in this chapter, utility value and historical cost value. With utility value information can be seen as a component in the value-add chain, which means that the value can be related to a revenue-generating product. The historical cost method is based on the accounting principle of basing the value of information on the cost of its acquisition, but adjusted through several aspects that are constantly being monitored throughout the information life cycle e.g. use, shelf life and accuracy.

In order to realize the full benefits of information assets it has to be managed strategically which is the main conclusion from the *increasing the value of information* chapter, in addition the infrastructure should promote the availability of the right information, at the right place, at the right time. This can be done by identifying various information resources and their users, gather, collect and reuse information by employing information refining and taxonomy as well as promote a culture for sharing information.

Risk management is about defending an organization from unknown events that can lead to financial harm. A conclusion drawn from the *Risk* chapter is that general operational risk like economical, legal, social and political are relevant to the pharmaceutical industry and can be related to information resources through several risk factors. Based on this it is therefore possible to focus on valuing information from a risk management perspective and based on the reason and the purpose of the valuation information can have several different values either quantitative or qualitative.

The methods for valuing information in the literature review where chosen due to their different qualities and contribution to approaching the concept of valuing information, they are; *utility value method*, *historical cost method* and *valuing information from a risk management perspective*. Although, these methods represent to a varying degree a usable method they pertain several usable aspects that can be adapted and used in analyzing the subject at hand. Table 4 highlights some differences in the approaches and how they can be used.

Historical cost method, *Glazer, Moody & Walsh.*	**Utility value method, *Glazer.***	**Information value from a risk management perspective, *Poore.***
Use: The value is based on the cost for acquiring the information at the time of the acquisition and adjusted through several aspects that are constantly being monitored throughout the information life cycle e.g. use, shelf life and accuracy. **Advantage:** Objective and quantifies a value. Theoretically this method can be used to highlight which information gives a good ROI. Contains usable definitions of information as a concept. **Disadvantage:** Difficult to implement, requiring special IT/IS infrastructure to monitor use. May not reflect the correct value since the value is based on the cost at the time of the acquisition.	**Use:** Information value is based on the benefits gained from having the information. Revenues that can be associated with the information is used to base a value. Can be used to measure increased revenues or decreased cost as a result for having information. Information not the technology gives the value which can be used to decide on what particular focus and commitment to have in the IT/IS strategy. **Advantage:** Identifies information that is valuable but not exploited for its value. Promotes focusing on information rather than on technology. **Disadvantage:** Value based on a subjective view, focus on revenue contribution which generally can be difficult to accurately correlate with a product.	**Use:** Organizations should value information based on the reasons for the valuation, which can give different valuation, accounting for various information risk aspects. Can be used to decide on what particular focus and commitment to have in the IT/IS strategy. **Advantage:** Considers risk aspects that can contribute to information value, gives examples on the quantifying and qualifying value concept. Identifies information value as multidimensional. **Disadvantage:** Not conclusive in demonstrating an information valuation procedure. Valuation is subjective based on previous knowledge and experience. Gives several values which can be difficult to interpret and be misleading.

Table 4: Overview of the valuation methods presented

The overall conclusion is that the methods analyzed in the literature review are by far flawless and not problem free to implement. Although, the most appropriate approach to the question at issue is believed to be based on Poore's method. The method demonstrates understandable associations between several risk aspects and information value that can be applicable although several modifications are necessary in order to represent a proper focus on the problem at hand.

3 Method

In this chapter the differences between qualitative and quantitative methods are discussed followed by a discussion of possible methods for collecting information that are relevant to this thesis. The chapter argues for the chosen methods that are used in addition to describing the work process for the literature and the case studies. The chapter concludes with a discussion on how to deal with uncertainties.

3.1 Type of examination

There are, according to Patel & Davidsson (1994), two different ways to work up collected information, which are qualitative and quantitative. Even if the type of examination mainly depends on the way collected information is treated, it is here considered important that this is clear from the beginning and therefore the whole examination process will be characterized by this choice. Below, the difference between qualitative and quantitative examination will be explained and at the same time the discussion will be linked to this study.

According to Patel & Davidsson (1994), quantitative information processing is built on statistical methods where the results from a research are described in numbers, graphs or tables or as a hypothesis where statistics are used to test statistical hypothesis. The purpose of qualitative investigations is to gather different and deeper knowledge compared to when using a quantitative methods. Quantitative observations strive to understand and analyze the entirety. Because qualitative measures often build on interpretation from text based material, the results can get characterized by the person that performs the observation more easily than with quantitative observations. The authors argue that it can be practical to do ongoing analysis in qualitative observations. To do an analyzes directly after an interview or an observation can give ideas on how the work can go on and at the same time it is always good to analyze the material while it is still fresh in the mind.

This study will use a qualitative approach since the purpose is not to give statistical answers on a number of concrete questions but to describe the situation using publicized material and by conducting interviews. The analysis will therefore mostly be in the form of text and model built on the authors interpretations of the material investigated in this thesis.

3.2 Possible methods for collecting data/information

In many cases various methods can be used for solving a problem. It is hard to say that a certain method is better or worse than anyone else, it depends first and foremost on the problem at hand which method to apply. When applying a method for solving a problem it is important to consider the time and means available for solving the problem. When choosing a method it is important to find out what techniques are to be used for collecting the information and which individuals will participate. (Patel & Davidson, 1994)

Based on this works problem specification various methods could be used to solve the problem, therefore the methods used in this thesis are:

- Literature studies
- Interviews
- Case studies

These methods will be described in the following subchapters along with their advantages, disadvantages and their relevance to the study.

3.2.1 Literature studies

Patel & Davidsson (1994) categorize literature studies as *document studies* along with studies of other various document types like statistics and register, government and private documents and documents with picture and sound. According to this, movies, fiction and technical literature can be classified as literature. The authors point out that it is important to choose literature that gives as complete picture as possible so that the problem can be seen and analyzed from many angles. A common trap to fall into is to only use sources of information that back up the researchers own ideas and opinions. It can be problematic though to use different sources since the credibility and quality can be compromised. It then becomes important to view the material from a critical point of view – that is the perception of the quality of the literature. It is important to ask questions about the authors' authority, the purpose of the text in addition to how, when and where was it published. Texts are often transformed through people's interpretations and therefore it is crucial to assess if the source is primary or secondary.

The benefit of literature studies is that the researcher can often control the examination in accordance to time and place. Literature studies can give a broad and scientifically recognized knowledge about the area of research and are often in some form necessary in context with other types of studies. The disadvantages with literature studies are that it can often be difficult to establish a real life connection to the thing being studied as well as that it can take a long time to get full knowledge of the research area.

It is important to build a theoretical picture of the research area in a study like this and therefore the literature study is conducted early with a purpose to use as a guide for the interviews.

3.2.2 Interviews

The interview techniques are based on asking questions to individuals or groups and document the answers. Interviews can be made in many different ways, but the form used in this thesis is personal interviews. According to Patel & Davidsson (1994) there are two main aspects that must be considered when information is gathered through interviews: a degree of standardization and a degree of structure. The degree of standardization is about how prepared the questions are and what their rank is before the interview. If the degree of standardization is low the questions are formulated during the interview and asked in the order that is appropriate each time. A high degree of standardization means well prepared questions asked to all the interviewees in the same order. That type of interview is often used for comparison and generalization. The degree of structure is about what kind of freedom the

interviewee gets in his/her answers. A low degree of structure means open questions, which the interviewee can answer freely to, while a high degree of structured interviews leaves little room for indirect answers. The answers are more predictable and easier to compare between different interviews with a high degree of structure.

The benefit with interviews compared to other techniques is that they can be very goal oriented and therefore give a high qualitative result if the right person is interviewed in the right way. The interviewer can also affect and stimulate the respondent and explain the questions and their meanings if that is necessary. The respondent can at the same time explain his/her answers and perhaps clarify them with the help of pictures, graphs, body language, etc. In this way interviews can give a better view of reality that e.g. literature studies. The disadvantage with interviews is that they can be time consuming in both preparation and realization. It is vital to get hold of the right persons; they can be uninterested, busy or be in a place that is geographically far away. Another possible risk is that the interviewer affects the respondent in a way that is favorable to the interviewer and therefore the wrong measure can be made.

The interviews are important since the academic literature within this thesis research area is insufficient in some way and the area as such is relatively young and unexplored.

3.2.3 Case studies

The method case study is, according to Svenning (1997) a study of intensive character that can be conducted over a short or a long period of time. The method means that the person conducting the study gathers material about one or several cases through e.g. interviews or observations. According to Patel & Davidsson (1994) case studies are conducted on a small group that can be represented by individuals, organizations or situations. When conducting a case study a broad perspective is assumed with the aim of getting information that covers as much as possible. According to Svenning (1997) the case study gives a clear and detailed picture that can be the cornerstone for generalizations. The disadvantage with one case is that it can get to specific for others to benefit from the lessons learned in the case while many or several cases often don't give a deep understanding of a problem. In order to collect the desired information for the case studies interviews will be used.

3.3 Approach

This section presents how the methods, from the previous chapter, where used in order to solve the problem statement. First an introduction on how the problem area was chosen will be presented and thereafter the literature study and the empirical study including the interviews will be outlined.

3.3.1 Introductory discussion

In order to decide the problem area of interest for this thesis the authors participated in a BizNet[1] meeting where representatives from Volvo, SKF, AstraZeneca, IT

[1] A network of organizations and researchers at Victoria Institute, with interest within the area of Business technology.

University and Viktoria Institute were present. After that meeting a contact with AstraZeneca was established and a basis for the research area was reached. This was done through several discussions with Kerstin Forsberg (Medical Informatics) and Elof Dimenäs (Medical Informatics) at AstraZeneca in Mölndal. This resulted in an area of interest being chosen, which was appealing to investigate further in a form of a masters thesis. During the work on the thesis the question at issue changed a number of times as the problem area became more apparent.

3.3.2 Literature study

It is important to read already published material within the research area before the work can begin (Patel & Davidsson, 1994). This was helpful in order to get a broader understanding within the research area, which in turn made the study easier to conduct. The aim of the literature study was to build up a background for the thesis and to get a wider understanding about the area of interest. The literature study conducted during the course of this work can be categorized into four groups; books, articles, documents and Internet material.

Books: Books are a good way to obtain recognized theories within a research area. Since valuing information is a relatively new subject is was difficult to find up to date books that cover this subject, relevant to the scope of this thesis. The books used have been obtained through Handelsbiblioteket at Göteborg University and the library at AstraZeneca.

Articles: Articles can provide up to date information about a certain research area to a bigger extent than books, which was most helpful during the course of this work. The articles used have been obtained through online electronic databases at Handelsbiblioteket at Göteborg University, the library at AstraZeneca and through the Internet.

Documents: While working on the Losec, Plendil and Exanta cases internal documents in the form of reports, articles, presentations and internal memos were reviewed. These documents were acquired through the projects supervisors at AstraZeneca, the persons interviewed and the company's Intranet.

Internet material: A great deal of information used in this work has been acquired on the Internet. Most of this information has been in the form of articles but even company information. The Bayer Baycol case is entirely built on information from medical databases, news related sources and Bayer's website.

3.3.3 Case study

The case study included four cases, three concerning AstraZeneca and one concerning the pharmaceutical division of Bayer AG. The information for the AstraZeneca cases was obtained though interviews with individuals at AstraZeneca in Mölndal and from the company's intranet, while the information for the Bayer case is solely based on information from medical databases, news related sources and the company's website.

Interviews
In the case studies three cases were examined and interviews were held with key individuals in each case. The interviewees were divided into two groups depending on their role in the case: a technical role and a business role. In the Losec case there were three interviewed held, two in the Plendil case and one official interview in the Exanta case. The respondents roles in each case are shown in table 5.

The interviews had more the character of a discussion where the questions were open and the respondents answered freely about their roles in the cases and how they played out in their view. Nevertheless several questions had been constructed beforehand as a basis for the interviews. Each interview was recorded on tape and after each interview transcripts were made based on these recordings. The transcripts where then send to the respondents for additional comment and validation.

Case	**Role**
Losec case:	*Technical:* Two persons where interviewed; one was the driving force in building the safety database and one who was responsible for retrieving the information from the safety database. *Business:* One person interviewed who was a key person representing the company in this case.
Plendil case:	*Technical:* One person interviewed who was a key persons in retrieving and compiling information for this case. *Business:* One person interviewed who was working with international marketing and involved with information sharing in this case.
Exanta case:	*Technical:* One person interviewed who worked on a proof of concept for the project as well as being a information architect for the consolidated clinical data storage (CCDS). *Business:* discussions held (not a formal interview) with a key person working on the business case for CCDS.

Table 5: Interviewees and their role

In addition to these interviews, discussions were held with the projects supervisors at AstraZeneca which gave valuable input to all the cases.

3.3.4 Dealing with uncertainties
It is important in every examination to value the validity of the study. According to Patel & Davidsson (1994) this means measuring the validity and the reliability of the study. Validity has to do with the concurrency between the subject being studied and what really was studied. A qualitative study like this one is about studying abstract concepts like value and information, which means that it is difficult by certainty to identify how the methods used, can generate answers to the questions asked. In this study the question about validity is about whether the questions used in the interviews fills it purpose. This so-called interview validity has in this study been accomplished through an analysis of the questions along with the project supervisors at AstraZeneca and therefore the questions are believed to have a fairly good validity. Another uncertainty concerning the validity is the number of interviews conducted and the fact

that two of the cases occurred ten years ago. Despite this, it is believed that the validity of the respondents and the material is valid since these persons where carefully chosen by the project supervisors. Additionally, the studies have benefited from having access to internal documentation relevant in each case.

According to Patel & Davidsson (1994) reliability is about how well the instruments used can resist different types of randomness. The results of interviews always contain an uncertainty factor that can depend on various things, e.g. the interviewer's ability to register and assess the respondent's answers can be defective. The prerequisite for a good validity is thus that the interviewer is well trained or that the interview is structured in a way that the answers don't need interpretation from the interviewer. Another factor that can affect the validity is the so-called interview effect. This is about how the interviewer can influence the respondent and help them to understand, aware or unaware, what is expected of them. The authors of this thesis have previous experience of using the techniques used in this study to conduct interviews and therefore the reliability has been increased due to this fact. Also the questions used are believed to be at such comprehensive level that the knowledge possessed by both interviewers and respondents within the research area is of great advantage when analyzing the material. Furthermore all interviews have been recorded, which gives the possibility to listen to the answers repeatedly and thus increase the quality of the interpretation. To sum up the credibility of this study is believed to be acceptable for a study of this size and within the research area.

4 Empirical study

The chapter begins with a short presentation of AstraZeneca as a company followed by a description of the medical informatics department at which the work on this thesis took place. Thereafter the case studies are presented and their key finding.

4.1 AstraZeneca company information

AstraZeneca is one of the world's leading pharmaceutical companies. The company's core competence lies within the areas of discovery, development and marketing of innovative pharmaceuticals for treatment of deceases in areas of important medical needs.

The company provides innovative medicines designed to fight disease in important medical areas like: cancer, cardiovascular, gastrointestinal, infection, neuroscience and respiratory [URL6]. The company is concentrated on seven important areas of decease: heart/vessel, stomach/intestine, cancer, alleviation of pain, central nervous system, respiratory systems and infections [URL7].

AstraZeneca's headquarters are located in London, while research and development is led from Södertelje, Sweden, in addition to having a strong presence in USA. AstraZeneca operates sales offices in over 100 countries, production in 20 countries and employs approximately 58.000 people of which 11.000 are located in Sweden. Total sales for the year 2002 were $17.8 billion. [URL7]

4.1.1 AstraZeneca R&D in Mölndal

AstraZeneca's site in Mölndal is one of the company's larger research centers. Approximately 2,300 people are employed there for research and development of cardiovascular and gastrointestinal medicines. [URL8]

The company's research in Mölndal has contributed to the production of a number of medicines. Omeprazol, which has been marketed under the name of Losec (Prilosec), has been the most successful to date. The follow-up to Losec, Nexium, was developed in Mölndal and was introduced to the market in the autumn of 2000. Researchers at Mölndal are also working on several interesting projects within cardiovascular medicine, such as, thrombosis inhibitors (Crestor) that will prevent the occurrence of blood clots and Exanta the first oral direct thrombin inhibitor. [URL8]

AstraZeneca R&D Mölndal is a complete research centre that covers the range of pre clinical, pharmaceutical and clinical trials and contact with authorities. Some hundred co-workers are involved in the global marketing of medicines that are developed at Mölndal. [URL8]

Medical Informatics

This thesis was done at the medical informatics department, which is a part of Clinical Science. The main goal of medical informatics is to implement strategic directions and create an environment that allows efficient access to all relevant internal and external scientific information. Its role is also to establish an information structure

within the company and motivate the organization to share, exploit and explore scientific information as well as increase personal networking across the organization.

4.2 Case introduction

The cases in this study were chosen due to their significance to AstraZeneca and in the Bayer case to the pharmaceutical industry as a whole. These cases portray the use of information or a lack thereof, supporting the value of information promoting accessibility of organizations information resources. The first three cases are presented to illustrate how valuable Clinical Research (CR) information are to pharmaceutical organizations and the role information plays in resolving possible adversities (issues) that occur to medicine. In addition a fourth case presents AstraZeneca's current information environment and a proposed future information environment. The Losec, Plendil and Baycol cases are given in order to highlight the importance of developing an information environment that promotes risk evasion in a proactive way, case in point the consolidated clinical data storage (CCDS) presented in the Exanta case.

4.2.1 Case overview

The first two cases (Losec and Plendil) are internal cases from AstraZeneca that capture in retrospect how issues where handled, at the time of Astra-Hässle and how the information infrastructure supported the resolution of issues. The cases highlight the technical and administrative initiatives put in place in order to resolve the issues as well as what effects they had on the organization and its markets.

The Losec case describes the occurrence of adverse events reported in Germany that brought on an intensive investigation by the authorities. The Losec case can be viewed as an example of successful issue handling and proactive thinking in constructing a information environment for CR information for defense purposes.

The medicine Plendil was questioned in context to its medical class and was implicated to several severe adverse events that occurred. The case can to some extent be viewed as less successful because of how costly and time consuming its resolution became, mainly due to the lack of information availability and usability.

The third case can be seen as a worst-case scenario and is based on the German company Bayer with its cholesterol lowering medicine, Baycol. The purpose of this case is to capture in retrospect the extremities of the situation that occurred when the drug was linked to patient's deaths and how the case played out. The economic ramifications to Bayer will be addressed and the case will seek to identify risks and their extreme consequences. Furthermore the aim is to establish what went wrong and if it could have been handled any differently from an information value perspective. This case can be viewed as a non-successful example of information management due to the ramification it had on the company as well as the pharmaceutical industry as a whole.

To get a current and future view on how issues are handled at AstraZeneca the fourth case presents in general terms how the information environment at AstraZeneca supports handling of issues and how well this environment can support handling of

future issues. This case will highlight and compare the differences between current and earlier information management environments at AstraZeneca as well as the business case for CCDS. The focus will be on risk management perspectives as well as the cost and benefits of a new information environment.

4.2.2 Key findings

At the end of each case key findings will be presented, highlighting the main points that form the basis for the analysis chapter. Thereafter, several *what if* questions that arose within the interviews are offered for consideration.

4.3 Case 1: Losec (omeprazol)

Key facts:
Losec (omeprazol) was first launched in 1988 and works by blocking the final step in the production of acid in the stomach, allowing any damage in the stomach, caused by excess acid, to heal. The medicine became the global standard in treatment of patients with acid-related disorders. In 1998 sales of Losec reached the $5 billion milestone, the world's biggest ever selling branded pharmaceutical and in the year 2002 its revenues were $4.6 billion. Today, Losec is a part of AstraZeneca family of mature brands and its revenues have provided the basis for the company's success. Patents protecting Losec expire in all major markets between 1999 and 2004.

Background

In July 1993 a German Consumer Drug Journal published a short notice that implied that omeprazole caused visual disturbances and blindness. The grounds for this were two cases of visual disturbances in severely ill patients that had gone through extensive medical treatments that included Losec and up to 25 other medications. Astra had received information about the two cases, informing the German authorities in addition to visiting the clinics where the patients where. Later that month a notice with similar content was published in the official Journal of the German Health Authorities (BGA) and also in "Pharmazeutische Zeitung". Both journals reported similar cases receiving considerable public attention as well as being picked up by other popular media.

In October 1993, Astra concluded in a report to the BGA that the symptoms observed were related to the patients' severe diseases and not the omeprazole treatment. This report included statements from experts as well as results from toxicological studies.

In March 1994, Astra Germany received a letter from the BGA, demanding modification to the instructions that came with the medicine. It was also suggested that the injection form of omeprazole (not the infusion form which also was available in Germany) should be taken off the marked and that Astra was to conduct a considerable amount of additional animal and human studies. Supporting their arguments BGA referred to a total of 16 reported cases from Germany, two from USA, one from UK concerning symptoms of reduced eyesight and blindness as well as reference to four cases of weakening or loss of hearing.

In March 1994, Astra sent a response to the BGA where it was explained that the results of careful evaluation of all available pre clinical and clinical information including some animal studies utilizing the most up to date technique available showed no evidence that suggested causal relationship between omeprazole and the claims made by the BGA. The response included a large number of supporting materials from independent international experts and opinion leaders within e.g. toxicology, internal medicine and ophthalmology (eye care physicians).

During the spring of 1994, the BGA/omeprazole issue was repeatedly brought up within CPMP (Committee for Proprietary Medicinal Products) the committee dealing with pharmaceutical products within the European Union. At a CPMP meeting in July 1994, BGA delivered a report demanding handling of the issue within the CPMP before the end of July. Astra was invited to a hearing at this extra meeting in July. Five external experts and three experts from Astra, represented Astra. The result from the meting was an official statement, which concluded that a fundamental association between the reported symptoms and the use of omeprazole was not established.

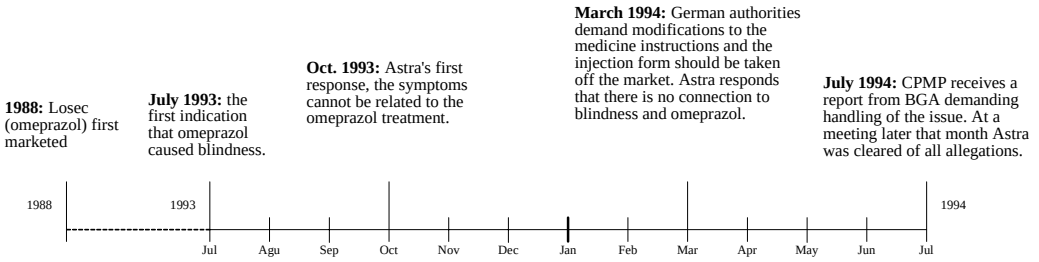

Figure 3: Timeline in the Losec case

Internal view

When the issue came up Astra quickly realized that it had to be dealt with. The Losec issue became almost an own organization with special funding and a management strategy team led by the vice president of the company. An executive team was built that included doctors, administrators, the chief of marketing and the chief of regulatory affairs. This made the decision making process very short. Later on when things got even more serious and the pressure of proving that Losec had nothing to do with the allegations a small organization was built to handle the issue, which included teams of scientists, regulatory affairs, legal affairs, IT/IS, strategic and crisis management people. These teams were based on current organization within Astra Hässle at that time, which made things easier.

From the very beginning Astra decided not to keep any information from the German authorities, they were to get all the information they needed. Astra provided them with enormous amounts of information, a total of seven thousand pages that included documentation from 75 million oral treatments, 4.5 million intra venous treatments, 177 pharmacological studies and 35 thousand patients (each with its own “record”) from clinical studies. All this information was provided in three week in addition to the various additional studies made. One such study was a study made on rabbits in Los Angeles in order to determine if Losec caused eye problems. Six of the biggest

experts within the field of neurological eye decease where also involved in viewing the material.

The information environment

The information needed in this case was stored in two databases, the safety database and the corresponding medicine database (in this case Losec). The data stored in the safety database included all information about marketed products that Astra Mölndal was responsible for including all substances that were relevant in clinical trials that Astra Mölndal was responsible for:

- Central clinical data and information on all patients
- Local clinical data and information concerning patients with SAE
- Post marketing surveillance, (from e.g. health professionals, authorities, literature) including reported adverse events/adverse drug reactions.

The safety database contained pulled data and information needed but clinical data per study was in the Losec medicine database, which was not pulled and therefore not ready for use in this case. The safety database proved an invaluable resource, since the Losec medical database was build to fulfill government regulations not for scientific purpose and therefore difficult to pull from.

The safety database was build for scientific use and the data could therefore easily be pulled. The database was build so that trends and side effects could be identified early on, which now can be seen as a very proactive thinking. All safety data was available since 8 years back. Individuals at the safety department knew that it was going to be a substantial requirement for quick access to information and data, especially safety data, for defending popular medicine. In the market there was fierce competition between pharmaceutical companies where positive effects of the drugs were not highlighted only the side effects.

Therefore, because of the information environment where the information was structured in a way that made it possible to be retrieved, Astra could pull all the information and data from the databases needed to respond to the allegations. This was done despite the short timeframe (3 weeks) given by the German authorities to produce information on side effects registered in clinical trials.

Market effects

The effect these allegations from German authorities had on Astra was relatively insignificant, although the effects where never formally investigated. Sales of Losec diminished somewhat for a short period of time especially in Germany without having a big effect on its long-term growth.

Losec was accountable for approximately 80% of Astra's sales and was therefore a important product for the company. If Losec had been withdrawn from the market it could have had severe effects for Astra in a way that today's status might not have been reached.

4.3.1 Key findings

The Losec case can be seen as best case scenario because of how it was handled. The success can mainly be attributed to the proactive thinking of handling information from clinical studies.

- Losec had been on the market for five years when it was implicated to causing visual disturbances and blindness.
- An extensive organization within Astra was established that consisted of various teams of experts from within the organization.
- An effective and uncomplicated hierarchical organizational structure contributed to solving the issue effectively.
- The most important data and information needed to defend Losec were not available in the Losec medical database, since it was build to fulfill government regulations and not for scientific purpose.
- The safety database was build for scientific use of data and information from CR studies and therefore proved an invaluable resource in defending Losec.
- The market effects were minor to Astra although not fully examined at the time.

What if questions

What if the proactive thinking of collecting and managing information had not existed at the time?

4.4 Case 2: Plendil (felodipine)

Key facts:

The drug Plendil (Felodipine) is a calcium channel blocker that works by decreasing the force of contraction of the heart muscle, decreasing the pressure of blood flow and improving the circulation of blood through the heart muscle. Plendil is mostly used to treat hypertension and angina. The product was first marketed in 1988. The sales of the product have been constant and somewhat increased in the period of 1997 - 2002 from about $370 million to over $470 million respectively (AZ3). Today, Plendil is a part of AstraZeneca family of mature brands, generating considerable revenues for the organization although the patent for the drug began to run out in 1999-01 for the most part.

Background

In the beginning of 1995 there was panic over the use of calcium channel blockers to treat hypertensions and angina. The issue started with a presentation of a study at the 35th annual conference on cardiovascular disease, epidemiology and prevention in March 1995 and was funded by the National Heart, Lung and blood Institute in USA. Following the conference and for several months a series of articles where published in science papers and media with many alarming stories to tell. Some of the headlines stated “Drug for Blood pressure linked to heart attacks: Researchers fear 6 million are imperiled” (The Washington Post, 1995). The study presented that rates of heart attack were higher among hypertensive patients taking a calcium channel blocker, risk

as high as 70%, than among patients taking a first generation medicine such as beta-blocker (Lenfant, 1995). Later there where even debates about other side effects like cancer, gastrointestinal bleeding and more that where supported by unsubstantiated research studies but provided enough information to fuel the debate.

There where heated debates for about a year within the medical profession as well as among the general public on the suggested health risks of calcium channel blockers. Physicians took sides either supporting the arguments or criticizing them on the basis of their professional opinion or in some case their allegiance. There where several pharmaceutical companies that joined the debate in full force either prosecuting or defending the drug, based on their own particular business interest. The pharmaceutical companies that felt most threatened by the events where Bayer with Adalat (nifedipine), Pfizer with Norvasc (amlodipine) and AstraZeneca with Plendil (felodipine) (Mackay & Sever, 1996).

The media used the opportunity they got to publish a potential sensational story and in the process criticize the medical profession and the pharmaceutical industry for providing "dangerous" drugs to the public. Even some of the pharmaceutical industries defensive tactics rose suspicions within the medical profession. The results where somewhat wide spread and in some cases resulted in risk full alterations in patient therapies, when either doctors or patients themselves changed their subscriptions with dire consequences for some (Mackay & Sever, 1996).

The adverse side effects that where presented in the debate seemed to be only connected to first generation short acting calcium channel blockers (nifedipine). The strongest arguments from the pharmaceutical companies defending their products stated that it was not valid to conclude that these adverse side effects could be connected to the newer agents as nifedipine GITS, amlodipine and felodipine which provide positive effects due to their slower and longer duration of action and no heart rate effects (Mackay & Sever, 1996).

The FDA held a hearing in January 1996 where all available information was reviewed which resulted in that no definite conclusion could be drawn from the information presented by either side and the use of calcium channel blockers could continue (Mackay & Sever, 1996).

Internal view on the situation

It became clear to people at Astra-Hässle rather early when the issue came up that it needed to put together resources to pull out security data on the product for analysis and potential presentation. In the beginning this was solely done as a preventive measure in order to be ready to respond to government request for information as well as preparing a document for publication to meet the general criticism if and when it came up.

In this case where a whole class of medicine was under attack and more pharmaceutical organizations where involved the pressure wasn't only on AstraZeneca to produce information. Rather all involved tried to produce information and use their contact networks to defend the medicine class for their own interest.

At the time of Astra-Hässle the roles and processes where of a more informal nature and not as defined groups as in today's work environment. Therefore existing people that worked on the issue needed to some degree to drop everything else and focus on this issue at hand.

The role of the marketing department

Resources that where put together within the marketing department at AstraZeneca in Mölndal, where not extensive. From the beginning the issue was handled through changed priorities of existing local staff and resources. Within the marketing department it became most important to make decisions on how to act in such a situation, how to defend oneself and most importantly to communicate the information and strategies to the international sales offices who worked directly with customers. From a marketing point of view the question was how much damage and growth opportunities could be lost for the whole medicine class and how much the damages could be offset by sharing information to all parties involved including keeping people motivated to work both internally and within different countries on the issue. For the international sales offices it was important to have the same information in order to answer questions from customers, publish in local media and have prepared arguments to use at local events etc. The international marketing department was responsible for writing and distributing the correct information to international media, magazines as well as international congresses etc. In order to have the information needed there was a significant cooperation with the Drug Safety department in Mölndal.

The role of the Drug Safety department

The Drug safety department can be said to have had two customers that demanded information in connection to the issue, authorities and the marketing department in Mölndal.

Information from clinical studies where divided to a large extent in two i.e. central data and data from local studies conducted by different sales offices around the world. The central safety database included serious adverse events (SAE) from both central and local studies but was missing complete information concerning less serious side effects or so called adverse events (AE) from clinical studies. The AE information was not available for direct search and therefore required extensive effort for the Drug Safety department to pull together from various resources.

This proved to be the basis for the problem that Drug safety was confronted with since the AE information was needed in order to confront the issue. In order to amass the AE information a significant administrative work took place on preparing questionnaire for requesting the correct information about clinical studies conducted i.e. study name, how many patients included, how many and what specific side effects where registered. This questionnaire was sent to local sales offices in about 20 countries. The communication with the sales offices proved to be quite resource demanding when firstly the right person needed to be found as well as extensive communication throughout the time it took to gather and register the information. There where several responses to the questionnaire that rose questions on the accuracy of the responses and as a result needed to be corrected, this was a time consuming process.

A central database was built specially for the purpose of entering the information from the questionnaire. There where some quality concerns about the fact that information needed to be keyed in to the database manually from the questionnaire papers. The whole process on amassing and analyzing the information took about 4-5 months.

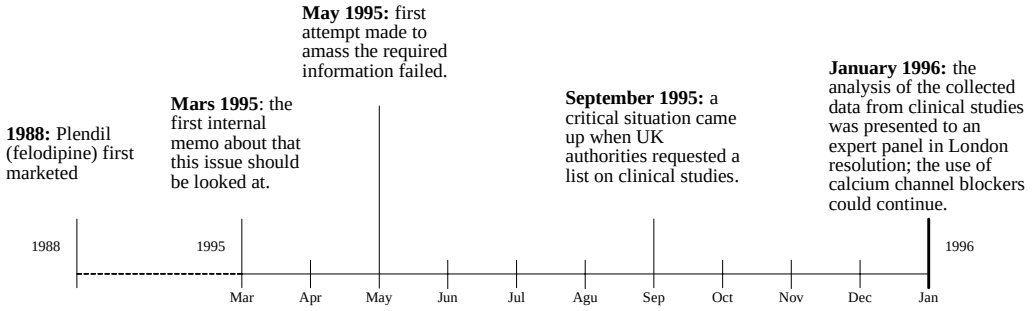

Figure 4: Timeline in the Plendil case

The issue demanded resources from various departments within Astra-Hässle including the medicine team for putting together the questionnaire, experts from IS/IT, experts on side effects, marketing people to judge the potential consequences from a marketing perspective as well as personnel from about 20 countries. An estimation done in 1996 showed that the effort of merely collecting the information for presentation to authorities took about 11 man months, as well as another 11 man months in lost time not including the efforts within each country.

Market effects

The market for calcium channel blockers was in 1996 around 8 billion dollars worldwide. Despite the lack of conclusive evidence against the overall use of the drugs, the controversy had a significant impact on the prescribing sales. Sales where registered to have decreased by 4% in the last quarter of 1995 while the concurring type of medicine experienced an increase in sales of 9% (Mackay & Sever, 1996).

4.4.1 Key findings

The Plendil case was resolved successfully but required extensive efforts in order to retrieve the information from clinical studies to effectively confront the issue. This included that the case was drawn out in time and became costly to resolve.

- The medical class, that Plendil belonged to, was implicated to heart attacks. These implications were based on somewhat unsubstantiated research studies.
- The media criticized the medical profession and the pharmaceutical industry for providing dangerous drugs to the public.
- Since the information and the information environment was less structured than in the Losec case the first attempt on collecting the information failed.
- The cost for collecting the information was estimated to be 11 man months plus lost time not including the effort within the 20 countries involved.
- Information from clinical studies were divided into central data and data from local studies conducted by different sales offices.

  - Central safety database included SAE's from both central and local studies but was missing complete data from AE.
  - The AE information was not available for direct search and therefore required extensive effort since it was crucial in order to confront the issue.
  - Significant administrative work took place to collect the AE information and a central database was built.
- A significant cooperation between the marketing- and the drug safety department took place in order to present the right information to the public and authorities.
- Market effects were significant resulting in stagnating sales for the pharmaceutical companies in this drug class for approximately ten months.

What if questions
What if the information for Plendil had been structured in the same way as in the Losec case?
What if Astra had not succeeded in presenting any information surrounding this case?

4.5 Case 3: Bayer's Baycol (cerivastatin)

Key Facts:
Baycol (cerivastatin) was a cholesterol lowering medicine. Medicines in this group are usually called "Statin" due to the active substance. The product was first marketed in 1997-98. In the year 2000 global sales of Baycol exceeded $586 million with forecast sales in the region of $1 billion for 2001. The withdrawal of Baycol was a high profile case that attracted significant media and public attention.

Background
Bayer pharmaceuticals business group represent about 20% of Bayer AG, with approximately 25 thousand employees and about $5 billion in annual sales in 2002. [URL9]

The cholesterol lowering medicine Baycol had been on the market for about four years when in the beginning of 2001 reports began to surface about patients deaths in the US as a result from using statins.

Cerivastatin was the most potent statin on the market, effective in fractions of milligrams (mg). Concern arose as a result of deaths from a severe muscle weakness (rhabdomyolysis) in the United States, 40% of which were associated with prescriptions of the drug in combination with Lopid (gemfibrozil), which is also a cholesterol-lowering drug. In June 2001, Bayer modified the label on Baycol after reports of patients suffering rhabdomyolysis. Deaths linked to cerivastatin continued to be reported despite two warning letters to United States' doctors advising them to start cerivastatin with the lowest available dose and not to prescribe cerivastatin with gemfibrozil. (Wright et al., 2002)

Bayer stated that the adverse events reported with Baycol were not specific to Baycol and had been observed in patients receiving a number of different statins. Bayer also stressed that, if Baycol was prescribed as directed these events should not occur [URL9]. Nevertheless, in the wake of the developments and the fact that all attempts to defend the drug as well as give warnings to doctors, pharmacist and authorities failed, Bayer pharmaceutical division voluntarily withdrew Baycol from the market, August 8, 2001. (SoRelle, 2001)

A story in the August 9, 2001, New York Times said the removal was made because of 31 deaths that had been linked to the cholesterol lowering medicine and a further 10 patients in Europe. The deaths were linked to a condition that causes muscle cells to break down, releasing their contents into the bloodstream and in severe cases can lead to kidney and other organ failure. Those patients at highest risk for developing rhabdomyolysis were taking a large dose of Baycol in combination with Lopid. (SoRelle, 2001)

The statin risk in context

Baycol was withdrawn from the world market because there were increased reports on muscle deceases (myopathy) and several instances of fatal rhabdomyolysis. Prior to the large dose of the drug no serious safety concerns had been observed. However, the risk of rhabdomyolysis greatly increased when Baycol was used at high doses or when administered in combination with Lopid. In a presentation by Professor Shepherd at the international symposium on atheroscleosis (ISA) congress in Kyoto 2003 was noted that the risk of rhabdomyolysis was much greater with cervastatin that with the other statins. Despite extensive testing, this had not been observed prior to the launch of the product. (Shepherd, 2003)

Much of the safety data for medicine is accumulated from adverse event reports during early drug development and from randomized clinical trials. However, relatively small numbers of patients are used in these studies and rare adverse events may not be observed. Furthermore, patients with poor health or associated medications that may increase the risk of adverse events are often excluded from clinical trials. Therefore, it is not until post marketing surveillance, when a medicine is used in large numbers of patients, that many adverse effects are observed. Professor Shepherd also noted that out of 484 million statin prescriptions in the USA, only 73 cases of rhabdomyolysis had occurred. (Shepherd, 2003)

Market effects

The global statin market is the largest drug class in the world with sales reaching $16.7 billion in 2000 [URL10]. These sales are fiercely fought over by many of the world's biggest pharmaceutical companies. Therefore, although the withdrawal was devastating for Bayer it created opportunities for their competitors. Bristol Myers-Squibb, Novartis, Pfizer and Merck enjoyed from 50-200% sales growth, to a large extent, as a results of the Baycol withdrawal. [URL11]

Effects on Bayer

The impact of the withdrawal on Bayer was significant. Not only did it lower the return on the R&D investment Bayer had made on Baycol's development, it also threatened the company's reputation and profitability as a whole. Sales of the drug accounted for about 25% of Bayers pharmaceuticals business group, so the

withdrawal left a significant hole. The drug had been forecasted to generate sales close to $1 billion in 2001 [URL11]. Bayer AG has been forced to cut more than 4.000 jobs and close 15 sites within its operation in order to reduce costs since the withdrawal. The threat of legal action and lawsuits was estimated to cost the company between $200 million and $3 billion. [URL11]

Bayer has paid $614 million (as of October 2003) to settle 1.683 cases out of court. The company will continue with their settlement policy trying to agree on a fair compensation for anyone who experienced serious side effects from Baycol on their own initiative and without acknowledging any legal liability. The drug is linked to more than 100 deaths since Bayer recalled Baycol in August 2001 and according to Bayer website the company now faces 11.300 cases because of the drug. [URL12]

After the withdrawal of Baycol there was talk at Bayer about abandoning the pharmaceutical operation altogether but it seems unlikely that that will be the case.

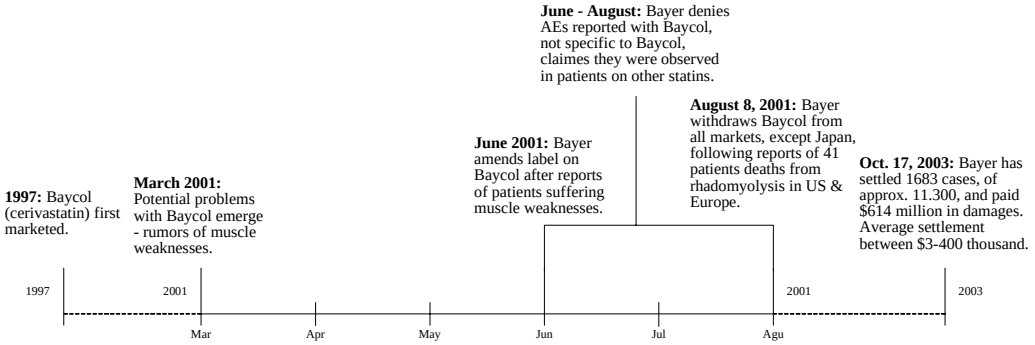

Figure 5: Timeline in the Baycol case

Regulatory effects

The FDA is expected to review information concerning side effects more rigorously in the light of the concerns surrounding the Baycol case and be more cautious of approving new statin therapies [URL11]. Even the European Medicines Evaluation Agency (EMEA) has promised to get tough with pharmaceutical companies if they fail to follow its rules for reporting product side-effects. It may resort to naming and shaming those that do not comply and could even prosecute offenders (Pharmaceutical Executive, 2002).

As several high-profile medicine withdrawals have shown, no matter how carefully companies carry out and analyze Phase III trials (clinical studies on humans), those studies are not extensive enough to pick up all potential serious adverse reactions that more widespread use may reveal.

There have been heated discussions on if it is really necessary to withdraw a drug from the market because of side effects. Although some patients obviously suffer because of the drug, many more experience benefits. But, the potential legal implications of leaving a “killer drug” on the market appear to be weighing more heavily on the corporate minds of pharmaceutical companies. (The Pharmaceutical Journal, 2001)

After Bayer's decision to take Baycol off the market, the issue of drug withdrawals has become strongly debated within the pharmaceutical industry. The effects of a product withdrawal go beyond a fall in the company's revenues, affecting the pharmaceutical industry as a whole. [URL11]

When the incident with Baycol occurred, AstraZeneca was in the late stages of developing a new statin, Crestor. The approval for Crestor was in fact affected as a result of the Baycol case, being delayed for several months wile the statin affects where researched in more detail. Today, Crestor has been launched in 22 countries and approved in 40 countries around the world.

4.5.1 Key findings

The Bayer case can be considered as a worst-case scenario for several reasons. Although some of the key findings can only be speculative due to the lack of having first hand information from within Bayer for obvious reasons.

- Baycol had been on the marked for 4 years and was one of many drugs within the so-called statin class.
- Baycol generated serious side effects because of two reasons.
    - Wrong dosage administration, although Bayer in later stages came out with recommendations for optimal dosage with little compliance from the market.
    - Prescription combination of another frequently administrated dug.
- Bayer tried to argue the case for Baycol and tone down the significance of the adverse events by stating that they where not specific to Baycol.
- Risk of serious adverse events was noted to be greater with cerevastatin (Baycol) than any other statin on the marked by leading marked opinion leaders.
- Baycol was tested prior to its launch without the severe adverse events being observed.
    - Relatively small number of patient in clinical trials.
    - Safety data is collected during early development from randomized clinical trials.
    - Patients with poor health and associated medication often excluded.
- Statistically there was a low likelihood of this particular SAE occurring; only 73 cases out of 484 million prescriptions were registered in USA.
- Baycol voluntarily withdrawn from the market in august 2001, 4 years after its launch, i.e. 6 months after the issue came up.
- The case had no visible negative effects in the statin market as a whole although other statin pharmaceutical companies enjoyed a significant increase in sales after Baycols withdrawal.
- Effects to Bayer have been extensive,
    - Bayer lost approximately 25% of its pharmaceutical business as a result of Baycol withdrawal.
    - Sales where projected to grow approximately 70% between 2000 and 2001, from $586 million to $1 billion respectively.
    - Downsizing within the Bayer group; 4000 laid off and 15 operations sites closed.

- Legal actions; compensations as of October 2003 $614 million in 1.683 cases settled out of court, face more than 11.000 cases, damages could reach up to $3 billion.
- Discussion on withdrawing from the pharmaceutical business altogether.

What if questions
What if they had monitored the market more closely for reports on SAEs?
What if they'd had an infrastructure for analyzing market data?
What if they had acted quicker to the reports/rumors on AEs?
What if they knew about the problem but did not act on the information?

4.6 Case 4: Exanta (ximelagatran) and consolidated clinical data storage

Key facts:
Exanta (ximelagatran) is a new class of medicine that is called oral direct thrombin inhibitor and works to prevent blood clotting (coagulation). The drug is in the last stages of development, currently being submitted for an approval worldwide (2002-04) and is expected to become a mega brand for AstraZeneca.
Consolidated clinical data storage (CCDS) is a proposal for a future information environment for capturing, storing, retrieving and sharing clinical study data.

Background
The proposed solution of consolidated clinical data storage (CCDS) provides a secure place for electronically stored clinical study data, product information and indications for quick and easy availability and utilizations. The solution is planned to give authorized users ability to access the information using the means they are most comfortable with.

The use of CCDS for Exanta information and data was as a first step planned to focus on being a risk management platform able to handle issues that come up i.e. Adverse Events (AE) and Severe Adverse Events (SAE). This initial step has been advanced and today the use of CCDS for Exanta can be seen more as a risk/benefit platform helping to identify and react to both positive and negative effects of a drug. This will enable the teams to be more proactive when it comes to defending the drug, identifying unknown potentials by having immediate access to basic studies. Normally, in today's information environment this is achieved reactively, when absolutely needed for some reason or another. Such solution more often than not require a group of people to work and being time consuming therefore only effective when absolutely necessary.

Present clinical study information environment
All AstraZeneca drug safety units and marketing companies have the responsibility to report all Adverse Events (AE) and Severe Adverse Events (SAE) in a report form into a central database called Clintrace Data Entry Site (CDES) in Mölndal. CDES is a document storage and information resource on all Adverse Events. Usually AEs are

reported at the end of each study while SAEs follow a stringent reporting structure demanded by authorities with serious consequences to the pharmaceutical company that delays its reporting. This structure has somewhat limiting usability i.e. not providing immediate access to information and data or any function for cross-referencing studies.

All knowledge that is captured from Clinical research information is stored within Global Electronic Library (GEL) and in the Product Knowledge Transfer (PKT) system. Regulatory reports are stored in GEL and PKT is a knowledge base that functions well for crossing over from R&D thinking to a marketing mindset, containing published scientific articles and information used mainly for marketing purposes. The main distinction from the proposed CCDS is that GEL and PKT contain extensive quantity of reports; articles and abstracts based on clinical science data or facts from documents that have been structured and packaged specially and sent to authorities while with CCDS the focus is on clinical data and its structure to enable internal exploitation. Today the clinical data is more or less not reused and essentially archived.

Extensive work has been put into building the current structure for accommodating flexibility for information and data utilization supporting the requirement to submit information to regulatory authorities. Primarily information coming from clinical studies are organized in a structure providing a document interchange format between industry and regulatory agencies. Meaning that, clinical documents are stored in a folder structure comprising a comprehensive table of contents [URL13] enabling data reviewers to navigate electronic submissions and clinical data within datasets per study and per domain (e.g. demographics, vital signs, adverse events) “suitable for reproducing and confirming analyses” [URL14,15]. This means that the data and documents are organized according to demanded by international authorities like the American food and drug administration (FDA), which can be argued as not being the optimal way for reuse within the organization.

Exanta benefits from CCDS

Exanta will be the first drug to benefit from the new information environment and the experience will be used for a continued development and expansion of the CCDS project. One of the advantages for the people working on the new drug Exanta will be that they will go from the former way of having data from each clinical study in separate datasets to being able to have access to integrated and consolidated data from across studies. This will enable analysis of the whole population of data from patients that have had the Exanta drug in clinical studies, approximately 30 thousand patients from 80 studies to date.

The mean cost for a clinical study patient has been calculated as being about $8000. This figure is important to highlight since this cost is fixed and unrelated to how the information is used or reused later on. Therefore it can be seen as significant improvement to the clinical study investment if data can be used more extensively.

Analysis and visualization of integrated and consolidated clinical study data will be available for authorized users from the scope and detail that is of interest to each and within their defined level of access, often being to support the continued development of the drug effects in detail.

CCDS information environment
The proposed platform will be designed as a classic data warehouse (DW) application utilizing an established and tested techniques for extracting, transforming and loading (ETL) data from different sources to a single pool of data storage.

It seems very trivial not being able to pool data from all submitted studies today, probably due to the fact that each project has been able to establish and have its own focus and different traditions developed. The fact remains that there hasn't been a single registration environment available due in large part to the uniqueness of clinical studies and the geographical structure of the companies in different sites world wide. With DW technology and ETL tools this can be remedied, nonetheless requiring extensive modeling and standardization.

The data will be linked together in order to be easily searchable as well as being profiled in a proper scientific and business context. The data will be linked to metadata details about different types of clinical study items (variables) to be accessed in a sort of clinical reference library.

The platform is thought to include a information model that is capable of integrating data and information in a extensible and robust way. The model will be capable of loading, organizing, combining and integrating clinical data both the study results as well as information about and surrounding the study itself. The model that will be constructed will be the key to how information and data are extracted from various operational sources and organized for usable presentation of information. The CCDS will be the key to use and reuse of data from clinical studies.

Users of CCDS
Initially the users of CCDS will primarily be a combination of representatives from each therapy area (TA), in this case concerning Exanta, having access to all data for statistical and medicine analysis.

Researchers from the group *Key brand team* involved in further development of the drug will have access to data within CCDS. The Key brand team will also have access to information in context to scientific articles, abstracts or studies.

Other researchers will use the system in order to address questions and defend issues that come up through and beyond the lifecycle of the drug i.e. act as the defending mechanism within the company. Operational users such as those working with biostatistics etc. will benefit from receiving data in earlier stages of development.

A DW such as CCDS is often referred to as a "drifting" system where the use and users initially thought for the system will evolve over time (Ciborra, 2002). Therefore, users that can be seen to benefit from using the system today might be different in the future. Some potential areas of future use can be seen to be within project related areas like project development, - management, - progress monitoring and - planning.

Initiators and the cost of the new information environment
The key initiators of the project come from the Medical Informatics department in Mölndal, which is along with the Information Systems department (IS) responsible for

the architecture and development of the CCDS. Operational departments, such as Drug Safety, Experimental Medicine and Clinical Information Management, are directly involved in the development of the project and give their input to the platforms functions and functionalities.

Initial cost for building and implementing the platform is estimated to be about 9 man- years ($100.000). The platform will eventually replace other information initiatives for extracting and transforming of clinical data, which will result in a operational cost reduction in the long run.

Authorities and data interchange

The increasing demands from authorities has resulted in a more stringent regulations on the pharmaceutical industry which has in turn increased their work and shortened the response time for reporting on medicine side effects. In the environment of tomorrow where authorities have developed solutions that allow them to do their own cross studies on medicines and projects internal solutions need to be competitive.

International authorities, particularly US, have required pharmaceuticals to follow standards for electronic data interchange and submission. The US Clinical data interchange standard committee (CDISC) has applied a standard for submission of clinical data, first with the requirements included in the so called item 11 standard which is being further developed based on an improved conceptual model. Being a specialization for the clinical domain from the generic HL7 Reference Information Model (RIM) [URL16], which is an information model for clinical -, administrative -, financial data, documents and structures (e.g. structure of electronic health record).

The FDA is also in the midst of developing a conceptual model for their data warehouse (called JANUS) that will be used for collecting information from clinical studies from different organizations and with capability for doing cross-references between drugs within diverse therapy areas. The JANUS project is being looked at as a potential standard for the CCDS core information model.

Challenges

The biggest challenges of developing the platform are not seen as being technical, although it will be challenging, but rather the issues of ownership and governance of data and metadata i.e. not the development but the administration in the long run. The ownership of data and metadata needs to get a greater focus within the project and perhaps within the organization in a wider sense.

4.6.1 Key findings

The project of building an information environment for Exanta is a future vision for optimal usage of clinical study information.

- Currently all data from clinical studies are stored in flat files and folders and not easily analyzed and not cross-referenced.
- Today the Clintrace database houses all AE data from clinical studies and a knowledge base of articles and abstracts is maintained in the product knowledge transfer database.

- New information environment is for handling risks and benefits of medicine clinical study information.
- The aim is proactive thinking for handling issues.
- Exanta will be the first drug to benefit from the new information environment and cross-referenced clinical studies.
- Clinical study data is used for submission to authorities and as references to scientific articles and thereafter archived. Clinical studies have a mean cost of approximately $8000 per patient and Exanta clinical studies have included 30.000 patients to date.
- Technically the solution is planned to be based on standard data warehouse and extract, transform and load (ETL) technologies.
- CCDS is a part of the new information environment that is planned to be the key to clinical study information and data reusability.
- The estimated project cost is nine man-years ($100 thousand) and the environment is expected to replace some current systems that will result in operational savings.
- In the environment of tomorrow where authorities have developed solutions that allow them to do their own cross studies on medicines and projects internal solutions need to be competitive.

What if questions

What if a serious issue came up today regarding e.g. Exanta, how would it be handled in the today's information environment?

5 Analysis

In this chapter the material from the case studies is analyzed and put in context with the literature review presented in chapter 2. The cases are analyzed from an information value and risk perspective as well as going through approaching information valuation based on several reasons relevant to the cases.

5.1 Case analysis from a risk perspective

When studying the different risk aspects within the cases, in relation to different medicine statuses on the market, the risks can be divided into four categories; first in class, second in class, the whole medicine class and one particular medicine in a class (interview with Dimenäs, 2003). The following analysis is done in order to put in context the general risk of each medicine presented in the cases.

First in class means, that it is the first medicine of a new class of compounds that is launched. Therefore, when a pharmaceutical company launches a first medicine in a class it is not without a risk. Often competitors with the help of media "attack" the medicine with negative implications and spread fear, uncertainty and doubt into the minds of the public and professionals, e.g. with the aim of protecting current market share. For the company that is marketing a first in class medicine it is a challenge to prove the concept combined with the competitors having established medicines in the market trying to question the approach. In order to succeed the medicine has to be considerably better than its competitors and needs to go through the process of establishing a name in the market as well as not being able to benefit from previous experience from e.g. market information, extensive scientific articles etc. From a clinical research perspective the risk for a first in class medicine not gaining significant market penetration can be said to be medium to high. Losec and Exanta are considered to belong to the risk aspects of a first in class medicine since they are examples of the first medicines in their class for treating acid related disorders and preventing blood clotting administered orally, respectively.

Second in class refers to launch of a compound where there are already at least one available, which therefore can be considered to pertain even less risk whereas its predecessor already is known and established in the class as well as making it possible to build on the in-house experience from its already known and documented forerunner. An example of a second in class medicine from AstraZeneca is Nexium (although not a subject of the case study in this report), which was a follow-up medicine to Losec. Risk of medicine withdrawal can be considered low.

The whole medicine class risk means that a whole class of medicines is subjected to accusations of not being safe e.g. causing harmful side effects or not being effective. Similar risk can be identified in the Plendil case, were the whole class was blamed for causing serious side effects and not being applicable medicine. The risk that a whole medicine class is "attacked" can be considered low, but even less so that one medicine in such "attack" is singled out and possibly withdrawn.

The Baycol case is an example of one medicine in a large medicine class that is accused of causing serious side effects and is an example of the fourth risk aspect, *one*

medicine in a class. Baycol was a single medicine accused of causing severe side effects, which led to its withdrawal from the market. The risk of this happening can be considered low in general. While, there was also the medicine combination effect, relevant in the Baycol case which can be seen to be a shared risk more or less within all the medicine classes.

Having gone through identifying and categorizing the risk aspects of the medicines it can be said that the risks mentioned can be reduced significantly by having proactive thinking when it comes to information management, case in point Losec and the future case associated with Exanta's information environment. Although for the purpose of this thesis the information management strategy and valuation are highlighted it is by no means meant as a suggestion for the replacement of a more traditional operational risk management, which is extensive within AstraZeneca e.g. when it comes to reducing the risk of new medicine development and within clinical trials.

Even though, it is mentioned that the risk of not having data and information available to spot trends of negative effects, like is implied in the Baycol and Plendil cases, it must be mentioned that the clinical study information and data would not have contained any indications of those side effects since the studies where in all probability not designed to focus on the particular issues that came up. Although, being able to analyze marketing information and data would probably have helped and the risk increases somewhat when it is not centrally known what studies are ongoing, especially if no information from these studies are readily available for analysis and cross-reference.

5.2 Approaching information valuation

Based on the cases studied and the information value theories, a valuation of clinical research (CR) information can be considered to be more applicable if based on qualitative value associations. The reason being high uncertainty of future events, therefore inability to establish a practical quantitative value, as well as differences in risk between medicine classes that can lead to misunderstanding of the valuation.

The approach in this chapter is based to some extent on Poore's (see chapter 2.1.8) approach to information valuation for security risk management, although somewhat modified for the purpose of this analysis. His method is used to establish a framework for the analysis of the cases in the empirical study, establishing connections between reasons for valuing information and risk factors that can have effect on information. The analysis establishes a connection between reasons for valuing information and the various risks factors in order to highlight and prepare possible defense techniques for risk evasion.

5.2.1 Information risk factors

According to Poore (2000) there are three security risk elements that affect information valuation for risk management which are, *confidentiality*, *integrity* and *availability*. He further explains that each element may have a value independent of (or in some cases interdependent with) the others and when searching for the value of

information, focus should be on the categories most directly related to the reason for the valuation.

For the purpose of this thesis, Poore's information security elements have been adapted and identified as information risk factors that in a similar sense affect the information valuation for risk management. Same as before, *confidentiality*, *integrity* and *availability* are seen as important aspects of information valuation, but even *reusability*. The additional risk factor is seen as significant in the sense that it is a determining factor for information value as established in the literature review.

The reason for making the multidimensional valuation is to bring to light risk factors that can affect information value. Table 6 shows the mapping of information value of CR information with the four risk factors that have been identified as important in the information valuation process.

Risk factors / **Inf. value**	Reusability	Confidentiality	Availability	Integrity
Exclusive possession		x		
Utility	x		x	
Original cost or cost of re-creation			x	
Potential liability	x	x	x	x
Operational impact	x		x	x

Table 6: Multidimensional information valuation for CR information

From a risk management perspective a close consideration ought to be on the risk factors since the more attention and commitment is made on reducing these risks i.e. increasing their status and focus through various commitments in IT/IS, the more valuable CR information can be considered to get.

5.2.2 Reasons for information valuations accounting for information risk factors based on the case analysis

Exclusive possession
Since pharmaceutical companies are required by law to submit all information from clinical trials exclusive possession can be redundant to uphold for information valuation purposes. It is inevitable that CR information will become known to authorities or competitors at some stage, which can be seen in the Baycol case where authorities seemed to be quicker than Bayer to discover and analyze information relating to the SAE's. Nevertheless, valuing CR information can be based on its exclusive possession at some stage in its lifecycle e.g. when it can be deemed harmful to the company if information is prematurely released (e.g. incomplete information that can be misinterpreted) and seen by competitors, authorities etc, therefore exclusive possession is preferred. Furthermore it can be vital to have exclusive

possession of CR information that includes or can lead to important discovery and new products.

Information risk factors
If CR information is considered to remain in exclusive possession a particular concern should be made on protecting its confidentiality while other risk factors can be seen as less important.

Utility
In the Losec and Plendil cases a safety database containing clinical data and information was available. The database was built for scientific reasons to contain safety data and information from all medicines of concern to Astra Mölndal, with the purpose of making cross-references and discover trends and side effects early on. Information is generally accepted as increasing in value with use as well as when it is combined with other related information. Information is also thought to be as least as valuable as the use it is put to. Therefore, this proved to be particularly proactive thinking at that time, giving the tone for the information value, even when compared to the market as a whole.

Losec was an important product to Astra and it was deemed essential to organize all its data and information in a way that it could be easily accessed and analyzed. From an information value perspective this is in line with Skyrme (1994) thoughts on adding value to information, through the value adding principles like accessibility, usability, quality and reusability. Nonetheless, the Plendil case demonstrated that information sharing and availability was not entirely perfect, having negative effects on its value. The issue handling in the Plendil case forced the organization to work reactively, which proved to be time consuming, demanding significant and costly resources, all stemming from unavailable information and data.

Clinical research information cannot be said to possess utility value in a traditional sense (transactional monetary value) but nevertheless possessing value based on its use. According to Glazer (1993), most organizational resources show decreasing returns to use but information increases in value the more it is used. When determining the utility value of CR information it is important to consider, as mentioned before, that the information is at least as valuable as the use it's put to. But, since CR information is not used for revenue generation no revenue stream can be directly linked to it. Nevertheless, CR information can be seen to have a utility value for research and discovery, whereas it can be used to shorten time to market and identify previously unknown potentials, which can lead to new product discovery. In that respect it would be possible to reach a qualitative value based on its future potential, although it would be highly subjective.

In the Bayer case, not being able to pull information could mean that the information environment did not provide them with enough information availability and reusability, which lessened its value. From a risk management perspective the CR information needs to be in such a condition (see chapter 2.2) that it is reusable for defense purposes. That being said, the utility value from a risk management (defense) perspective can be essential in the lifecycle of a medicine when an issue occurs. The CR information should be accurate and available in order to be useful, avoiding costly

regeneration of CR information. Therefore a significant value portion of the information can be justifiably used for building a risk platform.

Information risk factors
The utility value of CR information is its use within the development of a medicine, scientific knowledge, shortening time to market, new product discovery and reporting to authorities. In that sense the risk factors of reusability and availability are considered to be most directly related to the valuation. Confidentiality and integrity seems less important (although important to some extent) because of the reporting requirement to authorities as well as demands for publishing the results of CR in the scientific community.

Original cost or cost of re-creation
The safety database included safety data from Plendil as well as several other medicines as previously mentioned and in that respect consistent with the Losec case. The main difference between the cases is that a complete information from Plendil clinical studies where not readily available centrally. This turned out to be one of the main reasons for the difficulty when amassing the information needed to resolve the issue. The missing information in question concerned adverse events that were stored locally at local marketing companies. The information was important and needed to be available and analyzed in relation to the issue, which meant that significant administrative work needed to take place as well as building of a simple central database that could store the collected information. In a way it can be said that the information needed to be partly recreated centrally. Therefore the conservative method of assigning value to information based on how much it costs to acquire the information (Moody and Walsh, Poore et al.) is possible. If the information could be recreated for approximately the same cost the value is useful from a risk management perspective, but if the process cannot be repeated or it is too expensive the original cost of creation is not a good indicator for its value. The quantitative value of CR information could in that sense be said to be the cost of its acquisition, adjusted with relevant laws of information presented in chapter 2.1.2.

Information risk factors
If CR information value is to be based on the original cost or cost of re-creation the risk factor *availability* is considered to be the most relevant risk factor. The focus should be on keeping the information available so that the risk for re-creation is minimized.

Potential liability
The cholesterol lowering medicine Baycol was linked to many deaths and as a result it was withdrawn from the market. Although it is difficult to make a conclusive analysis from the case due to how little information there is concerning the information management at Bayer, it is possible to draw some conclusions. How Bayer handled the information they should have possessed, coming from clinical research and market, can be seen as being ineffective and inefficient when it comes to information management and utilization. By not acting on the information they had, due to some reason or another, the organization failed to respond to the situation that came up in a timely manner. Although, since authorities were able to pull and research information and data concerning Baycol, one can draw a conclusion that Bayer should have been able to do the same. By not acting on the issue earlier, as was apparent, suggests that

Bayer had the information but did not use it. Therefore from an information value perspective, information that cannot be used by those who possess it may actually have a negative value, that is, it may represent an extra expense or a liability (Poore, 2000).

Losec was a first in class medicine competing in a large market where competitors and media focused on side effects and not the positive effects of the medicine. Since Losec was Astra's biggest medicine it became apparent to individuals within the drug safety group that a safety database would be needed in order to respond to issues that could occur.

When information represents a relationship of trust (e.g. because of its personal or private nature, trade secrecy) then the person that possesses the information may assume liability for its protection (Poore, 2000). Clinical research information is both personal and private and therefore can the person/patient assume liability if the company (AstraZeneca) fails to protect it. From a risk management perspective the CR information in this context constitutes confidentiality and integrity. Poore suggests that, "If the information is itself a warning of a condition opposite to law, safety, or the interests of third parties, the company may cause it to have value by failing to act on it". In that respect it would mean that if the organization fails to notify patient/s of any irregularities, based on CR information, concerning his/her treatment the patient can assume liability. A quantitative valuation of CR and marketing information concerning Baycol, where third party was involved and resulted in thousands of lawsuits against the company with an estimated cost of up to $3 billion is possible, although highly subjective and therefore not likely. Obviously these figures are too high and not practical to value CR information that high but this can be used to give some idea of the impact based on previous knowledge.

Information risk factors
For an organization to be able to protect itself, in a timely manner and minimize the threat of potential liability it is important that CR information is available for analysis in order to protecting the integrity of the organization. If a potential liability is eminent it can be dealt with in a more efficient way if CR information is readily available in a reusable form to be accessed and presented in a timely manner, comparable to the Losec case.

Operational impact
It can be pertinent for the organizations to assign a value to CR information based on the impact that the absence of the information would have on the organization. Similarly, base the valuation on the impact that incorrect or untimely information would have (Poore, 2000). Therefore, CR information can be valued based on the severity of an impact that an issue could have on the company e.g. if CR information is inaccurate or none existent. Having unavailable and inaccurate information can result in harmful affects, but by quantifying the impact, based on previous experience, it is possible to use it for information valuation for risk management purposes.

An example of operational impact can be seen in the Baycol case where the medicine needed to be withdrawn costing Bayer 25% of its operation and future earnings, a figure that is estimated to be several billion dollars. If a valuation based on operational impact is applied to the Losec case given that the information had not been available

or not accurate, a qualitative valuation would also be an extreme amount based on sales loss estimation due to medicine modifications, delays and reduced market share. Comparable to basing information value on potential liability the figures are extremely high and it is not practical to value CR information in that sense, but can be used to give an idea of the impact based on previous knowledge.

Information risk factors
From an information value perspective in order to minimize the risk of operational impact it is important that CR information is made available and reusable through various information systems for defense purposes as well as to preserve organizational integrity. Confidentiality can be seen to be less important (although important to some extent) because of the reporting requirement to authorities as well as demands for publishing the results of CR in the scientific community.

5.2.3 Clinical research information value indicators

Based on the case analysis in the previous section the following summary can be made of the information value indicators that were identified. The indicators can be further developed into representing active value for CR information.

Quantitative value: can be both positive and negative where the summation of the two gives the total value

- How much it cost to acquire or recreate the information (adjusted with e.g. use, shelf life, accuracy)
- Operational impact of non available and reusable information (e.g. Bayer case)
- Liability (e.g. Bayer case)

Qualitative value: information value can be ranked from least to most

- Defense value (e.g. issue management)
- Medicine development, scientific knowledge, shorten time to market, reporting to authorities
- Can lead to important discovery of previously unknown potentials and new product development (R&D value)
- Protecting third party privacy
- Early indication of harmful effects
- Medicine integrity - at some stage CR information can be deemed harmful if released prematurely

5.3 Recommendations

The focus within this thesis has been on clinical research information therefore the recommendations are subjective in that respect. When approaching the valuation of information it is important to keep in mind that there are significant differences between the available valuation methods/theories and the purpose of the valuation as well as the nature of the information itself. As an example, a valuation for accounting purposes can differ significantly from a valuation for defense purposes, as is the subject of this thesis. The accounting approach establishes usually a value for presentation within a financial statement e.g. accounting for non-hardware information technology resources, market value of information or registers a value of

a R&D undertaking. The approach of this thesis is to use the experience gained from going through the valuation process to approach information value in order to support decisions on information systems and information management efforts for risk evasion purposes.

The following approach summarizes how the organization could go through the process of valuing its information assets for defense purposes.

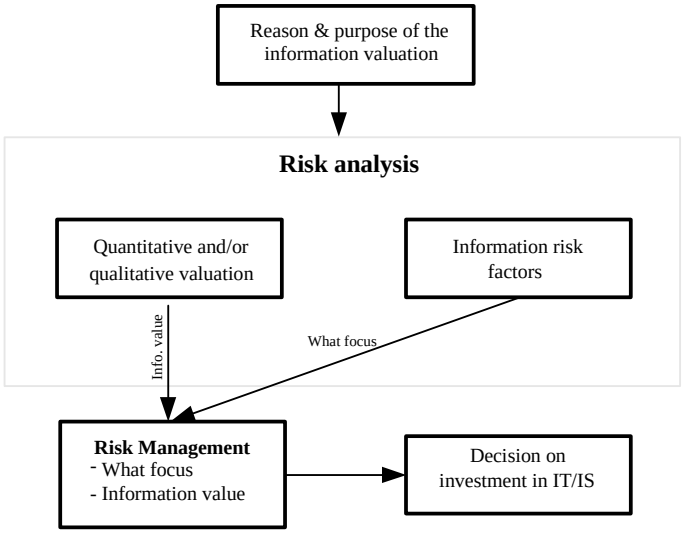

Figure 5: Method for approaching information value

The process of valuing information is best approached by a group of individuals with a compiled knowledge of the information to be valued, prior experience working with risk and market familiarity. The group establishes a reason and a purpose for valuing the information whereas information, by its nature, can have multiple values correlated to the reason for the valuation. In this thesis the focus has been on the reasons as presented by Poore; exclusive possession, utility, original cost or cost of re-creation, potential liability and operational impact. It is possible that more than one reason may apply or other reasons can be identified as being more appropriate. Nevertheless, some or all of the mentioned reasons are most often suitable to base on a valuation for risk management reasons.

Given the nature of CR information the authors of this thesis have observed that arriving at a valuation, whether qualitative or quantitative, is highly subjective and based on individual or collective assessment. Nevertheless, the method can be used to give an indication of an information value. Therefore, having established the reason(s) for the valuation a process to identify possible quantitative or qualitative (or both) aspects of the information is done. As an example; assuming that a *operational impact* and *potential liability* are the basis of the valuation the next step would be to identify different situations that could occur if information is inaccurate or missing, considering the probability of the occurrence. The outcome of the process gives an

indication of the value of the information to the organization. Some examples of possible *quantitative valuations* where given in chapter 5.2.3 when analyzing the cases.

As previously mentioned in this thesis, information has a value based on its use and the situation it is used in, therefore table 7 gives an example of how a *qualitative value* can be associated with a situation where information is not available and/or reusable for defense purposes. The table identifies several stages of severity portraying the groups collected view on the information readiness, accounting for e.g. risk aspects, medicine class and market situation. As an example if the reason for the valuation is operational impact and/or potential liability the proactive thinking in the Losec case is comparable to having ranked the information value as 4 or 5 and based on that made a decision on constructing a safety database. In the same way a conclusion can be made from the Bayer case that an information valuation was not done or at least the information was not ranked for defense purposes.

Possible results if CR related information are not available or reusable when an issue occurs	**Qualitative value for valuation**
Medicine can give adverse event that are non life threatening	1
Medicine can give adverse event that are non life threatening but medicine can be marginally effected on the market	2
Medicine can be identified as ineffective and possibly harmful resulting in significant sales drop and market loss	3
Medicine can be confirmed to give serious adverse events resulting in withdrawal from the market	4
Medicine can be linked to causing harm and deaths to third party, resulting in organizational liability	5

Table 7: Information value related to the severity of the issue and the readiness of CR information (liability and/or operational impact)

Going forward with the process the aforementioned risk factors (table 6), which can affect information value, are identified in relation to the reason for the information value. These risk factors are used in order to identify possible limitation of the information and its management. The focus on a relevant risk factor being, reusability, confidentiality, integrity or availability (or a combination there of) is put in the center of attention and used in order to identify possible means for defense e.g. medicine, organization etc.

Having gone through the valuation process and approached a value for the information an assessment can be made to determine the extensiveness of the commitment needed for risk evasion. As suggested in the beginning of this thesis the valuation can be used to support a decision to invest in appropriate IT/IS to secure and uphold high value of information assets, through availability, confidentiality, integrity and reusability.

6 Conclusions

This thesis has discussed mainly the possibility of valuing information in relation to risk analysis and its management as well as how the valuation can be used in practice to identify and appreciate information as a valuable asset. The work has resulted in a conclusion that the effort to value information is not entirely problem free, although at least theoretically, it is possible to establish information value. The question arises on how relevant the valuation is and to whom it has value, which is precisely one of the deciding factors that need to be looked at when a valuation work begins.

Within AstraZeneca clinical research (CR) information has been identified as a valuable resource deserving special attention in order to reach its full potential for the organization. Since, CR information is a foundation for medicine development it leads to the question at issue "*What is the value of Clinical Research information from a risk management perspective at AstraZeneca?"* where the purpose was to establish an approach to valuing CR information at AstraZeneca accounting for risk management issues. The main conclusion of the thesis, for the purpose of the question at issue, turned out to be that information value can be seen as multidimensional therefore based on several reasons different information value can be established. The reasons identified where; *exclusive possession, utility, cost or cost of recreation, potential liability and operational impact,* as a result several indicators for qualitative and/or quantitative information value where identified. The scope of the risk is seen as being manageable by focusing on one or more of the four risk factors identified; reusability, confidentiality, availability and integrity, which can directly effect information value in a positive or negative way. Therefore, AstraZeneca has to decide which reason(s) for valuation is relevant, based on the information to be valued, and have a special focus on the risk factors identified as affecting the valuation.

With reference to the first sub question "*What methods are there for valuing clinical research information?"* where the purpose was to explore suitable methods for valuing clinical research information, several candidate methods were explored and evaluated. The various methods for valuing information that where evaluated did in fact prove to a large extent non suitable for valuing clinical research information but having some usability for information valuation in other respect. This can be seen in both the theoretical framework and the analysis chapter.

Methods like utility value, historical cost and various knowledge management methods are not practical to use when it comes to valuing clinical research information as mentioned earlier in the thesis. The focus of some of the more advanced methods is on measuring the value of knowledge management initiatives, intellectual capital (employee knowledge and expertise, customers), information value in decision-making, transaction value and information in use. The first two methodologies proved to be based on to broad perspectives with vague relation to information valuation, treating information valuation in a more general sense. Information value for decision-making as well as transaction value is irrelevant for the type of information in this thesis while information in use value can be seen requiring extensive follow-up on how information is used (access time, access frequency and relevancy) which can be misleading.

The second sub question "*How does clinical research information support risk and issue management at AstraZeneca?*" had the purpose of finding out how CR information supports risk and issue management that could be used for establishing the value of CR information. Clinical research information can be said to hold significant value to AstraZeneca when it comes to supporting risk and issue management but needs to be available and in a reusable state to minimize the risk of liability and operational impact. Presently the information is not in an optimal state for reuse where the information can be said to be somewhat spread between departmental, central (safety) and local sales office databases e.g. not supporting cross referencing of CR information, data and projects. The future plans of consolidated clinical data storage (CCDS) improves the support for handling risk and issue management as is supported within the case studies.

7 Discussion

Information valuation has been a fashionable topic in business and technology related literature with extensive references to methods and methodologies for valuing information. On the other hand, the various methods referred to in the literature primarily refer to knowledge management (KM) methods, which have been presented and put to use by known KM leaders (Sveiby, Edvinsson, Kaplan & Norton etc.) as well as various other information value authors (some mention in this work) with different approaches and reasons for the valuation. Nevertheless, it seems that information is merely a small part of a larger context within most available methods. Therefore it seems that relatively little progress has been made in the area of presenting a practical model for the value of information. Regardless of the amount of literature available, referring to valuation methods e.g. Edvinsson (1997) where he measures the value of knowledge and intellectual capital; Kaplan & Norton (1992) measure the company's performance by indicators that are bases on the strategic objectives of the firm (financial, internal, customer, growth and learning). Sveiby (1997, 2001) measures the success of knowledge management initiatives. Skyrme (2002) and Broadbent (1992) measure the value of information centers. These methods seem to have that in common that they do not succeed in isolating the information value, merely touch upon it as a part of a larger context. Other known information valuation methods available where not deemed suitable for valuing clinical research (CR) information e.g. due to their focus on valuing information in trade, transaction value (utility) and information based on decision making to name some. At the same time various authors in the literature discredit all of the information valuation methods available, demonstrating in fact, that there is a shortage of suitable methods for valuing information in use within organizations.

7.1 Reflecting on the work

In this work a value of clinical research information has not been established due to the aforementioned reasons. The result of this work became a more general reflection on how organizations can approach valuing information based on the reason for its valuation in order to harness its full potential but also identifying several risk factors that can be associated with information value. The bottom line is that for valuing information in a successful manner it requires a complex and extensive operational focus on how information is used, how frequently and how users rank (value) information, within the organization as well as how information affects different organizational functions. The approach mentioned requires a different and broader focus identifying available technologies that are appropriate to measure and monitor information use (e.g. Balanced scorecard with indicators, Knowledge Expert Systems with tacit knowledge focus), but deemed inappropriate by the authors for the scope of this thesis.

When reflecting on the methods identified and presented in this thesis it became clear that they could not be fully exploited as presented in theory. The historical cost method referred to in chapter 2.2.3 was not used to its full extent for valuing information. In the thesis historical cost of CR information could be used in order to apply the method, but use statistics need also to be established, among others, which was not deemed appropriate in the scope of this work. This would have required a

considerably investigation into information use and available technology tools. In theory this method could be used within organizations but as pointed out in chapter 1.5 Expected results, the benefits could probably be seen in the valuation process itself rather than in the quantitative value of the information.

According to McGee & Prusak (1993) information is infinitely reusable and its value is determined by its user and the more information is used the more valuable it gets (Glazer, 1993). The authors of this thesis agree that information value can be stated as such, therefore it could be beneficial for certain type of information to base its value on how information is eventually used (e.g. how often, in what context, how many use it, relevance). Research on this subject has been done with focus on information access, access time, search redundancy and time per access to establish a relation between quantitative and qualitative measures of information use (Booske & Sainfort, 1998) but the application seems imperfect and requiring extensive information technology effort to be workable.

Glazer's method of utility value can be used to value information that has monetary transactional value, i.e. information that generates revenue or can be referred to as being a part of a product or an asset. The utility value approach is used in order to show that the method can be partly applied when referring to the value of information in use. The reason utility value cannot be applied as presented by Glazer is that CR information does not generate any revenue on its own but has a utility value of a more qualitative character.

The main problems the authors encountered during the work on this thesis can be said to be twofold, lack of relevant literature related to the question at issue (e.g. case studies) and the broad scope of the empirical work, providing a more qualitative knowledge to support the information valuation concept. Perhaps a closer encounter with the information would prove a more successful approach in order to generate a more precise and practical results to the question at issue. Further problems that where encountered are related to associating risk and information value, which lead to a more general qualitative approach to the subject. The reason being high uncertainty of future events, together with differences in risk between drug classes, leads to difficulty in establishing a practical value that wouldn't be misunderstood.

7.2 Further studies

Valuing information is an extensive topic, which can be studied from many different angles. During the course of this work several interesting angles have been identified as being applicable for further development and studies.

- Apply the approach presented in this thesis with the purpose; firstly, to see if the approach can be applied as stated. Secondly, to demonstrate if the process of going through the valuation is in fact more important than arriving at a specific value, e.g. monetary value.

- Go through a decision analysis to establish how clinical research information support decision making when deciding on the validity of a project or further studies.

- Establish the value of information based on historical cost adjusted by its usage, shelf life and accuracy.

- Follow how clinical research information effects the operation of the organization by establishing indicators that can be monitored (e.g. balanced scorecard)

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