BPR in the Pharmaceutical Industry

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Abstract

This thesis investigates the use of Business Process Reengineering (BPR) as a change approach in the Pharmaceutical Industry.

The pharmaceutical industry is undergoing profound changes. New opportunities, e.g. in the field of bio-technology, price pressure from governments, insurances and through generic products have created a variety of dynamics in the industry. Today, pharma-companies are also closely monitored with regard to their R&D pipeline and their ability to execute efficient R&D projects. As a result, pharma-companies have been looking for approaches that would enable a substantial improvement of their R&D processes, among them Business Process Reengineering.

During a study at Astra Hässle in Mölndal, a research subsidiary of Astra (now AstraZeneca), two change initiatives under the label of BPR were investigated and analyzed. The first one, FASTRAC, was a local project, aiming at improving research and development at Astra Hässle. CANDELA, the second initiative, was aiming at an overhaul of R&D at Astra corporate level.

FASTRAC resulted in several IT initiatives, of which one was investigated in detail. This investigation identified several critical aspects of the implementation of a new data collection process and IT-solution for remote data capture (RDC).

Furthermore, this thesis proposes measures that go beyond the concept of reengineering. It proposes a new conceptual model for clinical research and suggests a different way of technology use for supporting the clinical R&D process. It also describes organizational aspects of organizing R&D in alternative ways.

Content

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X

1. Introduction

At 14.00, we arrive at the AstraZeneca (at that time Astra Hässle) office in Mölndal. We had scheduled an appointed for a meeting with a group of managers from the company to discuss possibilities for research cooperation in the field of Informatics and Organization.

"Let me briefly introduce you to our organizational structure", one manager says and puts a slide on the OH-projector. He starts explaining, but is suddenly interrupted by one of his colleagues. "These are the slides from before our last re-organization. Since then, there have been some changes in our organization."
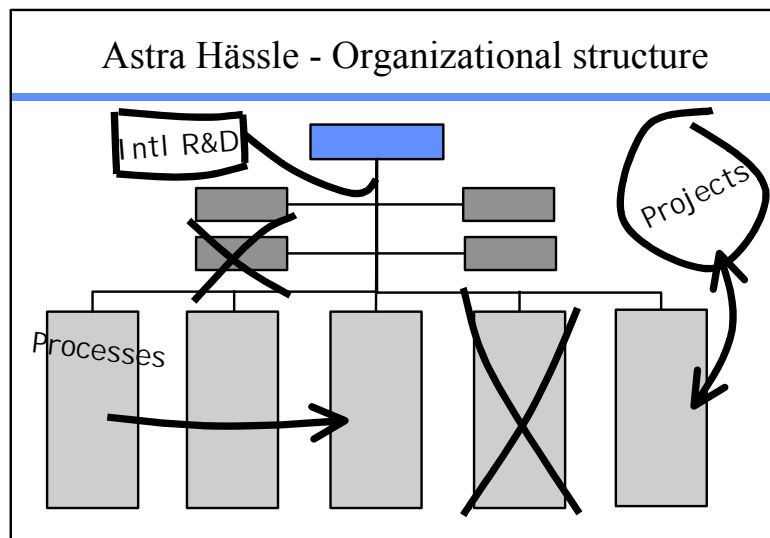
This anecdote is not specific for AstraZeneca. It could have happened in any large organization, and it probably has in one way or the other. In my stock of business cards that I have received, there are many with additional notes regarding changed titles, and organizational divisions. A frequent comment when handing over a business card seems to be "We recently re-

organized, but I haven't received my new business cards yet. However, the phone number is still the same."

During the 1990s, change was the word of the day and companies re-organized, re-engineered their business processes, down- and right-sized their organizations and introduced new technology for managing their workflows and tying together their value chains. The aim of all these efforts was to become faster, more competitive and cost efficient. This wave was sweeping over private and the public sector alike and resulted in large-scale change initiatives under the label of Business Process Reengineering, Business Process Redesign, or company specific names such as T50 at ABB, with its goal to reduce cycle time in all processes by 50%.

Also companies in the pharmaceutical industry have been initiating change programs aiming at squeezing cycle time out of R&D and marketing and reducing excess cost in the research pipeline. Today, virtually any pharmaceutical company has worked extensively with process improvement initiatives. Within Astra, the Swedish pharmaceutical firm that merged with UK-based Zeneca to form one of the major players in the industry, multiple projects have been conducted at corporate level and within several of their subsidiaries. Two of these initiatives are documented in this work: FASTRAC, a process improvement effort aiming at clinical research and development at Astra Hässle[2] in Mölndal and CANDELA, a corporate-wide R&D process reengineering project. Primarily as a result of FASTRAC, combined with organizational changes and the introduction of new technology for data capturing in clinical trials, Astra Hässle has been able to realize significant cycle-time reductions in clinical R&D.

On the other hand, these change programs were not free of problems or unexpected outcomes. As the detailed study of one part of FASTRAC revealed, the implementation of a new

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[2] After the merger of Astra and Zeneca, the local companies became part of a global structure and were also renamed. Astra Hässle is now AstraZeneca R&D Mölndal.

infrastructure, consisting of a re-designed process and a rigid information system for data collection, resulted in work-arounds that actually prevented the realization of some of the targeted benefits. Local adaptations outside the pre-defined organizational process and intended use of information technology caused a "drift" of the infrastructure in use. In other words, the actual use of the implemented infrastructure was not congruent with the originally designed process for data collection.

Also, the business process reengineering (BPR) approach was met with ambivalence in the company. While the concept of "out-of-the-box" thinking was highly appreciated, the requirement for designing and defining business processes at a high level of detail, leaving limited room for improvisation in daily work, was not easily accepted in an organization with a traditionally high degree of freedom for local initiatives.

This book is aiming at describing the change initiatives that have taken place at Astra Hässle under the banner of BPR and to outline critical issues that have arisen during the projects. It also suggests some areas for additional organizational and technological improvement, especially with regard to clinical research and development.

However, it does not prescribe the one best way to create optimum organizational structures or clinical R&D processes for all pharmaceutical companies. As Galbraith (1977) has pointed out, there is no one best way to organize, and no structure that fits all organizations. This conclusion leaves managers and change agents with a problem: To find and select an organizational form being effective for the specific situation and context of their company. Since not all the ways to organize are equally effective, this problem is difficult to resolve and any research on this topic can only provide guidance and point at critical issues, but not offer a general and simple solution with a success-or-money-back-guarantee.

1.1 Global dynamics

The society we live in has brought us, who live in industrialized countries, an incredible wealth. Despite the high unemployment rates we are currently experiencing in many countries, the standard of living has never been as high as it is today. This development, taking its departure in the industrial revolution of the 18th and 19th century, has been made possible by "modern" organizing, where modern stands for ideas and concepts being developed 100 and more years ago for industrial production and, subsequently, administration.

Industrial processes have been rationalized and mechanized, large organizations have been built in the private and public sector, based on the ideas developed by engineers and management theorists such as Frederick Taylor and Henri Fayol, or based on the Weberian approach to bureaucracy. While most of these concepts were originally developed for industrial production, i.e. mass manufacturing of standardized goods, they also found their way into other sectors, including the pharmaceutical industry. Many of the pharma-giants of today were founded in this era and developed their first products during the early decades of the 20th century, governed under the same principles that have been developed by "classic theorists".

It is often claimed that the ways of organizing and managing that have constituted success in the past, are no longer applicable in today's highly competitive and information and knowledge-oriented economy. The forces that influence organizations and govern companies in their striving for improved competitiveness are often condensed into three factors, labeled the three Cs or C^3: Competition, Customers and Change. The US Manufacturing Futures Survey from 1992 revealed the following outlook on managers' expectations regarding important issues for their companies' business environment (Rolstadås et. al., 1995).

- Market globalization, resulting in higher competition, but also cooperation and consolidation.

- Increasing speed in technology development and deployment.

- Stronger focus on quality and time, enforced by higher customer expectations.

- Shorter product life cycles.

- Changes in the workforce with respect to attitude, competencies and capabilities, task structures and compensation mechanisms.

- Increasing concerns for environmental issues, followed by national and transnational regulations.

- Declining or stagnating domestic markets.

Although the survey was conducted in the manufacturing industry, its results are also valid for pharmaceutical companies. Especially the following factors are influencing the behavior of pharmaceutical businesses.

1.1.1 Market globalization

Many economies have for a long time been carefully protected from threats imposed by potential foreign entrants. Customs barriers were high, and regulations made it practically impossible for companies to enter foreign markets, thus allowing domestic companies to prosper without being subjected to fierce competition. Japanese car manufacturers, for instance, had to open factories within the EU member states in order to circumvent the import restrictions for cars being built outside the European Union.

Governmental regulations also regulated the flow of investments and limited individual and corporate mobility in order to protect local companies and their national tax base. Especially high-tax countries have had a natural interest to prevent corporate and private money from free transfer across

borders. Agreements such as the common market in Europe and the introduction of a common currency, the GATT (General Agreement on Traffic and Trade) and the establishment of the World Trade Organization (WTO) on a global level, enforced by international organizations and courts, have opened new opportunities for foreign market entrants, while increasing competitive pressure on previously protected national companies and markets.

First Asian and later also Eastern European companies have successfully taken up competition with traditional market leaders from the US and Western Europe in a variety of areas, ranging from industrial manufacturing to high-tech services in the computer and software industry. Today, India is one of the countries educating most computer engineers worldwide, and many Western companies have started to open subsidiaries in India, thus making the city of Bangalore the 2nd largest assembly of IT-development resources in the world. The concept of global sourcing, i.e. the mobility of tasks around the globe, will increase pressure on companies and also governments, which see their tax bases erode.

The liberalization of capital movements and the increasing the amount of foreign direct investments, able to disrupt entire economies when used in a speculative manner, has limited national governments' navigation space and significantly contributed to shrinking the world economically.

For many companies, this development means an increasing struggle for sustained competitiveness, taking its expression in large-scale change efforts, aiming at improving corporate performance. Commonly taken measures are cost reduction efforts, personnel layoffs, structural renewal and striving for reduced time-to-market. Also, information technology has come to play an important role, not only as a supportive tool for operational activities, but as a major enabler for organizational change, improved quality, and cycle-time reduction.

Pharmaceutical companies have responded to these challenges in several ways, addressing internal as well as

external issues. In order to increase effectiveness and efficiency, virtually all firms in the industry have been initiating large-scale improvement initiatives to speed up discovery and clinical research and development. In order to spread investment loads, some are pursuing horizontal integration strategies, such as Glaxo or Ciba Geigy, who have acquired Wellcome and Chiron respectively. Other are moving into new areas or aim at vertical, downstream integration, such as Merck and Smith Kline Beecham, acquiring Medco and Diversified Pharmaceutical Services, thus trying to gain control over a larger portion of the industry value system and getting closer to the end-customer.

1.1.2 Information technology development and deployment

Since the personal computer conquered the desktop in the late 1980s, information technology and its use have developed at an accelerating pace. Computers have become more powerful, but have also found their way into new application areas. From being primarily a tool for individual work, the computer has now turned into a communication medium, allowing communication and cooperation within and outside the organization. Instant information access and distribution through networks has become standard in most companies and, in the industrialized world, the number of households with access to the Internet has been growing at an accelerating pace over the past years. The increasing use of global infrastructures, such as the Internet, has also opened new external communication and business channels, allowing companies to integrate their processes with suppliers and customers in a cost-efficient way.

Another considerable change has taken place in the perception of IT's role in organizations. While the traditional view has been utility-oriented, i.e. technology was primarily conceived as a tool for supporting the daily operational work in a company, we now find a different perception. When looking at businesses and also public organizations today, IT is considered as being the major enabler for organizational redesign. Instead of being used mainly for providing technical support of existing business

and organization strategies, IT allows us to question the very existence of these strategies. Insurance companies can improve customer services by equipping field sales personnel with mobile equipment, companies with the Internet as their primary location can market their products and services and circumvent traditional sales channels, and short-term, opportunistic networks of organizations can be formed around the exploitation of business ideas.

Considering the potentially disruptive nature of IT, it is easy to understand that the major change concept of the 1990s, Business Process Reengineering (BPR) takes its departure in the clean-slate approach. Instead of taking the existing organizational structures and activities as the analytical starting-point, the image of a new, business process oriented and customer-focused organization is developed, based on current technology and knowledge.

At the same time, the attitude towards information technology has changed significantly, too. Traditionally, the IT-department in many companies has been an organizational appendix to the accounting department. Since IT, or electronic data processing as it was termed, was first introduced as a tool for automating payroll management and other administrative processes, this was rather natural. Now, having taken the position as a strategic asset, information technology is seen as a factor that very well can make the difference between a company's existence or disappearance from the market. In a recent study among Sweden's 500 largest companies, conducted by Ernst & Young Management Consulting, 80% of the responding companies indicated that information technology was an important aspect of their change initiatives. (Ernst & Young 1998)

The rapid development in the field of IT, combined with the progress in biotechnology has opened new windows of opportunity for many firms, but it also constitutes a significant threat to established companies. The development of blockbusters, such as AstraZeneca's Losec, is no longer depending on vast amounts of resources alone, but also on the

innovative use of IT. Genomic research, combinatorial chemistry and high-throughput-screening open for a significant increase in the number of NCEs (New Chemical Entities), but it is not self-evident that the established firms have a competitive advantage in this development. Networks of small, specialized firms can outperform large, integrated companies by aggregating their power and competencies along the R&D process. Financed by the stock market, a biotechnology firm and a clinical research organization can jointly develop and test new products, without building a large, formalized organization.

1.1.3 Customers and consumers

When economic globalization is discussed, fierce competition between companies, taking place on the global marketplace, is frequently stressed. However, as foreign entrants now have access to markets they previously were unable to penetrate, global competition has given customers and consumers access to a wider variety of options. While they often were limited to buying products from national vendors, they now have the opportunity to choose from a wide range of products. Having access to a wider variety of choices, customers also tend to claim a higher level of service and lower prices from their suppliers. At the same time, product loyalty is fading away, customers become more opportunistic and quality labels such as "Made in …" seem to loose more and more of their importance.

Also in this area, information technology has had a major impact on the change of market structures. Many products traditionally purchased locally – e.g. books, but also food – are now available through electronic shopping areas on the Internet, and open new opportunities for customers, while traditional suppliers and national legislation struggle with maintaining their influence and domination.

The pharmaceutical industry has two client bases. (1) Doctors and healthcare institutions for prescribed drugs, and (2) consumers for non-prescribed drugs. So far, a significant share of marketing activities has been directed towards the

"professional" customers, whereas patient communities have not been in the focus of marketing. However, this situation is about to change and many pharmaceutical companies are starting to employ IT as a means for creating and sustaining customer relations by investing in various mechanisms for developing Internet-based communities for users of their products, but also for expanding their recruiting base for clinical R&D projects. Also, the emergence of managed care programs has put emphasis on the cost and time aspects of product development and has forced the pharmaceutical industry to deploy their resources more effectively and efficiently.

1.2 Industry specific dynamics

Historically, after World War II, the pharmaceutical industry developed into one of the most profitable business sectors. The discovery of new drugs against so far intractable diseases, with about 1.000 new products in the 1950s alone, resulted in the emergence of large-scale pharmaceutical companies, often with a heritage in the chemical industry. The industry has been characterized by its dependency on blockbuster products and their patent depending life cycles, a strong vertical integration from basic research to marketing, and sales driven market behavior with a rather peripheral role in the health system it is supplying.

However, the end of the millennium has represented for the pharmaceutical industry a period of substantial change. The current wave of mergers and acquisitions is an obvious indicator of a changing sector. The creations of giants, such as Novartis, Pharmacia & Upjohn and AstraZeneca, through horizontal integration have put a focus on that business in the pharma-industry is no longer what it used to be.

Instead of pursuing a strategy of organic growth, which has been the predominant approach, many companies are now aiming for deploying economy-of-scale. In addition, some are also pursuing vertical integration strategies, as shown by the

examples Merck-Medco, SmithKline Beecham-DPS (Diversified Pharmaceutical Services) and Eli Lilly-PCS. This strategy is not primarily aiming at growth within the same segment of the industry value system, may it be through mergers or acquisitions, but tries to increase the span the company covers in the industry value system, e.g. by purchasing a supplier or reseller of their products. The vertical integration strategies chosen also differ between companies. While some are attempting to integrate up-stream in order to purchase specialized R&D firms with a high discovery potential, others might follow a down-stream integration strategy, aiming at getting closer to the consumer and exploiting the potential margins in the reseller segment of the industry system.[3]

In 1997, more than 400 mergers or acquisitions involving life sciences (pharmaceuticals and bio-technology) companies took place worldwide (PWC global market and deal survey for 1997, 1998), with the following geographical distribution. Considering the period from 1988-97, the number of deals involving pharmaceutical companies has increased with a factor of 8.5, from 50 to 426.

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[3] The terms forward/downstream and backward/upstream might appear confusing, since they use different "directions" for describing the same phenomenon. The reason for this terminological confusion is the existence of different ways of graphically describing industry systems, where one uses a vertical, and the other a horizontal angle.
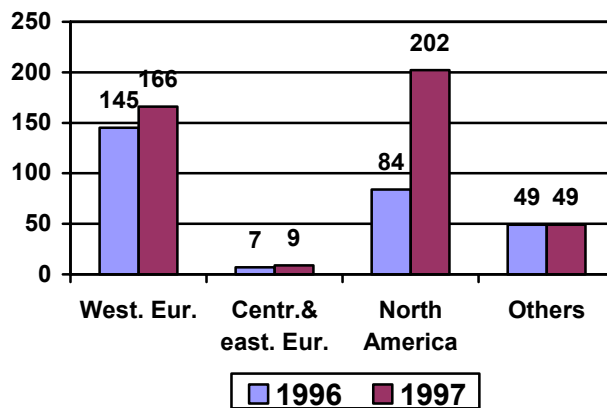
Chart 1: Deals in the life sciences industry

These figures indicate, that the large mergers and acquisitions, despite their publicity, only represent a fraction of all transactions taking place in the industry. The reasons for this development can be found in several areas. The most obvious is a striving for economy-of-scale and the attempt to develop stronger research pipelines and to develop capabilities for leveraging R&D results.

The pharmaceutical market structure is also very different from consumer good markets. It has been a highly regulated oligopoly with high profits due to branding and patent protection. In addition, the huge investments in R&D required for developing and testing new drugs could be passed on to patients, government health care programs and insurance companies. At the same time, the dependency on a small number of high-volume selling products, so called blockbusters, makes it difficult to sustain long-term competitive advantage and patent expirations and the resulting market entrance of generic products could reverse the situation even for highly successful companies. The conflict between required investments in long-term research programs and the demand for increased short-term profits and shareholder-value is another tension-creating factor. Expectations from investors are high after a period in the 1990s when the pharma-industry delivered an average of +11% in annual earnings, outperforming the S&P 500 index by 90%.

During the past few years, significant changes have taken place in the pharmaceutical industry and the future is expected to require even more radical adaptation, breaking with the paradigm of today. This means leaving the concept of organizational integration from basic R&D to marketing, and creating alliances with small and medium-sized specialized companies; reducing the development of drugs for large populations and instead focusing on specialized drugs for smaller communities; and embracing new information technology for managing bio-informatics and high-throughput screening as well as developing systems allowing the inclusion of stakeholders such as patients in research and development activities.

Also, new drug indications and niche products, in combination with higher demands for documentation and drug safety[4] by regulatory organizations (such as the US Food and Drug Administration (FDA) and its correspondents in other countries), have increased development costs and resulted in longer development cycles. The increasing costs for health care, in many countries consuming 12-15% of national spending, and the following governmental regulations regarding price setting and drug prescription have further endangered profitability. Despite the fact that profits still are high, these developments have forced pharmaceutical companies to rethink their business strategies and to reconsider their way of developing, testing and marketing products.

Similarly, industry studies conducted by consulting firms[5] urge pharmaceutical companies to reconceive their competitive focus. They commonly identify several factors that will have a

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[4] The sleeping pill Thalomide, developed by Merrill in 1962, caused serious side effects such as birth deformities resulting from women taking the drug during pregnancy. This event was the starting point for increasing documentation requests, and resulted in drug safety becoming a priority among customers as well as drug approval authorities.

[5] Industry reports from the following consulting firms have been investigated: The Boston Consulting Group, McKinsey & Co., PriceWaterhouseCoopers, Andersen Consulting.

considerable impact on the pharmaceutical industry over the next years. When taking a closer look at the most important factors influencing the pharmaceutical industry in the future, we can identify the following most prominent ones.

Discovery. The number of New Chemical Entities (NCEs) has been relatively low during the 1990s. A study conducted by Andersen Consulting (1997) states that the large pharmaceutical companies have brought forward less than one NCE per firm in the period 1990-94. On the other hand, new mechanisms and an increasing understanding of the genetic base are expected to boost discovery in the next few years. An industry study conducted by The Boston Consulting Group (1999) projects a significant increase of NCEs in the next decade, as a result of developments in pharmagenomics and technologies such as HTS (high throughput screening).
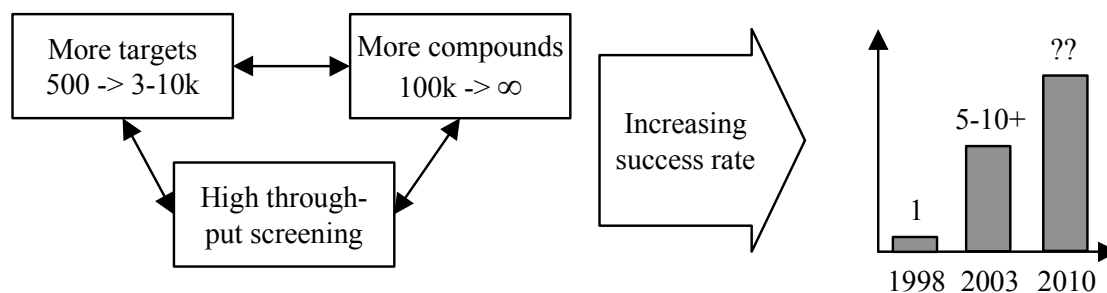
Figure 1-1: Projection of developments in discovery6

However, while these figures apply to large pharma-firms, a large number of NCEs will also be developed in small biotechnology firms which, in turn, will need to engage in alliances in order to bring their products into the market.

New indications and patient community segmentation. The result of genomic research and a better understanding of molecular intervention will allow a higher segmentation of patient communities, i.e. that drugs can be developed for highly specified indications. Consequently, the pharmaceutical industry has to address the issue of diversified

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[6] Analysis applies to large pharma-companies and is based on a BCG evaluation of analyst estimates.

product development and marketing for relatively small patient communities and their sub-segments, instead of relying on standardized blockbuster drugs for millions of patients. While the effects of this market segmentation are considerable for downstream activities, such as marketing and sales, they also have a considerable impact on the design and deployment of R&D processes and resources. How should, for example, clinical studies be performed within very small, or even individualized, patient groups?

Information technology. Traditionally, information technology has been considered as being a tool for improving organizational performance, e.g. in clinical trials, but also with regard to speeding up internal communications, especially in geographically distributed settings. In fact, many firms managed to realize substantial cycle-time reductions in clinical R&D by deploying IT efficiently. New simulation models, more efficient data management and the emerging field of bio-informatics promise a high level of data re-usability. The simulation of trial outcomes can also obliterate the conduct of "real-world" studies, not only saving companies high costs, but resulting in more informed decisions about research directions and prioritization. On the other hand, these technological developments also require substantial investments and force pharmaceutical companies to re-think the design of their R&D organizations and processes, technology portfolios and external cooperation models.

Networks and alliances. In addition to the already mentioned mergers and acquisitions, the number of alliances and partnerships, primarily between traditional pharmaceutical companies and biotechnology firms, has been increasing significantly over the past years. Also, the number of contract research organizations (CROs) has been growing and exceeded the number of 800 in 1998. Besides the out-sourcing of operational activities, such as clinical trials, pharmaceutical companies are looking for new ways of acquiring promising compounds, a process for which several strategies can be

chosen: Discovery stimulation, idea acquisition, or product acquisition. (McKinsey, 1999)
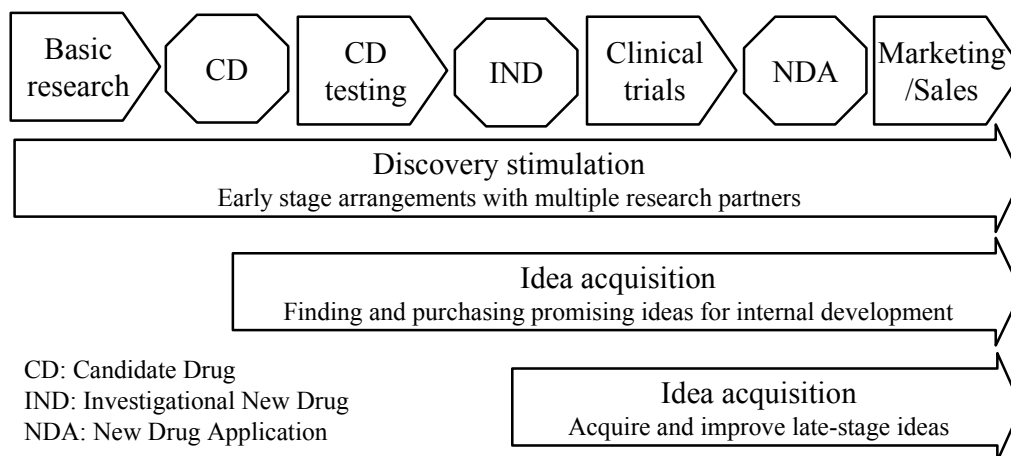
Figure 1-2: Networking and alliancing strategies (McKinsey, 1999)

Requirements from authorities. The requirements for documentation have increased dramatically over the last years. Some decades ago, clinical trials involved a handful of patients and New Drug Applications were short documents. Today, clinical research regularly involves several thousands patients and has become a lengthy and costly process, constituting a considerable investment also for large firms.

Blockbuster dependency. Most large pharmaceutical companies gain a considerable share of their revenues from a small number of successful products developed in the 1970s and 80s. As patient protection for many of these products run out in the next few years, it becomes important to develop and market new products.

Long and short term requirements. With a time-to-market of 15-20 years, pharmaceutical R&D requires a long-term investment perspective. In fact, most of today's blockbuster drugs, such as AstraZeneca's Omeprazole[7], stem from decisions made in the 1970s and 80s. On the other hand, the shareholder

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[7] The product, based on the substance Omeprazole is in most countries known under the name Prilosec.

value concept has found its way also into the pharmaceutical industry and shareholders demand increasing short-term pay-off. Powerful actors on the stock market, such as pension funds, investing billions of dollars and being light-footed in their investment behavior have also contributed to this dilemma.

1.3   Research issues

It is often proposed, that we are currently in the process of societal transition, that we are about to enter a new era, moving from a modern, industrially dominated society towards an information- or knowledge-society, more generally termed post-industrial society. The changes taking place during this transitory process may include the establishment of new economic market models, changes in the structure and content of work and the contractual arrangements surrounding it, and the emerging of new organizational forms, such as hordes.

These profound changes in the nature of society are often referred to as paradigm shift. We can say that a paradigm shift is a fundamental change in the way we consider a phenomenon. A typical example of paradigm shift is the abundance of the geocentric image of the universe, developed by Claudius Ptolemy, in favor of the heliocentric worldview as Copernicus described it. However, while the geocentric worldview today has gained a 100% acceptance, paradigm shifts in other areas might just as well be incomplete, i.e. that a minority is not willing to accept the new concept.

As Tapscott and Caston (1993) notice in their discussion of paradigm shifts impacting businesses, the notion of paradigm has grown beyond the dictionary definition. When used today, the term paradigm includes the concept of framework or scheme for understanding reality.
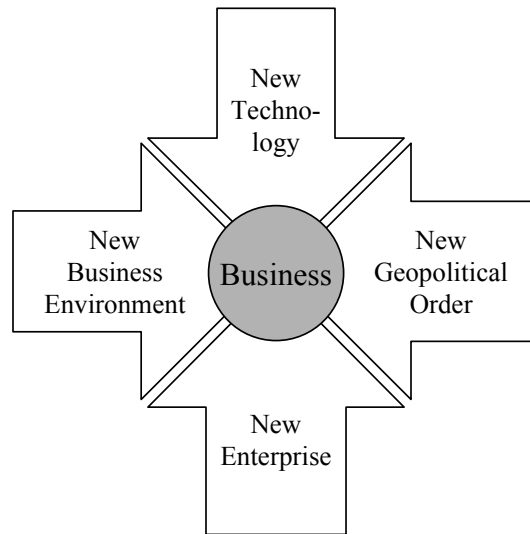
Figure 1-3:Paradigm shifts affecting businesses (Tapscott & Caston)

Tapscott and Caston (ibid.) have identified four paradigm shifts that influence businesses in the information age, and that shape a general framework for understanding the need for change. Whether the changes taking place within these areas can be considered as paradigm shifts in accordance to the dictionary definition of the term, is a question that will be left to science theorists to discuss, but it is obvious that organizations are struggling with adapting themselves to what they perceive as a new situation.

For pharmaceutical companies, this process of transition imposes changes at various levels. On the macro-level, mergers and acquisitions create new corporate giants, such as Pharmacia & Upjohn or AstraZeneca, to mention the deals involving large Swedish companies. Other companies employ vertical integration strategies and acquire distributors, or engage in strategic alliances with small biotech-firms. On the micro-level, we can observe changes in drug discovery and clinical research. The traditional organizational models and sequential approaches to organizing R&D processes are abandoned and new concepts, based on common information spaces, are developed and adopted. During this journey, many companies have also embarked on large-scale business process improvement

initiatives, often under the banner of BPR - Business Process Reengineering.

1.4   Research question

The return on R&D has been traditionally high in the pharmaceutical industry and the industry has not been affected by economic fluctuations to the same extent as, for example, manufacturing companies. However, several factors have contributed to a reduction of return-on-R&D.

First-to-patent companies fight an increasingly intensive war against producers of generic me-too drugs. In 1997, the market share of follower drugs among the top 100 products was approximately 47%, thus leaving about 53% of a total sales volume of 85 billion US$ to the first-to-patent company. Blocking new market entrants and increasing the own market share is therefore an important strategy for first-to-patent companies. The importance of this choice is supported by the fact that overall R&D returns are generally expected to decline not only because of cannibalizing generic products, but also due to managed care programs and excess costs for new product development, which must be balanced against demands for cost savings and increasing shareholder returns.

Trying to achieve economy-of-scale and R&D synergy, drug-makers have had to downsize, consolidate, and reorganize during the past years. In an industry, where a product's life cycle often does not last more than a dozen years, and profits are no longer guaranteed, efficiency suddenly has taken on a new urgency. In their striving for productivity and an accelerated pace of innovation, many pharmaceutical companies have initiated large-scale change initiatives in order to implement new organizational and technical infrastructures.

Considering that every day lost in the development of a drug equates up to $ 1 million, it is easy to understand why pharmaceutical companies are prepared to invest heavily in organizational change programs, business process re-

engineering initiatives and technological solutions promising to squeeze time out of R&D. After all, the potential return of these change initiatives is immense and if successful, the ROI (return on investment) is very short.

In pharmaceutical companies, BPR is a potentially highly rewarding approach. Taking a new product to the market is a lengthy and expensive process and clinical R&D accounts for a considerable share of it. Reducing time in development can extend patent protection, keep cannibalizing generics away from the market and significantly increase return-on-investment of R&D.

When pharmaceutical companies embark on BPR projects, the integration of functional activities and removal of departmental barriers in the chain from pre-clinical research over clinical testing, to production and marketing, are frequently used measures. New technology for remote data collection, study management and bio-informatics is brought in place and as a result of these combined efforts, many companies have actually achieved significant cycle-time reduction in R&D. The most advanced firms today manage to run the clinical part of the overall R&D process in about 4 years, as opposed to the 8-12 years being common a decade ago.

Since the pharmaceutical industry is important, both from an economic point of view and with regard to the importance of their products, it is naturally interesting to investigate the impact of change initiatives on companies within this sector. In the management literature, pharmaceutical companies are frequently used examples for the need for change due to a changing market environment. Also the publications from consulting firms frequently feature change projects in the industry, often with a focus on process orientation, as success stories. However, there are few case studies available that actually describe these projects and their contribution to improved R&D productivity in detail. This has lead me to ask, in which way large-scale change initiatives, especially with a BPR label, actually contribute to R&D process improvement.

In which way do large-scale BPR initiatives in pharmaceutical companies contribute to the improvement of R&D processes?

As a case study, I have selected Astrazeneca R&D Mölndal (at the time of the study, before the merger of Astra and Zeneca) still named Astra Hässle), a major research unit within the Astrazeneca group. At this facility, specialized in research in the area of gastro-entestinal diseases, some highly successful products had been developed, among them Losec/Prilosec (Omeprazole), the best-selling drug worldwide in the 1990s, and Selocen. These results had placed Astra Hässle in a relatively comfortable position within the Astra group and had ensured increasing returns and profits over many years.

However, it became clear that also a highly successful company had to reconsider its working practices and use of IT in order to sustain competitiveness and efficiency in the research pipeline. The decisions to initiate large-scale change initiatives were further impacted by the fact that the first patents that protected the blockbuster Losec would expire in 2002, resulting in generic drugs finding their way to the market. As a consequence of these considerations, a first re-organization took place in 1994, followed by two BPR projects, one targeting Astra Hässle, the other the R&D processes within the entire Astra group.

These two projects were subject of an in-depth study. When investigating process improvement initiatives, especially those under the BPR label, the aim is very often to prove the usefulness of the approach with regard to the targeted quantum leap improvements. Time and cost reduction are analyzed and related to the changes of processes and organizational structures. This thesis is not only aiming at determining success or failure of the BPR projects at Astra or the pharmaceutical industry. It is also pointing at how such projects can be carried out beyond the application of a formal method. As a consequence, the focus of the research has not been on the

quantitative and measurable benefits that BPR projects are expected to reap. It also investigates side effects of process and technology infrastructure implementation efforts that do not take into account local conditions and therefore are locally adapted. Finally, it suggests measures that go beyond the concept of BPR, based on the experiences from the case studies and based on discussions with industry practitioners from Astra and other companies, and researchers.

1.5   Research method

The case being presented in this book is not a case study in the conventional meaning, where researchers investigate certain and defined areas. Since the first contacts with Astra Hässle were established in year 1995, the relation between the company and the researchers from Göteborg University and the Viktoria Institute has become a partnership, involving elements of traditional case study research, but also informal meetings and discussions around issues not being directly related to the change initiatives being described here. During a period from 1995 to 1999, I have been "floating" around in the organization, meeting many different people for discussions and interviews of formal and informal character. At the same time, my role has not been limited to be an observer - intervention has been a natural part of the relationship, i.e. I have provided my points of view on the organization, its use of information technology and also the FASTRAC and CANDELA projects.

There are several research methods for doing research in organizations. Braa (1995) has described and compared the concepts of hard and soft case studies, action research and field experiment. She has identified the following ideal type characteristics of these methods.

	Action research	Field experiment	Case study
Duration	Long	Short	Any

	Action research	**Field experiment**	**Case study**
Aim	Intervention	Hypothesis testing	Description /Intervention
Time focus	Building future	Real time /future	Historic perspective
Change perspective	Planned/ deliberate changes	Controlled variables	Accidental changes

Table 1: Characteristics of research methods

The major difference between these research methods is found in the role of intervention. Braa (ibid.) has stated that case studies attempt to minimize the impact of the research activity on the subject (organization) under concern. Field experiments, with their focus on hypothesis testing also require the context to be constant, whereas action research is aiming at supporting change in the organizational setting.

Of these ideal method types, action research is the one being most suitable for describing the nature of my research collaboration with Astra Hässle. Nonetheless, it is not fully sufficient to capture all of this collaboration's facets. As an additional method spanning over multiple of the above-mentioned methods, Braa has proposed the concept of Action case. In order to illustrate how action cases relate to other organization research methods, Braa (ibid., page 152) has depicted the methods in a triangular model, the research space.

The research space's corners represent science, interpretation and intervention in their pure form, whereas the sides of the triangle represent the trade-offs between the different foci of the research and the dilemmas they might constitute for the researcher with regard to delivering scientific, useful and pragmatic results.
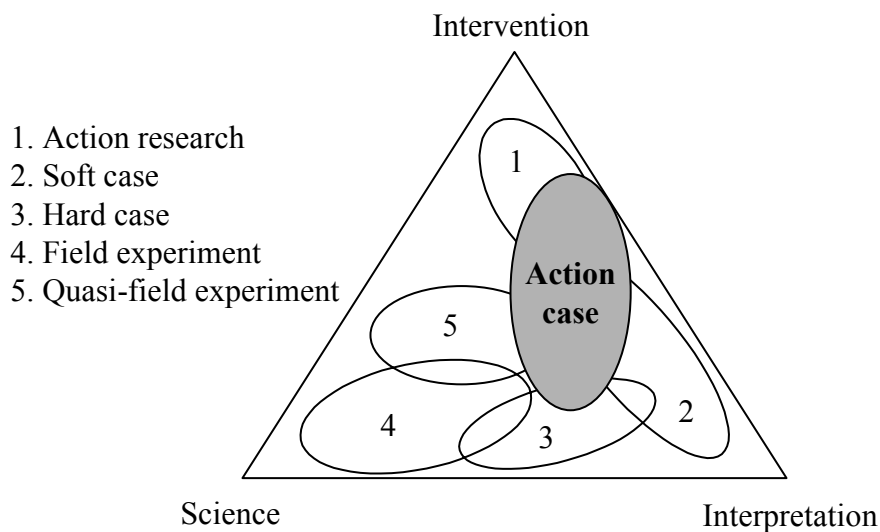
Figure 1-4: Action case research domain

1. Action research
2. Soft case
3. Hard case
4. Field experiment
5. Quasi-field experiment

The action case research method, as the name indicates, is mainly a combination of action research and case study. However, it also contains some characteristics of the field experiment, namely the requirement for reduced complexity and the reduction of variables, i.e. aspects of the organizational context might be disregarded in order to maintain the manageability of the research project. In the Astra Hässle case, this reduction has taken place through the focus on the clinical study part of the R&D process, despite its close interrelation with pre-clinical research and development and marketing. Also, the cultural aspects of the organization are not extensively discussed. Instead, the relation between IT and its use within the organization has been investigated.

Braa brings forwards two main arguments for the action case method. The first one is pragmatic and builds on the observation that most research projects actually involve aspects of both case study and action research and that the two methods, in practice, are difficult to distinguish. The research collaboration with Astra actually supports this argument. It was hardly possible to take on the role of either pure case study, or action researcher. The interviews and discussions, the participation in meetings, always included aspects of interpretation and intervention.

Braa's second argument refers to the applicability of the method in the investigation of information systems, since it allows the testing of theory and techniques on a small scale and does not require the same consideration of complexity in the organizational setting as full scale projects. In addition, the possible limitations of the research scope allow the researcher to better address contextual constraints. This argument did not have the same relevance for the Astra Hässle project, since the possible problems mentioned did not appear. The scope of the research, even though it covered a range of different aspects in the organization and its IT-use, was clear. Additional issues being relevant from an intervention perspective, and having a consultative nature rather than being research oriented, were discussed and resolved separately from the research project in discussions with Astra managers.

Although the action case method seems to be the most suitable one for describing the research presented here, there are some deviations from the concept as it is described by Braa. The following table relates the research at Astra to the characteristics of the action case method.

Action case	Astra Hässle research
Short duration	The project was not set up with a specific duration, but was considered as a long-term mutual commitment.
Real time	Intervention took place in real time. Issues that were considered as being relevant for intervention were immediately addressed in discussions with company representatives.
Some description	The conduct of the major change initiatives that have taken place in the company during the past years and that have been the scope of the study are described.
Some intervention	Intervention took place through frequent discussions with Astra managers and other personnel.
Some experiment	No experiment until now, small-scale experiment with new organizational concept and IT-support planned for the future.

Action case	Astra Hässle research
Some reduction of complexity	The project scope was not clearly defined from the beginning, but emerged during the project and changed over time. However, only one area was focused at a time. Complex issues were handled outside the project.
Changes in small-scale	No direct changes as result of the research, but influence on the future development of organization and its use of IT.

Table 2: Action case and Astra Hässle research characteristics

1.5.1 Data gathering

The descriptions of the process improvement approaches being used by Andersen Consulting (now Accenture) and McKinsey & Company are based on documentation material provided by the consulting firms, public sources such as handouts from conferences and discussions with employees of these firms taking place at various occasions. In addition, all firms were offered to comment on the description of their methodology.

The case material for the descriptions of the FASTRAC and CANDELA projects at Astra Hässle are based on many discussions with employees at various levels of the company, taking place over a period of several years. In addition, written material, provided by the company, has been used and the project documentation on the corporate intranet has been followed. For the SCODA description and analysis, additional semi-structured interviews with study monitors were conducted in Spain, Sweden, Germany and the USA.

1.5.2 Aiming at practitioners – the rigor versus relevance issue

Research it often described as a process of finding universal solutions to an identified problem or situation. If it is not possible to define and describe optimum organizations and IT-use, why making the effort of writing a doctoral dissertation about organizational change, business processes and

information technology in the pharmaceutical industry? The rather pragmatic answer and goal for this work is to deliver a theoretical and practical contribution to the area of business improvement, aiming at academics and practitioners alike. This attempt has been made having in mind, that this approach also provides a fertile ground for critique. A critique claiming that this book is an airport-bookstore publication for managers traveling between two meetings, rather than a theory loaded academic work that will contribute to the development of the knowledge body of the scientific world. However, it is my conviction, that these intentions are not excluding each other and this thesis contributes to the requirements of Benbasat and Zmud (1999) and Davenport and Markus (1999) to make the results of academic research available to practitioners and students.

In March 1999, Izak Benbasat and Robert W. Zmud (Benbasat & Smut, 1999) published an article in the well known IS journal MIS Quarterly (MISQ), in which they discussed the issue of practical relevance of IS research. They argued that, due to academic rigor, a considerable portion of research in Information Systems fails to produce output that is relevant to practitioners in the field.

In a response to Benbasat and Zmud, published in the same issue of MISQ, Davenport and Markus are even more critical and claim that, in many cases, academia has been outperformed by consultants when it comes to conducting and publishing research in a way that makes it readable and understandable for practitioners (Davenport and Markus, 1999).

Benbasat and Zmud (1999) proposed that senior practitioners are the key target group for practical research. Davenport and Markus (1999) argue that today's student - tomorrow's practitioner should be considered as an equally important audience. In either way, they argue, it becomes necessary to take into account the requirements from non-academic audiences:

> […] we are saying that our field desperately needs more
> relevant research than it has today. The regard in which we

are held by the world-and our long-term access to essential resources-will ultimately depend not on the regard other academics give our research, but on our demonstrated service to external customers. (Davenport and Markus, 1999)

Having combined research and practice over the past years, I have been able to observe the same dilemma. Research results that would be highly interesting to the professional community cannot be applied due to the standards of the academic world, that do not appreciate practical relevance, but focus on its internal norms, procedures and traditions.

With this dissertation, I have tried to make a difference. It is an effort to write a thesis that satisfies the scientific community's requirements for scientificness, method and writing, but also allows practitioners to make sense and use of its content. I have deliberately have chosen a simple, descriptive language and the structure is kept in a way that makes reading as easy as possible. Unfortunately, this does not make this text an easy reader. The issues being discussed are of complex nature, but still it is my hope that this work will contribute to the development of an understanding of the difficult world of organizational change, and assist theorists and practitioners in their struggle with organization analysis and design.

1.6   Disposition of this book

This book is divided into 7 main chapters. The introduction given in chapter 1 provides an overview of the changing business environment that influences the pharmaceutical industry and describes the most important global and local dynamics. The introduction also addresses the issue why pharmaceutical research and development constitutes an interesting area for research in the field of organization and information technology and contains the research question and method and, finally, this disposition.

Chapter 2 provides the theoretical framework of this thesis. It gives a short introduction to BPR and some of the theories the concept is based upon. It sets off with a description of the MIT study "Made in America" that has played a substantial role in the development and diffusion of BPR and continues to introduce the concepts of business processes and reengineering. Also the critique that BPR is a rebirth of Frederick Taylor's scientific management is discussed. Subsequently, the BPR methods being used by two consulting firms that have been involved in the initiatives at Astra – Andersen Consulting and McKinsey & Company – are briefly described and compared.

Chapter 3 contains a description of the FASTRAC project at Astra Hässle and the corporate CANDELA initiative. In order to provide a context to FASTRAC, a brief introduction to product development in the pharmaceutical industry is given. In the following, the rationales of FASTRAC and CANDELA are outlined and the initiatives and their outcome are described.

Chapter 4 addresses the IT-aspects of both FASTRAC and CANDELA. This includes the detailed analysis of SCODA, a system being introduced for remote data collection in clinical trials at Astra Hässle, and its impact on the related organizational processes and the actual data collection work in a clinical project.

Chapter 5 is the first of 2 chapters containing the results of the study. The chapter discusses SCODA from an infrastructure perspective using the concept of organizational and technological inscription. It also addresses the issues of global and local aspects of infrastructures and rigidity versus openness in the design of infrastructures. Finally, it goes into some methodological aspects of IT infrastructure implementation and the role that consultants have played in the change initiatives at Astra Hässle.

Chapter 6 goes beyond the actual case. It describes the deployment of COOL, the web-based data collection system that was successfully introduced in Astra Hässle, in the context of a new model for performing clinical R&D and the use of a clinical R&D portal or common information space and suggests that

spinning-off R&D into a separate organization might be a considerable approach for improving R&D efficiency.

Chapter 7 contains some brief final remarks and summarizes the most important lessons learned from the case.

2. Theoretical considerations

The concept of processes is not new. Laying out inter-related activities in a sequence and creating a flow of work has been part of organization design for more than 300 years. One of the first to explicitly describe processes was Adam Smith (1776) in the famous example of an English pin factory. He described the production of a pin in the following way.

"One man draws out the wire, another straights it, a third cuts it, a fourth points it, a fifth grinds it at the top for receiving the head: to make the head requires two or three distinct operations: to put it on is a particular business, to whiten the pins is another … and the important business of making a pin is, in this manner, divided into about eighteen distinct operations, which in some manufactories are all performed by distinct hands, though in others the same man will sometime perform two or three of them."

Smith also first recognized how the organizational outcome could be increased through the use of advanced labor division. Previously, in a society where production was dominated by handcrafted goods, one man would perform all the activities required during the production process, while Smith described how work in a pin factory was divided into a set of simple tasks, which would be performed by specialized workers. The result of labor division in Smith's example resulted in productivity increasing by 24.000 percent (sic!), i.e. that the same number of workers made 240 times as many pins as they had been producing before the introduction of labor division.

It is worth to notice that Smith did not advocate labor division at any price and per se. He observed and noted that, under certain conditions, several tasks could very well be integrated into one, which a single worker would then perform. However, Smith did not provide any guidance for criteria that could be used for finding the optimum level of task division or

integration and the determination of the appropriate level took place through experimental design of the production process.

This approach to integration could be considered as an implicit proposition of a process-oriented approach, but there is one aspect that constitutes a significant difference to the idea of business processes as it is perceived today. The integration in accordance with the idea of Smith would take place only within the same functional domain and comprise activities that are in direct sequence in the manufacturing process, whereas today's process concept includes cross-functionality as an important characteristic. It is also interesting to note that while Smith is generally accepted as the first to discuss labor division and specialization, only the division of labor was widely adopted, while the integration of tasks into functional, or cross-functional, processes was not considered as an alternative option to increase performance and productivity.

2.1   The emergence of BPR

In 1990, Michael Hammer, a former professor of computer science at the Massachusetts Institute of Technology (MIT), published an article in the Harvard Business Review, in which he claimed, that the major challenge for managers is to obliterate non-value adding work, rather than using technology for automating it (Hammer 1989). This statement implicitly accused managers of having focused the wrong issues, namely that technology, and especially information technology, has primarily been used for automating existing work. Hammer's claim was simple: Most of the work being done does not add any value for customers, and this work should be removed, not accelerated through automation. Instead, companies should reconsider their processes in order maximize customer value, while minimizing the consumption of resources required for delivering their product or service. A similar idea was advocated by Thomas Davenport, at that time a member of the Ernst & Young research

center, in a paper published in the Sloan Management Review the same year as Hammer published his paper.

This idea, to unbiased review and "reengineer" a company's business processes, was rapidly adopted by a huge number of firms, which were striving for renewed competitiveness, which they had lost due to the market entrance of foreign competitors, their inability to satisfy customer needs, and their insufficient cost structure. Even well established management thinkers, such as Peter Drucker[8] and Tom Peters, were accepting and advocating BPR as a new tool for (re-)achieving success in a dynamic world. During the following years, a fast growing number of publications, books as well as journal articles, was dedicated to BPR, and any consulting firm with self-respect developed a BPR method[9]. However, the critics were fast to claim that BPR was a way to dehumanize the work place, increase managerial control, and to justify downsizing, i.e. major reductions of the work force (Greenbaum 1995, Industry Week 1994), and a rebirth of Taylorism and its mechanistic worldview under a different label.

Despite this critique, reengineering was adopted at an accelerating pace and in 1993, as many as 65% of the Fortune 500 companies claimed to either have initiated reengineering efforts, or to have plans to do so. This trend was fueled by the fast adoption of BPR by the consulting industry, but also by a study conducted by the MIT (Massachusetts Institute of Technology), that showed how companies in many US industries had lagged behind their foreign counterparts in terms of competitiveness, time-to-market and productivity.

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[8] On the cover of Hammer's and Champy's book on BPR, the following statement of Peter Drucker can be found: "Reengineering is new, and it has to be done".

[9] E.g. Andersen Consulting: Value driven reengineering, McKinsey: Core process redesign, Coopers& Lybrand: Break-point BPR, Frontec (Sweden): Value added control

2.2   The MIT study Made in America

In 1986, the MIT established the Commission on Industrial Productivity. The task assigned to this formation was to study the performance of industry in the US, but also to compare it to industry in other countries and to consider global economic developments that might impact the requirements for successful performance in the future. The commission also aimed at defining recommendations that should allow America's industry to sustain productivity growth and competitiveness. The study, named Made in America, included firms in eight industries - automobile, chemical, commercial aircraft, consumer electronics, machine tools, computer and office equipment, steel, and textiles - and researchers scrutinized the participating organizations with respect to efficiency, quality, productivity, innovativeness, agility, etc. About 200 firms were visited and more than 500 interviews were conducted. The study revealed some serious shortcomings of US companies in comparison with their foreign, especially Japanese, counterparts. In all industries, except chemicals and aerospace, productivity development had fallen behind. The analysis identified six areas in which significant performance barriers were found and identified a set of best practices - focus areas for improvement - that US companies should focus on in order to regain competitiveness.

2.2.1 Performance barriers

Obsolete strategies. During the 1980s, the economic environment had begun to change significantly. Competition had become global and companies were under attack from foreign entrants on their previously protected home markets. Since foreign competition had been largely ignored and the size of the US market had limited the need for export, many companies were taken by surprise when foreign products invaded their home turf.

After World War II, most US forms had developed towards mass production, i.e. the manufacturing of commodity goods in

large volumes. Due to market size and high demand, many firms neglected the concept of product customization for different market segments. Consequently, customers were attracted by foreign products that offered more choice and often also higher quality and that were supported by a high service level. This factor became especially obvious in the automobile industry, where Japanese companies had managed to achieve considerably shorter time-to-market, higher quality, and a wide range of products.

High expectations for ROI. Many investors have a short horizon for investments, i.e. they expect a return in considerably shorter time than their foreign counterparts. This forces companies to seek for faster pay-off and limits the ability to hider

- Continuous improvement of products and processes is underestimated, or even neglected.

Inappropriate use of human resources. The study pointed out two major weaknesses about human resource deployment. (A) The shortcomings of the basic education system to provide schooling with industrial relevance and (B) insufficient training of employees within companies. To keep pace with their foreign counterparts and to be able to implement the concepts of self-managing teams and empowerment, companies need to provide their workforce with the appropriate skills through training and education.

Lack of coordination and cooperation within organizations. The effective coordination of work within and between organizations is a critical factor for sustaining and improving performance and productivity. Lack of coordination and cooperation is hampering the development and exploitation of new products and sets up barriers for the efficient employment of resources within and between organizational value chains. Within the Made in America project, lack of coordination was identified at various levels: (A) Between individuals and groups within companies, (B) between firms and their suppliers and customers, (C) among firms within the same industry, and (D) between firms and government and its regulatory authorities. As an additional factor, many companies suffered from a lack of vertical communication within their organization, i.e. poor contacts between managers and workers.

Interest conflicts between industry and government. Companies behavior is directed not only by internally developed strategies and their global business environment, but also by the macro-economic situation created by local governments and the restrictions, guidelines and policies of various authorities with regulatory power. This includes aspects such as taxation, basic research, the education system and social regulations and welfare policies. Consequently, government has a considerable, though mainly indirect, influence on corporate performance. A discrepancy between the politics driven by government and the

need of companies for stable business areas can impose constraints on companies' abilities to sustain performance and productivity.

2.2.2 Industry best practice

When looking at the above-mentioned factors that the MIT study identified we can conclude that they are basically congruent with the pathologies pointed out in the reengineering literature. The study, however, did not only outline problems, but suggested also a set of actions that were described as industrial best practice. Also these practices show a significant congruence with the measures proposed by the reengineers.

Improvement in cost, quality and delivery. In can be claimed, that low cost, high quality and fast and accurate delivery of products and services are characteristics that should be paramount for all business organizations. However, many companies are not aiming at the simultaneous improvement of all these properties, but are focusing their improvement efforts at only one or two areas. The MIT study showed, that best practice companies had developed the ability to achieve simultaneous improvement in all three areas.

Cooperation with customer and suppliers. Close relationships with suppliers and customers can improve performance throughout an entire value system. Collaboration with customers can elevate responsiveness to market signals and allows firms to pick up changing customer demands faster. The development of concepts such as Supplier-Retailer Collaboration and Efficient Customer Response, today nominated as Supply Chain Management, indicate the emphasis that many customers put on establishing tighter relationships with their customers. In the same way, closer cooperation with suppliers can improve the flow of goods and information between companies' value chains and reduce transaction costs and time.

Use of information technology. The use of information technology for improving efficiency in product development, time-to-market and other areas of internal and external

communication was another feature shared by best-practice companies. Successful organizations had included technology management into the managerial agenda and used IT purposefully for achieving competitive advantages.

Flatter organizations. Another common trait for companies that were successful in their industry segments was a focus on cross-functional work and flatter organizations with fewer hierarchy levels. Following this rationale allows faster reaction to changing business environments and reduces departmental barriers and closure. The establishment of cross-functional teams and concurrent work, together with the associated increasing responsibility for individuals, has proven to be a successful concept. Teamwork also allows to bring individuals with various skills and competencies together for fast problem solving.

Human resource policies. In order to break ground for new organizational forms, flatter organizations and individual empowerment, it is necessary to employ human resource strategies and policies that promote commitment, the taking of responsibility, learning and knowledge sharing. This includes also reconsidering incentive mechanisms and career paths and must allow employees to take part in the development of their work environment and the future of the firm.

2.3 What is a Business Process?

In the early 1990s, US corporations, and subsequently companies all over the world, started to adopt the concept of reengineering in an attempt to re-achieve the competitiveness that they had lost during the previous decade. A key characteristic of BPR is the focus on business processes, rather than functional organizational structures. Consequently, the investigation of BPR as a concept for organizational renewal should take its departure from the idea and concept of business processes. Davenport (1993) defines a (business) process as

"a structured, measured set of activities designed to produce a specific output for a particular customer or market. It implies a strong emphasis on how work is done within an organization, in contrast to a product focus's emphasis on what. A process is thus a specific ordering of work activities across time and space, with a beginning and an end, and clearly defined inputs and outputs: a structure for action. ... Taking a process approach implies adopting the customer's point of view. Processes are the structure by which an organization does what is necessary to produce value for its customers."

This definition contains certain characteristics a process must possess. These characteristics are achieved by a focus on the business logic of the process (how work is done), instead of taking a product perspective (what is done). Following Davenports definition of a process we can conclude that a process must have clearly defined boundaries, input and output, that it consists of smaller parts, activities, which are ordered in time and space, that there must be a receiver of the process outcome- a customer - and that the transformation taking place within the process must add customer value.

Hammer & Champy's (1993) definition can be considered as a subset of Davenport's. They define a process as

"a collection of activities that takes one or more kinds of input and creates an output that is of value to the customer."

As we can note, Hammer & Champy have a more transformation oriented perception, and put less emphasis on the structural component–process boundaries and the order of activities in time and space.

Rummler & Brache (1995) use a definition that clearly encompasses a focus on the organization's external customers, when stating that

"a business process is a series of steps designed to produce a product or service. Most processes (…) are cross-functional, spanning the 'white space' between the boxes on the organization chart. Some processes result in a product or service that is received by an organization's external customer. We call these primary processes. Other processes produce products that are invisible to the external customer but essential to the effective management of the business. We call these support processes."

The above definition distinguishes two types of processes, primary and support processes, depending on whether a process

Summarizing the four definitions above, we can compile the following list of characteristics for a business process.

- **Definability:** It must have clearly defined boundaries, input and output.

- **Order:** It must consist of activities that are ordered according to their position in time and space.

- **Customer:** There must be a recipient of the process' outcome, a customer.

- **Value-adding:** The transformation taking place within the process must add value to the recipient, either upstream or downstream.

- **Embeddedness:** A process cannot exist in itself, it must be embedded in an organizational structure.

- **Cross-functionality:** A process regularly can, but not necessarily must, span several functions.

2.4   Reengineering defined

While there are almost as many definitions of BPR as there are authors publishing on the topic, we can identify multiple aspects that they have in common. Let us first review a number of definitions.

Hammer and Champy (1993) define BPR as

"the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical contemporary measures of performance, such as cost, quality, service, and speed".

Thomas Davenport (1993), another well-known BPR theorist, uses the term process innovation, which he says

> "encompasses the envisioning of new work strategies, the actual process design activity, and the implementation of the change in all its complex technological, human, and organizational dimensions".

Additionally, Davenport (ibid.) points out the major difference between BPR and other approaches to organization development (OD), especially the continuous improvement or TQM movement, when he states:

> "Today firms must seek not fractional, but multiplicative levels of improvement – 10x rather than 10%."

Finally, Johansson et. al. (1993) provide a description of BPR relative to other process-oriented views, such as Total Quality Management (TQM) and Just-in-time (JIT), and state:

> "Business Process Reengineering, although a close relative, seeks radical rather than merely continuous improvement. It escalates the efforts of JIT and TQM to make process orientation a strategic tool and a core competence of the organization. BPR concentrates on core business processes, and uses the specific techniques within the JIT and TQM "toolboxes" as enablers, while broadening the process vision."

In order to achieve the major improvements BPR is seeking for, the change of structural organizational variables and other ways of managing and performing work is often considered as being insufficient. For being able to reap the achievable benefits fully, the use of information technology is conceived as a major contributing factor. While IT traditionally has been used for supporting the existing business functions, i.e. it was used for increasing organizational efficiency, it now plays a role as enabler of new organizational forms, and patterns of collaboration within and between organizations.

BPR derives its existence from different disciplines, and we can identify four major areas being subjected to change in

BPR - organization, technology, strategy, and people - where a process view is used as common framework for considering these dimensions. The approach can be graphically depicted by a modification of "Leavitt's diamond" (Leavitt 1965).
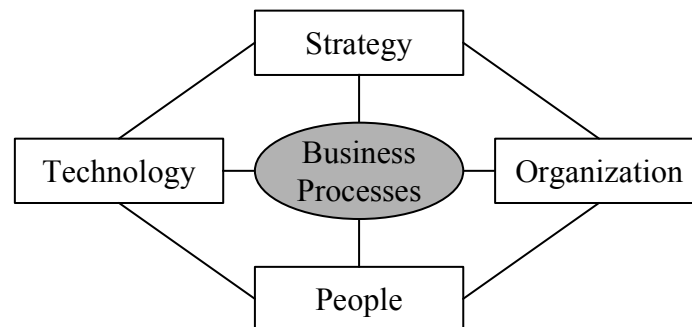
Figure 2-1: Leavitt's diamond, modified

Business strategy is the primary driver of BPR initiatives and the other dimensions are governed by strategy's encompassing role. The organization dimension reflects the structural elements of the company, such as hierarchical levels, the composition of organizational units, and the distribution of work between them. Technology is concerned with the use of computer systems and other forms of communication technology in the business. In BPR, information technology is generally considered as playing a role as enabler of new forms of organizing and collaborating, rather than supporting existing business functions. The people, or human resources dimension deals with aspects such as education, training, motivation and reward systems. The concept of business processes - interrelated activities aiming at creating an value added output to a customer - is the basic underlying idea of BPR. These processes are characterized by a number of attributes: Process ownership, customer focus, value-adding, and cross-functionality.

By its critics, BPR is often accused to be a re-animation of Taylor's principles of scientific management, aiming at increasing productivity to a maximum, but disregarding aspects such as work environment and employee satisfaction. It can be agreed that Taylor's theories, in conjunction with the work of the

early administrative scientists have had a considerable impact on the management discipline for more than 50 years. However, it is not self-evident that BPR is a close relative to Taylorism and this proposed relation deserves a closer investigation.

2.5 BPR - A rebirth of Scientific Management?

In the late 19th century Frederick Winslow Taylor, a mechanical engineer, started to develop the idea of management as a scientific discipline. He applied the premise that work and its organizational environment could be considered and designed upon scientific principles, i.e. that work processes could be studied in detail using a positivist analytic approach. Upon the basis of this analysis, an optimal

Photo: Bettmann/Corbis

organizational structure and way of performing all work tasks could be identified and implemented. However, he was not the one to originally invent the concept. In 1886, a paper entitled "The Engineer as Economist", written by Henry Towne for the American Society of Mechanical Engineers, had laid the bedrock for the development of scientific management.

The basic idea of scientific management was that work could be studied from an objective scientific perspective and that the analysis of the gathered information could be used for increasing productivity, especially of blue-collar work, significantly. Taylor (1911) summarized his observations in the following four principles:

- Observation and analysis through time study to set the optimal production rate. In other words, develop a science for each man's task–a One Best Way.

- Scientifically select the best man for the job and train him in the procedures he is expected to follow.

- Cooperate with the man to ensure that the work is done as described. This means establishing a differential rate system of piece work and paying the man on an incentive basis, not according to the position.

- Divide the work between managers and workers so that managers are given the responsibility for planning and preparation of work, rather than the individual worker.

Scientific management's main characteristic is the strict separation of planning and doing, which was implemented by the use of a functional foremanship system. This means, that a worker, depending on the task his is performing, can report to different foreman, each of them being responsible for a small, specialized area.

Taylor's ideas had a major impact on manufacturing, but also administration. One of the most well-known examples is Ford Motor Co., which adopted the principles of scientific management at an early stage, and built its assembly line for the T-model based on Taylor's model of work and authority distribution, thereby giving name to Fordism.

Picture 1: Ford's assembly line, 1907

Later on, Taylor's ideas were extended by the time and motion studies performed by Frank Gilbreth and his wife Lillian. Henry

Gantt[10], a co-worker of Taylor, developed Taylor's idea further, but placed more emphasis on the worker. He developed a reward system that no longer took into account only the output of the work, but was based on a fixed daily wage, and a bonus for completing the task.

Taylor's work can be, and has been, criticized many times for degrading individuals to become machinelike. One of the most famous critiques of the situation that an application of scientific management could result in, is shown in Charles Chaplin's movie "Modern Times". Despite that fact, Taylor was inspired by the vision of creating a workplace that is beneficial to all members of the organization, both management and workers.

> "The great revolution that takes place in the mental attitude of the two parties under scientific management is that both sides take their eyes off the division of the surplus as the all-important matter, and together turn their attention towards increasing the size of the surplus until this surplus becomes so large that it is unnecessary to quarrel over how it should be divided. They come to see that when they stop pulling against one another, and instead both turn and push shoulder to shoulder in the same direction, the size of the surplus created by their joint efforts is truly astounding." (Wren 1972)

When looking at Taylor's ideas retrospectively, we can conclude, that they very well fitted the organizations of the early 20th century. The kind of organization he proposed requires certain pre-conditions, which were satisfied in the technological and socio-economic environment of his time and the heritage from economic individualism and a Protestant view of work. However, despite the good intention of designing organizations where managers and workers could jointly contribute to the common achievements, Taylor missed the fact that he had been building his principles on wrong assumptions. There are three major critical issues that can be brought forward.

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[10] Henry Gantt is also well known for the "Gantt-chart". This technique for planning and phasing activities is still frequently used today.

The strict belief in man being totally rational, and the history of protestant ethic, which considered work as being a manifestation of religious grace, made him disregard the crucial issue of human behaviour and the fact that money is insufficient as the single source of motivation (Tawney 1954).

The lack of considering the organizational environment as a conceivable factor, and the overemphasis on organizational efficiency. As Thompson (1969) notes:

> "Scientific management, focusing primarily on manufacturing or similar production activities, clearly employs economic efficiency as its ultimate criterion and achieves conceptual closure of the organization by assuming that goals are known, tasks are repetitive, output of the production process somehow disappears, and resources in uniform qualities are available."

If accepting Thompson's critique as valid and relevant, we can conclude that the strict hierarchical organization seems to be unfit to take on the challenges that are imposed by fierce competition and dynamic market structures. Due to the focus on improvement through repetition and resource uniformity, the applicability on organizations and processes without these characteristics, such as pharmaceutical R&D, can be questioned.

Peter Drucker noted a third problem related to scientific management, namely that there was no real concern about technology, i.e. that Taylor considered his theory as being general, and that it could be applied to any organization, independently of the technology used. Drucker (1972) stated:

> "Scientific management was not concerned with technology.
> It took tools and technology as givens."

This point brings forward a clear argument against the application of Taylor's principles and methodologies for improving today's organizations. Considering that the rapid

development in the IT field actually constitutes a driving force in itself, it appears to be unfit to employ organizational concepts that neglect the changing and enabling role of technology. On the other hand we can argue that the application of scientific management in the early 20st century, as we look at it retrospectively, must be considered as the contemporary use of a concept that would look and be applied in a different way today. Taylor did not neglect technology, he considered it as an important contributor to organizational performance, but given the pace of development, he could not consider it as a major driver of change.

Looking at the suggested relationship between BPR and Taylor's principles we can conclude that primarily Thompson's and Drucker's criticism build a strong case against BPR being a successor of Taylorism. An organizational concept that does not take into account changing business environments and rapid technological advancements is not fit for serving as an improvement method today. Also the BPR literature offers a harsh critique of the continuous application of tayloristic principles in the modern business world, rejecting the separation of planning and doing and the strict functional division of labor. BPR proponents claim that taking BPR for Taylorism is a major misunderstanding of the concept, and responsible for a considerable number of reengineering project failures. On the other hand, there is also a similarity which stems from the methodological approach: Both scientific management and BPR have a focus on productivity and efficient use of resources that can be achieved through an optimum process design and its sub-sequent deployment. The following quote, referring to scientific management can equally be used to describe the intention of reengineering:

> To conduct the undertaking toward its objectives by seeking to derive optimum advantage from all available resources.
> (Loyd 1994)

At the same time it cannot be denied, that the practical implementation of process-based organizations in practice often is accompanied by massive lay-offs and an emphasis on managerial control. A study by CSC Index from 1994 revealed that 73% of the companies applying BPR reduced their workforce with an average of 21%. Thomas Davenport, an early contributor to the BPR-field, provided a harsh critique against labeling substantial workforce reductions reengineering and in a paper from 1995 he stated that

> "reengineering didn't start out as a code word for mindless bloodshed. ... The [other] thing to remember about the start of reengineering is that the phrase 'massive layoffs' was never part of the early vocabulary." (Davenport, 1995)

2.6   The role of information technology

Ever since the 1950s, when computers first were employed in business organizations, information technology has played a major role in businesses, and with increasing computing power at constantly lowered prices, powerful applications for all business areas, and the development of networks, computers have come to play a more and more important role in most organizations. While the use of IT in the 1950s and 60s was mainly restricted to transaction-processing, such as in banks and insurance companies, the development of database technology in the following decade enabled the rise of Management Information Systems (MIS). When personal computers (PC) appeared on the desktops in the 1980s and they became connected to local networks (LAN), and later on wide networks (WAN), information technology started to gain a reputation as strategic asset, thus the discussion in the 1980s was dominated by the term "strategic information systems" (SIS). However, even though many companies were already highly depending on their information systems, the real break-through for business critical applications came during the recent years,

with the development of extremely powerful desktop computers, computer support for collaborative work (CSCW and workflow technology), and the recognition of IT as enabler of organizational transformation.

In the BPR field, information technology is considered as being the major enabler, and even driving force for organizational change. Hammer & Champy (1993) have identified eight areas where IT, as they call it, can play a disruptive role. Similarly, Davenport (1993) has identified a set of areas, where IT can play an important role for substantially changing the way business is done. When looking at the most frequently proposed application areas of information technology in conjunction with BPR efforts, we find the following.

Shared databases. The concept of database sharing, in order to allow a wide distribution of critical business information, is considered to be one of the most important areas where IT can contribute to a more effective and efficient performance of business processes, and has gained considerable attention since client/server technology has become a widely used solution. Shared databases allow companies to move from a sequential to a parallel performance of activities in a process, and provides information to all people involved in it.

Expert systems. This type of technology, which has its root in the Artificial Intelligence (AI) field, can possibly allow non-experts to perform expert work by capturing and widely distributing knowledge. As Hammer (1993) points out, however, the concept of expert systems in BPR does not refer to the earlier attempts of replacing experts by computer systems, but means to provide specialized knowledge to individuals in order to elevate their skills. Despite the term "expert systems", the applications described in literature[11] has relatively little to do with artificial intelligence, but could be categorized as decision

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[11] See for example: Tapscott & Caston (1993), pp 69-70

support systems, since they most often lack several of the characteristics of expert systems.[12]

Mobile computing and communication. With the development of powerful laptop computers and new telecommunications technology, such as GSM (Global System for Mobile Communication), ISDN (Integrated Services Digital Network), ATM (Asynchronous Transfer Mode), new forms of work have been made possible. This includes telecommuting, and field staff being able to keep in contact with their company.

Workflow technology and groupware. Business processes are sets of activities performed by individuals, thus improving their capabilities of working together will improve the performance of the process. Even though workflow technology and groupware have different application scopes, they both share the intention of managing the transaction of work. While workflow systems generally are designed for supporting a smooth flow of a case through the organization, often following pre-defined routing rules, groupware is focused on collaboration within working groups and teams, and provides mechanisms for sharing knowledge and ideas.

2.7   BPR – the consulting way

There are probably as many methodologies for process improvement and change management as there are consulting firms and even scholars from various disciplines, mainly the Business Administration field, have contributed to this flora of improvement approaches in a conceivable way. Any of the major internationally working consulting firms keeps itself with a change methodology and also smaller, local firms have developed their own approaches to business and process improvement. The applied approaches range from complete concepts, covering all steps of the transformation process, to techniques and tools

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[12] For a discussion of the characteristics of expert systems, see Jackson (1986).

used for specific purposes during a specific part of the change process.

We will not advocate any approach as being superior to any other. The aim of this chapter is to provide an overview of some approaches that are used by large, internationally working management and IT consulting firms and to discuss them with regard to their steps and tools, as well as to relate them to more theoretical aspects, which are discussed elsewhere.

In the work of consulting firms, methods play an important role for different reasons. Methods are normally considered as explicit mechanisms for problem solving (Jayaratna, 1994). However, their role is not limited to solving problems, they can also be used for other purposes. Werr (1999) has analyzed the role of methods in the work of management consultants, with a focus on BPR-style improvement projects. He identified three major areas in which methods are important.

2.7.1 The project work with the client

Methods can be considered as being a medium for constructing reality, i.e. that the method serves as a tool for describing how reality is perceived. This social construction process is fed by the images of all participants in the project group and the common image of reality derives from the individual contributions.

A second role a method can play is to provide a structure for action. In this case, the method provides guidelines, techniques and tools for supporting the problem analysis and diagnosis, as well as the change implementation process. The level of detail can vary from simple rules for facilitating meetings to a detailed rulebook with elaborate descriptions of each step in the change process, its deliverables and the tools and techniques being required, e.g. for process modelling.

Finally, a method can also be seen as an argumentative structure for justifying and driving a change process. Werr (ibid., p 317) concludes that a method ca provide a "discursive framework for communication", i.e. that the logic of the method

is used for legitimizes the direction and steps of the change process.

2.7.2 Problem solving and knowledge creation

A methodology[13] can be defined as

> a coherent collection of concepts, beliefs, values and principles supported by resources to help problem-solving groups to perceive, generate, assess and carry out, in a non-random way, changes to an information situation. (Jayaratna, 1994)

Consequently, problem formulation, solution design and solution implementation are important parts of methods and problem-solving processes. In order to support this process, a method normally contains a set of tools and techniques for these steps and also for documenting results.

In addition to the purposes mentioned above, methods are also part of the organizational knowledge system. In his study of the use of methods in management consultancies, Werr (1999) has found that methods actually play an important role in these firms' knowledge systems and described the knowledge system in the following way.

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[13] The difference between methodology and method, although existing, can be considered as merely semantic, since both terms are regularly used as synonyms.

Tacit
knowledge

Experience

Provide a language
to articulate

Abstract
knowledge

Apply

Specific
knowledge

Articulate,
make visible

Apply

Specify and exemplify

Methods

Cases

Provide language
to articulate

Articulate
knowledge
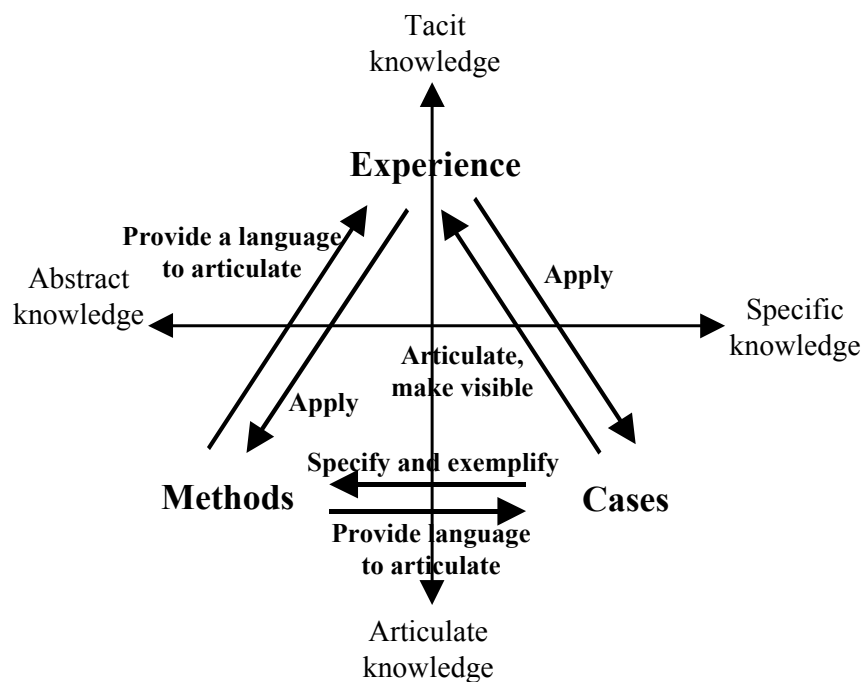
Figure 2-2: Methods as part of the knowledge system (Werr 1999, p 320)

Consequently, methods are an integrated part of the knowledge creation and sharing process of organizations and support the process of extending and transferring individual knowledge through the language they provide, and that is shared among all members of the organization.

2.7.3 BPR methods in consulting firms

In most firms, the need for consultants for complex change initiatives, such as BPR projects is generally accepted. The impact of reengineering as a change concept on companies and consulting practice can be illustrated with the fact, that BPR consulting revenues in 1994 were 3,5 billion US$, with an estimated growth rate of 20% on annual basis. In 1994, 69% of US and 75% of European firms were involved in projects with BPR label, or strong BPR characteristics. Of the remaining firms, 50% intended to embark on reengineering during 1995-1996 and we can conclude, that no other change concept that has

been introduced over the past decades has had a similar adoption and impact on the corporate world.

In 1995, Thomas Davenport, the author of one of the most prominent reengineering books – Process Innovation: Reengineering work through information technology (1993) – published an article in which we addressed a serious criticism towards BPR (Davenport, 1995). He claimed, that most change initiatives under the banner of BPR had been based on misunderstandings of what reengineering was supposed to be. Today, reengineering has become a word non-grata in many organizations. At the same time, the ideas that had been made famous by BPR – customer focus, process orientation, use of information technology – have become standard in corporate change initiatives and consulting methods alike. Most consulting companies have dedicated process practices, focusing on business process analysis and improvement.

Another observation is that the reengineering market, and the objectives of projects being launched under the banner of business process improvement have changed from being cost-reduction oriented, to become initiatives for growth and improved customer relations, service, and product development. The Astra Hässle case being presented in this book, and especially the FASTRAC project, is also a clear example for this development.

Virtually, all international and also national consulting firms being involved in strategy, organizational improvement or information technology offer process improvement services under the name of BPR, or related labels. In addition, many smaller firms have specialized in reengineering, often with a niche focus on specific industries. When considering the major firms worldwide, it can be concluded, that BPR market shares in percent are generally low (under 10%, except Andersen Consulting), which can be derived from the fact that most firms are offering multiple kinds of consulting services, e.g. accounting, tax auditing, strategy development, etc., or have been entering the BPR market relatively late.

Also Astra has been relying heavily on external consultants for its business improvement projects. Specifically, consultants from McKinsey & Company and Andersen Consulting have been involved in the BPR initiatives. In the following, the methodological approaches being used by these firms are briefly introduced and compared.

2.8 McKinsey & Company

McKinsey uses a set of basic guiding principles, or prerequisites, which must be satisfied in order to achieve reengineering success. McKinsey, with its background in strategy, organizational change and rationalization, traditionally has a strong organizational scope, and emphasizes the consideration of variables related to the organizational structure of the client company. The firm has developed its own reengineering flavor, going under the name of "Core Process Redesign". The focus of the McKinsey approach is on primary, customer value adding processes and the necessary changes of organizational variables to establish these processes.

Despite the fact that the Core Process Redesign approach is conceptually de-composed into three phases, McKinsey emphasizes the fact, that these three phases, applied to a reengineering project, cannot be divided. Additionally it is pointed out, that the change process is highly iterative, i.e. that the application of the model, despite its graphical representation as a straightforward process, is not linear. The diagnostic phase is considered as being the key for the identification of performance improvement opportunities and obstacles.

2.8.1 The role of IT

Even though McKinsey recognizes the need for IT analysis in reengineering projects, there is no emphasis on that point, i.e. that IT analysis and design are not considered as main objectives

of a reengineering effort. McKinsey identifies the role of IT during the different phases of the BPR exercise as following.

Diagnosis. During this stage, the fit of the IT architecture and organization with the needs implied by business is assessed. This is achieved through a simultaneous mapping of process and information flows, together with the identification of the architectural and organizational barriers to change.

Redesign. The different process design options are assessed with regard to the technological implications. This includes the consideration of investments required for technology development, implementation and deployment, the possible effects of IT-use on lead times and operational costs and the benefits from eliminating non-value adding work.

Pilot test. When new processes are tested in pilot studies, the performance of the new IT systems is measured according to the capacity required to fulfil the process objectives. This business simulation phase investigates the functioning and co-functioning of the different technological components. Depending on the complexity of the targeted solution and the level of business criticality of technology, this simulation phase can be of high importance.

Generally, McKinsey accepts the fact that IT often accounts for substantial improvements in the areas of cycle time and improved information flow. However, redesigning the IT core architecture must not necessarily be a part of the redesign effort. The replacement of IT with newer systems is no main objective, and not a goal in itself. Much IT value can be realized by improving information flow and access with innovative solutions within the existing infrastructure, keeping the need for IT investments on a moderate level.

Observing the increasing importance of IT for many businesses, McKinsey also reconsidered its service offering. Since 1998 an information technology practice, the Business Technology Office (BTO), has been established as a virtual organization with office locations in various places around the world. In order to extend the firms service offering into the electronic commerce market, McKinsey has also recently

established a practice in this field under the name of @McKinsey.

2.8.2 Reengineering principles

McKinsey uses nine reengineering principles, which are divided into two time related categories. The first category contains prerequisites, i.e. factors to be addressed in advance of embarking on the improvement effort. The second category describes the aspects requiring attention during the project.

2.8.2.1 Before

Senior management readiness. The ability of senior management of being open to organizational change, to understand its implications and possible outcomes, is crucial to the success of any improvement effort, but is also a major enabler of positive performance impact.

Strategy must drive reengineering. Business strategy must be sound, well described and feasible in order to provide a context for core process definitions and to allow the creation of processes being aligned with the business' objectives and performance requirements.

2.8.2.2 During

Cross-functional participation. The process redesign teams must include people from the relevant business functions, i.e. all functions being affected by the initiative. As part of the choice of team-members it must also considered that they are serving as members of the project team, not as stakeholders of the existing business functions.

Focus on performance metrics. The selection and application of relevant performance metrics is critical to achieving success in high impact areas. Performance metrics must also fit the business objectives and it must be considered that metrics in a process-based organization are substantially different from those being used in a functional structure.

Analytical depth. In order to create a balance between breath and depth of the analysis, the aspects of detail richness

and holistic perspective must be considered. This includes emphasizing both the need to adopt an end-to-end process view, and the need for a quick identification of leverage points.

Solid diagnostic. Of the two basic reengineering approaches, either starting with process design from a clean slate, or departing from the current processes, McKinsey proposes the latter one. A careful process diagnosis is advocated in order to create a redesign based on facts, which is considered more powerful than if current processes were disregarded, since improvement potentials and performance gaps might remain undetected.

Performance impact. While a reengineering project as a whole is aiming at long-term improvements, it is essential that substantial benefits can be reaped already during the initial 6-12 months, in order to create positive examples and sustain a climate of success in the organization.

Creativity. The ideas generated in the initial phase must be taken into account without constraints, i.e. that nothing is principally disregarded, while the feasibility is tested during a later stage. This approach, similar to the idea collection phase in brainstorming sessions, prevents innovative ideas from being lost or abandoned.

Accountability. The overall performance of a process must be referenced to a single point, i.e. that factors influencing process performance must be identifiable and measurable.

2.8.3 The reengineering approach

A reengineering effort guided by McKinsey typically involves three broad phases with different time frames – diagnostic, redesign, and implementation, each of them consisting of a number of partial steps and activities.
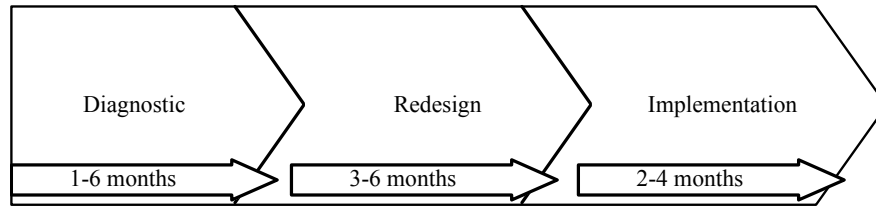
Figure 2-3: McKinsey's reengineering phases

2.8.3.1 Diagnostic - Steps

Definition of core process scope. The initial step is to identify the organization's core processes - the processes being most important to the implementation of business strategy and with the highest value delivery. The scope refers to their organizational span, i.e. their range across business functions.

Quantification of performance gaps. Performance gaps, i.e. the difference between targeted and current performance need to be identified in a way that makes them quantifiable and measurable during the diagnosis phase.

Diagnosis of existing processes. The existing processes need to be scrutinized and the previously identified performance gaps diagnosed. The underlying causes are identifiedj by analyzing the activities being part of the process in terms of speed, quality and cost. Additionally, the relations and interdependencies between activities are analyzed in order to identify wait-states and insufficient coordination and communication.

2.8.3.2 Diagnostic - Activities

Develop value driver understanding. Certain drivers create business value, and these factors must be understood in order to identify and assess the value creating potential of organizational processes. Value drivers are those activities that make a process' output more valuable than its input.

Define 3-5 core processes. For each organization, it should be possible to identify a limited set or core processes, i.e. processes where the primary value stream takes place and that have the highest contribution to business objective achievement.

Identify core processes with maximum performance impact. In order to achieve substantial improvements fast, the core processes with the highest impact on organizational performance are selected and targeted as the initial objects. This does, however, not mean that the remaining processes can be neglected. The argument for selecting a sub-set of processes first follows the Pareto-principle, i.e. that a small number of processes account for the largest share of potential improvement.

Identify process activities. Each process can be broken down into a number of activities. This de-composition process is iteratively continued until the level of desired remaining complexity has been reached, i.e. that the process is broken down into nearly de-composable sub-systems.

Set performance goals. For each of the selected processes, a set of performance goals is developed. These goals are set upon the basis of an ideal process design and are used in order to identify the magnitude of the identified performance gaps.

Measure current performance and identify performance gaps. For each of the processes chosen for investigation, the relevant performance variables are measured and related to the identified performance goals. The magnitude of performance gaps, i.e. the difference between desired and actual performance, is identified in the primary dimensions time, quality and cost.

Identify sources of pathologies. While performance gaps are symptoms of pathologies, the underlying sources need to be revealed. For this identification process, it is necessary to look beyond the boundaries of a specific process, since possible causes might be found in interdependencies with other processes.

Determine causes. The process of determining the causes of pathologies includes the verification of possible causes that have been identified in the previous activity. It also means to divide direct and indirect causes and to track symptoms over multiple steps to the original generator.

2.8.3.3 Redesign - Steps

Definition of redesign vision. The redesign phase starts with an overall description of the future objectives of the organization and the business processes existing within it. It also describes the new business process at an overall level and their primary sub-processes and interconnections.

Redesign of processes in detail. In this phase, a detailed map of the processes' future design is developed, including all sub-processes, relations between activities being part of the processes, interrelations, process-teams, etc. The level of detail can vary significantly and is mainly depending from the desired complexity to remain and the amount of local decision making and design that is considered feasible.

Pilot test of new processes. The new process design needs to be tested in order to verify the process logic. The test also includes the assessment of the resource allocation and the process' interconnections with other processes.

2.8.3.4 Redesign - Activities

Develop clean slate process design. The design of the new process is following the clean-slate approach. Following this rationale means to develop a new process without taking departure from the existing one and to rearrange it. However, it does not mean to disregard the results of the analysis of the existing process. Learning from analysis during new process design means to consider the shortcomings of the existing process that have been identified.

Identify IT and organizational implications for new processes. A new process design will possibly new opportunities and needs with regard to IT-use and the organization being required for establishing the process. These implications need to be identified and described in order inform the change specification activity.

Generate redesign initiatives. Process redesign activities need to be initiated from within the organization by gathering together people who bring their specific competencies and capabilities into the design process. It is crucial, that the design

activity is initiated and conducted within the company, and not done by outsiders.

Specify changes required in practices, organizational structure and information systems. Based on the process design scheme and the identified organizational and technological implications, the actual changes in work practices, organizational structures and technological systems are outlined. This process also includes cost estimations for the necessary changes that are balanced against the targeted benefits from the new process.

Design process pilots and system prototype (if necessary), test pilots in an iterative way. The new processes are developed as pilots, together with the technological support systems. Within a "process laboratory", the new process are tested and tuned iteratively.

2.8.3.5 Implementation - Steps

Define implementation plan. The implementation plan consists of a road-map for the process implementation and roll-out. It contains descriptions of the implementation time-frame, resources, migration activities, training, and other related activities.

Roll out initiatives throughout the organization. In the same way as process design, the roll-out of new processes must be driven internally. In many cases, the process design teams also take on responsibility for implementation.

2.8.3.6 Implementation - Activities

Identify required phasing, resource assignment and performance objectives. The initial activity of the implementation phase contains the development of a master-plan for the new process introduction. In order to avoid inter-locks and mutual dependencies, it becomes necessary to develop a phasing model. Also, the resources being required for the implementation must be defined and assigned.

Designate change management leadership. Change management can be facilitated, but not driven by external consultants. Consequently, selecting people that are determined

and dedicated to the change effort is important to manage the actual change process. At the same time, change managers need a sound understanding of the organization and business in order to foresee and overcome barriers to change.

Develop actual organizational change management program. The change management program is the detailed description of how the new processes, and the related organization and technology are to be introduced. A change management program includes time-plans, training programs, workshops, etc., but also resource allocations, feedback mechanisms and adverse events handling. Another important aspect is the migration plan, describing how changes can be introduced without disrupting ongoing operations.

Launch initiatives. In order to sustain momentum, process implementations are normally conducted in parallel, i.e. that multiple processes are introduced simultaneously. To launch several implementation initiatives at the same time therefore requires high-level project management capabilities.

Manage to explicit performance objectives. Although the new process designs have been tested and tuned as pilots in a lab-environment, the "real" processes need to be adjusted in order to ensure performance according to the defined objectives. This fine-tuning process is the final stage of implementation and has no clearly defined end. From here, process management and improvement is carried forward into a continuous improvement phase.

2.8.4 Final considerations

Typical McKinsey guided process improvement efforts have a strong focus on organizational issues, such as the reduction of levels in the structural organization, the re-organization of units and departments, and the development of organizational strategies. When considering the objective, approach, and scope used during reengineering efforts, the following picture emerges.

Objective	Approach	Scope
Reengineering is a targeted effort to gain substantial improvements in business unit performance...	by reconfiguring activities and information flows...	that are sufficiently broad to comprise core processes.
• One time effort • Major bottom-line impact • Breakthrough performance goals • Simultaneous improvements • Phased impact (short/long term)	• Concurrent information and activity flow redesign • Focus on high leverage areas • Driven by fact base • Iterative design	• One of 3-5 activity/information flows required to deliver value • Cuts across organizational boundaries • Holistic process view

2.9   Andersen Consulting

Disregarding companies that offer both consulting and accounting services, Andersen Consulting[14] is the world's largest consulting firm. The company offers a collection of integrated services, comprising strategy consulting, change and process management, and technology development. This integrated concept, named "Business Integration", has made AC to one of the major players on the reengineering market. The integration of IT services is also the main reason for many companies to choose Andersen Consulting for supporting their process improvement initiatives.

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[14] Since January 2001, Andersen Consulting has changed its name to Accenture. Since this study was performed prior to the change of name, the old name has been used.
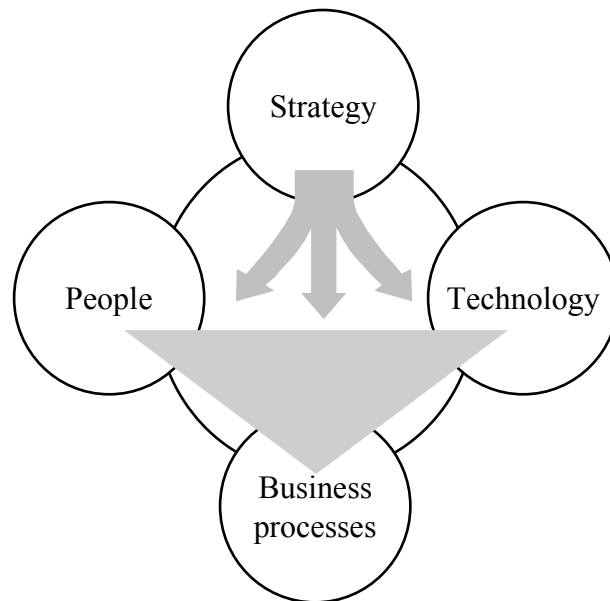
Figure 2-4: Andersen Consulting Business Integration

2.9.1 Reengineering principles

Andersen Consulting uses six basic principles for their engagements with clients.

Flexibility. Given the complexity of problem situations that clients have to face, it is necessary to offer a wide range of integrated services. Together with the client, the necessary selections can be made in order to ensure that the right services are delivered.

Joint teaming. Change can be facilitated, but not delivered, by consultants. Effective projects require joint teams and working closely with clients creates full-service partnerships and ensures long-term results and client relations.

Work toward strategic objectives. Any improvement project must depart from the strategic objectives of the client company. The service offering from Andersen consulting should include all client needs, from strategy formulation, change management, IT solutions, and full-scale system implementation.

Knowledge management and transfer. Knowledge must be transferred into the client organization and must be

maintained and developed. Project success is depending from fast delivery and a knowledge leverage process.

Willingness to assume an implementation and/or an advisory role. Andersen Consulting can take on multiple roles in a project, including pure advisory, but also development and implementation of solutions. In addition, Andersen Consulting also offers outsourcing services on the IT-side.

Delivering value. Results of change must be linked to client success, defined by measurable outcomes, such as increased profitability, shareholder value, ROI, and cost savings.

2.9.2 The role of IT

Andersen Consulting has a strong focus on IT issues, considering its own capabilities in this field as a competitive advantage for clients, as well as AC itself. Systems development, implementation and sourcing services are an integrated part of the Business Integration concept. In its process improvement projects, information technology is considered as an enabler and also driver of change and is considered as one out of four main target areas within the Business Integration approach. Technology is considered as being vital in the following areas:

Communication across organizational boundaries. Taking a process view includes a re-consideration of the communication and interaction structures within the organization and between the organization and its external partners, such as customers and suppliers. Information Technology can significantly contribute to make these communications more efficient.

Information sharing. Work consists of the execution of tasks and activities according to a plan and workflow, but includes also the instant and ad-hoc sharing of information. Information technology can enable and support both forms of work and interaction.

Support new ways of doing business. IT can provide significant improvements in operational performance, but technology can also facilitate new ways of doing business, e.g. by

short-circuiting supply chains and industry value systems, and it can allow companies to re-consider their business scope.

Elimination of clerical effort. On an operational level, technological solutions can reduce manual work by creating electronic workflows and automating clerical routine tasks.

Support for knowledge workers. When work becomes increasingly knowledge oriented and knowledge provisioning and management becomes more important than the physical flow of goods, information technology plays an important role for supporting knowledge workers by delivering information timely and accurately, but also by facilitating communities and networking.

2.9.3 The reengineering approach

Andersen Consulting's reengineering methodology, termed "Value-driven reengineering", consists of five sequential stages and support process for team management, change management and the development and introduction of a client specific adaptation of the overall Business Integration framework.

| Shared vision | Assess /Align | Master plan | Design, Pilot, Implement. | Operate |

Team management, Framework, Program management
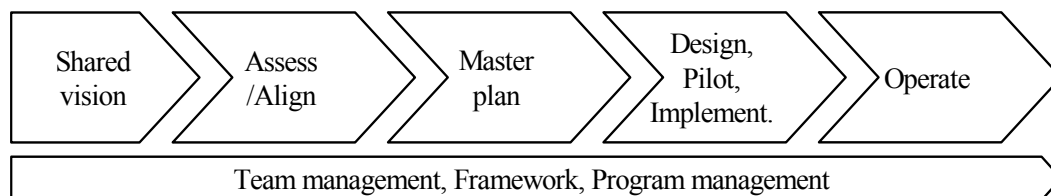
Figure 2-5: Andersen Consulting reengineering approach

2.9.3.1 Shared vision

The initial set-up phase is concerned with identifying and defining the scope of the initiative, based on a value assessment and the positioning of the company. This part is normally conducted by executive management, together with major stakeholders.

Define stakeholder value. Any improvement effort must provide value for the organization's stakeholders in some way. In

most cases, shareholder value if highly prioritized, but it is often achieved indirectly, by increasing value for other stakeholders, such as customers.

Define core competencies. The identification of core competencies is an important measure to assess the current and possible future positioning of the company. The identification process includes competencies within the own organization, but also those of competitors that have an impact on the competitive position.

Develop shared vision. The future vision must be shared broadly among the company's stakeholders in order to create initial momentum and prepare for the necessary commitment in the organization.

Determine strategies and priorities. Based on the future vision, strategies are developed in the areas business, organization/processes, technology and people. Within the areas, the most important improvement areas are targeted.

Develop operational vision. Based on the overall vision and strategic priorities, an operational vision is developed, describing how the new organization is supposed to work.

2.9.3.2 Assess and align

Create next level process models. The results of the initial phase are used as input for developing new process models, supporting organizational structures and sketches for IT solutions. The future process models are conceptually describing the future state of operations and structures, but defined by using a process approach and terminology.

Benchmark current operations against vision. The new process models are now benchmarked against current operations with regard to performance in terms of time, cost, quality and service level. For this purpose, the models are run through a first business simulation, allowing an evaluation of their potential and limitations.

Analyze gaps. Gaps are defined in terms of performance differences between current and future operations, as identified in the previous benchmarking process. The identified

shortcomings, which are symptoms, are then analyzed in order to detect underlying causes.

Assess barriers to change. Factors that can hamper organizational and technical change and development can be found in multiple areas. Strategic mis-positionings, lack of competencies, threatened power bases, etc. Most of the barriers are related to people aspects.

Identify quick hit initiatives. In order to show results fast, a number of limited and targeted initiatives is defined that can be executed in a short-term perspective and with limited resources, but still can provide significant improvements within their scope.

Define major program initiatives. The remaining areas are grouped into a number of major initiatives. Each of these initiatives has a specific scope, based on the major business processes that have been identified.

Project benefits and costs. In order to justify a project, it becomes necessary to run a sound and realistic cost/benefit analysis. The factors to be included are direct costs and benefits and alternative costs, i.e. the cost for not choosing a specific solution.

2.9.3.3 Master plan

Profile current operations. Within the profiling phase, the current operations are considered with regard to their necessity and their value contribution. Non value-adding activities and multiple instances of the same activity can be removed, similar areas can be grouped and functionally streamlined.

Create top-down solutions. Depending on the overall objectives that have been defined for the future operations, processes are designed in a top-down way, from a macro-level to a detailed map of activities.

Build bottom-up solutions. A reverse design process, building on the integration of individual activities bottom-up is conducted in parallel to the top-down design phase.

Synthesize solutions. The top-down and bottom-up design phases have resulted in two sets of process descriptions with different perspectives that must be taken into account. The synthesis brings together both approaches into one consistent image of the future process design.

Create master plan. The master plan contains a detailed outline of the change program initiatives for each area. It synthesizes, synchronizes and coordinates the individual plans within each program area.

2.9.3.4 Design, pilot and implement

At this time, the overall initiative is split up into sub-areas, each of them targeting a specific area of improvement. Regularly, the division is made upon major business processes. A change management team, being responsible for design, pilot implementation and roll-out, is assigned to each program area.

Design. The change team designs a local plan for organizational and, if necessary, technical development in compliance with the master plan. These plans include time-schedules for migration, training and education programs and a definition of working procedures .

Pilot implementation. Within the different areas, the new processes are introduced as pilots and evaluated in a real-world environment. Where necessary, adjustments are made at process level if the overall process structure integrity is not compromised. Otherwise, the required adjustments are referred back to the overall integration team. The same procedure is, if applicable, performed for IT-systems.

Roll-out. The finally approved process is introduced in full scale and the migration from current to future work procedures is initiated. At the same time, the finalized version of the technological support systems is implemented and put into production.

2.9.3.5 Operate

Balance sheet. An opening balance sheet is set up for the new operational processes as a starting point for ongoing

evaluation. At this stage, the new processes are brought into continuous improvement phase.

   Scorecard. Scorecard based models for measuring internal and external performance have proven to be powerful instruments for operating and improving processes. Scorecards are introduced at different levels, for individual processes and activities for managing individual processes, and aggregated in order to provide an overall image.

2.10 Common aspects and differences

Generally, BPR approaches here have relatively few differences on the conceptual level. This holds true for those described above, but also for those being in use in other companies.[15] They all contain the phases Initiation, Analysis, Design, Implementation and Deployment, but each firm adds specific elements to the general concept. The specific characteristics of the approaches being used by Andersen Consulting and McKinsey can be summarized as follows:

   The reengineering effort is a highly iterative process between the diagnostic and design phases, i.e. that diagnosis and design are not performed as one-time sequential activities, but as an on-going loop where the two elements are informing each other.

   McKinsey uses pilot approach, where the new processes are tested in a laboratory environment before full implementation. This business simulation is used for verifying the process prototype against the defined performance objectives. If the new process design involves the deployment of technological solutions, these are included into the business simulation in order to ensure functional fit and usability.

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[15] Besides the approaches used by McKinsey & Company and Andersen Consulting (now Accenture) that are described above, those being used by Bain & Company and The Boston Consulting Group have been investigated.

Andersen Consulting has a strong emphasis on technology from the diagnostic phase, i.e. that the current IT-infrastructure and the applications in use are analyzed concurrently to the business processes. The new process implementation is, where necessary, complemented with the introduction of a new technological solution.

Also, the methods and tools being used within the different methodological stages are basically identical and are based on the theoretical bedrock of the reengineering concept, as it has been described in the early articles and textbooks. They share the striving for order-of-magnitude improvements, the focus on business processes and their value adding capability, the aspect of cross-functionality and the enabling role of information technology.

In the strategy area, McKinsey has a very solid base and is widely recognized as a leading consulting firm in this field. Andersen Consulting, on the other hand, has a very strong practice in the IT-field, including not only advisory on the strategic level, but also systems development and implementation.

The main differences can be derived from the consulting companies' traditions and core competencies. McKinsey, with its roots in organization and strategy consulting, has a stricter focus on the strategic foundation of the reengineering effort, whereas Andersen Consulting, with its background and strong competence in the IT-field, seems to highlight the impact and enabling capabilities of technology. The recent efforts of the strategy firms to develop their IT-practices has increased their capabilities in this field, but of the two companies investigated here, only Andersen Consulting provides full-range IT-services.

Both firms recognize information technology as a key enabler for organizational change, but have different levels of involvement and participation when IT issues are addressed and solved. These differences can be derived from the different backgrounds of the consulting firms. More recently however, this traditional image has also begun to change industry-wide. Many of the traditional strategy-consulting firms have established

practices in the IT-field, mainly e-commerce, but also covering Enterprise Resource Planning, Customer Relationship Planning and others. McKinsey & Co. Has established its @McKinsey e-commerce practice and the Business technology Office and BCG has started a prototyping lab for WWW-site development in the e-commerce field. Andersen Consulting, with its traditionally strong proficiency in the IT-field, on the other hand, has attempted to strengthen its profile in the strategy field.

An important aspect to note is that all approaches contain the design of new processes as a step, but that no concrete guidelines are offered with respect to the level of detail to be chosen, despite the fact that this issue is crucial to the acceptance and usability of the design. Naturally, there is no given level of specification that fits all organizations - the design of the loan management process in bank is substantially different from a process designed for pharmaceutical R&D - but the absence of any guidelines involves the risk of being too general or over-detailing a process design. A very general design leaves room for adaptation of work procedures and technology use on a local process level, which might compromise the overall performance of the process and result in negative consequences in sub-sequent sub-processes. A very detailed process, on the other hand, can limit individuals' creativity and result in strictly controlled processes that can not be easily adapted to specific demands, or it results in organizational work-arounds.

3. Reengineering à la Astra Hässle

The research documented in this case study was conducted mainly prior to the merger of Astra and Zeneca. After the merger, the situation changed significantly. However, in order to give the reader an impression of the company during the research period, the following description refers to year 1995.

AstraZeneca R&D in Mölndal is a research site within the AstraZeneca group. Prior to the mergers of Swedish Astra group and British Zeneca, the organization was, under the name of Astra Hässle, a research company within Astra. The research focus of AstraZeneca Mölndal lies on the development of pharmaceuticals for cardiovascular and gastro-intestinal diseases.

Before the AstraZeneca merger, when having its own company status, Astra Hässle employed about 1.400 people at three locations: Mölndal and Umeå in Sweden, and Boston (MA) in the United States. The company had a line/staff organizational structure, consisting of four operational and four staff units. This organizational structure, as depicted in the following picture, derived from a major restructuring project in 1994.
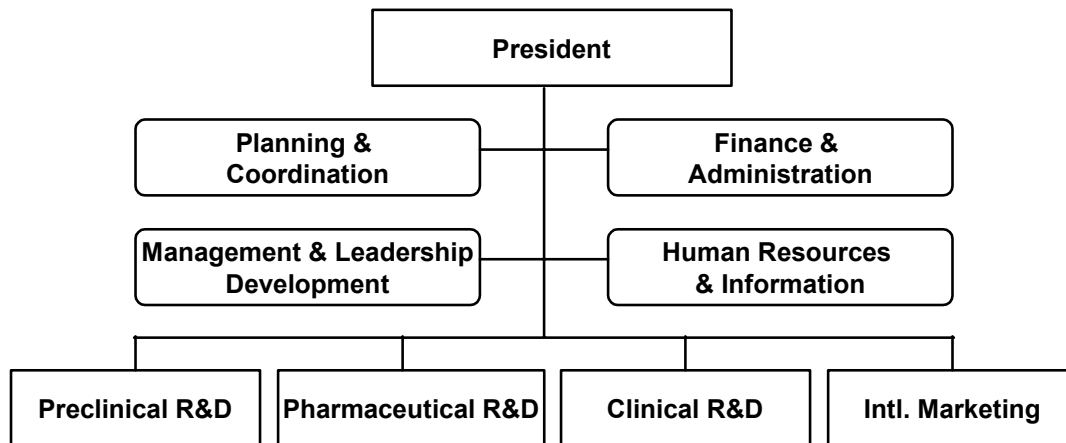
Figure 3-1: Astra Hässle's organizational structure 1994

While the organizational chart provides the image of a clear and simple hierarchical structure, the real picture is more complex than that. Astra Hässle appeared to be a line/project matrix-organization, where product development is conducted in project groups, staffed with members from functional areas. Consequently, the organization also showed the typical characteristics of this organizational form, including both advantages and deficiencies.

- Specialized staff could be shared between different projects and contribute to both, but time-sharing also constitutes a risk for goal conflicts and sub-optimization.

- The matrix-form enables greater organizational flexibility, but this criterion is not totally relevant for multi-year R&D initiatives that follow a pre-defined plan.

- Technical excellence and knowledge improvement was achieved by bringing together people with varying skills and competencies in clinical R&D projects. Individuals considered the participation in clinical R&D projects as an opportunity for personal development and knowledge gaining.

- Once the projects were initiated, the need for close supervision by top-management was reduced since

project management was delegated to dedicated project managers.

- Individuals showed a high level of commitment to "their" project and took pride in participating in the development and testing of new products.

- Project approval included the allocation of a budget, but project managers had to negotiate with line managers for people to staff their projects and the terms of participation.

The organization also contained elements of local, unofficial initiatives, ad-hoc teams solving self-assigned tasks and elaborate network structures. These network structures are neither official nor formalized and do not appear on the organization chart, but at the same time they provide structures and communication channels besides the official ones. It was also admitted, that there are individuals that do not formal high-level positions, but still possess a considerable influence over strategic R&D decisions. While the importance of these informal channels and their impact on organizational processes was recognized, they were not included into the list of issues to be addressed in the coming process improvement initiative. There were no official reasons given, but two explanations are possible:

- It is not possible to formalize these informal structures and relations to make them fit into a designed business process.

- The organization, with its history of entrepreneurial behavior and short and informal ways of communicating and taking decisions would not easily accept the formalization process and its result.

3.1 Product development in the pharmaceutical industry

The conduct of clinical trials, used for investigating the effect of a drug on humans, is the final stage in the product development process. The development process as a whole consists of three sequential sub-processes. Traditionally, the three phases within the clinical trial period have also been conducted in sequence, and a major aim of the change initiatives was to parallel the planning, conduct and analysis of multiple trials within the same study.

Pre-clinical studies			Clinical trials				
Synthesis and screen — Docum. of CD	IND*	Phase I	Phase II	Phase III	NDA*	Phase IV
Search for Candidate Drug (CD)	Approval by authorities	Effect study 50-200 indiv.	Patient studies 100-1.000 indiv.	Comaparative studies 500-5.000 ind.	Application investigation by authorities	Further comparative studies
Choice of CD						Registration, introduction
2-4 years	2-6 months		3-6 years		1-3 years	

* IND: Investigational New Drug
 NDA: New Drug Application

Figure 3-2: The drug development process

During chemical synthesis, different chemical substances are synthesized with regard to their usability as components in drugs. The biological testing and evaluation results in a number of substances possibly usable as drug components. These "candidate drugs" are further investigated through scientific and patent literature studies. For prospective candidate drugs, a patent application is submitted. The patent protection for a new drug begins after patent protection has been approved. All further activities are reducing the patent protection time, thus reducing the R&D return-on-investment (ROI).

The pharmaceutical research process investigates various delivery mechanisms for candidate drugs (pill, injection, aerosol, etc.). The delivery mechanism promising the most effective

absorption of the drug in the human body is developed and tested.

Clinical trials comprise a series of steps, where a new drug is tested on different patient groups. The purpose of these studies is to find the optimum dose, detect side effects, and evaluate the drugs treating effect. These investigations are conducted at different clinics in various countries. The results of the clinical trial phase, extensively documented and analyzed, are the basis for the application for approval to the respective authorities in different countries. The compilation and content of the New Drug Application (NDA) is crucial for the regulatory authority's approval process, since the decision is taken on the basis of the documentation provided together with the NDA. After approval, the product is handed over to a production unit within the Astra group, and marketed by local market organizations in various countries. In addition, further comparative studies are conducted and the use and results of the drug are monitored for control and further improvement.

3.2   BPR comes to Astra Hässle

In 1997 the Astra group achieved a total sales volume of 44,9 billion Swedish kroner (SEK). For 1998 a 27% increase was accounted, raising total to 57,2 billion SEK. Products originating from Astra Hässle accounted for more than 80% of total Astra group sales. The Astra group's main product, Omeprazole (Losec©), which also was originally developed by Hässle, accounted for about half of the group's sales, including licensed products, thus making it the best selling drug world-wide.

Possessing a blockbuster product provides a certain amount of financial stability during the patent protection time. On the other hand, the dependency from a single product also constitutes risks:

- Sales and profits can decrease significantly when generic products enter the market after the end of the patent

protection time. In the case of products with a high revenue share, the overall impact can be considerable.

- The increasing demand for shareholder value, i.e. higher profits and stock prices, cannot be satisfied.

- Necessary changes in the organization can be postponed as a result of unawareness and the absence of a sense of urgency.

The core competencies of Astra Hässle have traditionally developed and sustained in four areas–medicine, biology, pharmacology and chemistry–with a focus on technical knowledge within these disciplines. Today, these four core areas spread over a wide variety of sub-disciplines, and new competencies have been added as a result of technical development, extended research, documentation requirements and trends in society. Especially the use of information technology has begun to play a major role in pharmaceutical research, used for communication of research results, data collection and analysis of data in clinical trials, and cooperation and coordination purposes within and between research groups. The employment of IT is also industry-wide considered as a major enabling factor for successfully elevating performance, finding new indications and more efficient ways of conducting clinical trials, thus reducing the time and resources required for testing new drugs and contributing to an increased return-on-investment and shareholder value.

In order to sustain their competitive position, virtually all pharmaceuticals companies have embarked on large-scale improvement projects. Also Astra Hässle, as a research company in the Swedish Astra group, has found itself in the position of needing to elevate its organizational processes and to find new ways of employing information technology. The company has a strong R&D record, the products developed at Astra Hässle include blockbuster substances Selocen and Omeprazole, the latter one being the world's best selling drug since 1996.

However, there was an increasing awareness within the organization that sustaining this position would require considerable investments in organizational improvement and consequently, several improvement initiatives with varying scope and scale were initiated and conducted since the early 1990s.

After several limited structural modifications, aiming at achieving local improvement within different functional areas, a large-scale re-organization took place in 1994, resulting in the new organizational infrastructure with its four operational and four staff areas. The new structure succeeded in delivering some operational improvement and a more efficient functional organization, but was considered as inappropriate for achieving the radical improvements the company was aiming at. Management became increasingly aware that a general overhaul of the company's business processes would be required in order to meet the goals being set in terms of cycle-time reduction, quality improvement and cost reduction. Consequently, a large-scale reengineering-style project was initiated in 1995 under the name of FASTRAC - Fastest and Smartest to Registration and Commercialization.

The project was also considered as a major leap forward to achieve the strategic goals of the company that are to be realized by the year 2000. They comprise three new, original drugs, a total of 20 new registration applications, the establishment of a new research area and the establishment of a research unit outside Sweden. Accordingly, the new research area, biochemistry, has been established and a research facility in Boston has been opened. However, the ambitious goal for product development and registration could not be achieved with the organizational and technical infrastructure in place and the FASTRAC project was seen as the most important effort to bring the company forward in its striving for improved efficiency and effectiveness in clinical R&D.

The re-organization of Astra Hässle in general, and the clinical R&D unit in particular, did not only provide some operational improvement. Partially, it also had the purpose of preparing the organization for a general overhaul of the clinical

R&D process. Consequently, in the spring of 1995, a steering group, consisting of the department managers within the clinical R&D unit, was formed to prepare and set up a re-engineering project for clinical R&D. The project was named FASTRAC - Fastest And Smartest To Registration And Commercialization.

3.3 The FASTRAC rationale - forecast or crisis?

Davenport and Short (1990) have identified two basic methods for process identification, which they termed "targeted" and "comprehensive" methods. Targeted methods take their starting point in the identification of a relatively small number of processes being critical to the business, which are determined by interviews or discussion with managers of the organization. This approach can provide a fast pay-off and results often occur relatively fast.

In opposite, the comprehensive approach is striving for first identifying all business processes, and then prioritizing them according to their reengineering-need and potential. This method is more time and effort consuming, but allows a more well thought out rationale for BPR in terms of project prioritization that fits into the overall strategic goals of the organization. (Grover & Kettinger, 1995)

There are no general recommendations for organizations, willing to embark on reengineering projects, which approach may be the more feasible. This choice generally depends on the specific firms or institutions situation. We can identify two main reasons for initiating BPR efforts, either the firm is in a critical situation and needs rapid improvements in order to ensure survival, or the reengineering effort is started from a position of strength, and strives for sustaining leadership, rather than regaining competitiveness. Given these two extremes, a firm can choose different options, each of them with different attributes.

	"Crisis" reengineering	"Forecast" reengineering
Time scope	Short	Medium

	"Crisis" reengineering	"Forecast" reengineering
Primary method	Targeted	Comprehensive
# of processes	Small	High
Primary aspects	Cost, time	Strategy
Tools	Financial, time-based	Full range
Role of IT	Cost efficiency	Strategic impact

Table 3: Generic reengineering approaches

Looking at the situation in the pharmaceutical industry in 1995, the FASTRAC project was clearly a response to the initiatives that already had been initiated in other companies. Several of these were regarded as successful BPR-style projects and the Astra Hässle senior management reasoned that, despite the current success of the company, preparations had to be made for the future. Also the fact that several patents for the Hässle blockbuster drug Losec would run out in the first years of the next decade was a contributing factor.

Consequently, the FASTRAC initiative can be seen as a forecast re-engineering project, released through a senior management decision to sustain competitiveness and ensure future success. However, when looking at the characteristics of FASTRAC, it had characteristics from both categories, forecast and crisis re-engineering.

Time scope. A 2-year scope was targeted for the project. This does not indicate a crisis, but a purposeful attempt to address the future.

Method. The methodological approach followed the re-engineering "rulebook" in the sense that and all steps of a typical re-engineering project were included. The involvement of consultants for methodological support also suggests a forecast focus, rather than a crisis or quick-fix initiative.

Number of processes. The FASTRAC project was primarily aiming at the improvement of one process – Clinical R&D. Even though the overall process involves a number of sub-processes that were part of the initiative – Drug acquisition, Clinical trials, Market Support and Safety - the limited number

of processes to be scrutinized and the limitation of the project to one unit within the organization suggests a crisis reengineering approach.

Primary aspects. The FASTRAC project had time compression in the clinical R&D process as its primary goal. Even though cost savings were considered achievable indirectly, i.e. as an effect of increased time efficiency, it was not a primary aim. Also headcount reduction, a frequent measure in re-engineering projects, was not part of the FASTRAC goals. This limited number of addressed improvement aspects also would let the project fall into the crisis category. On the other hand, the inclusion of operating values, i.e. cultural aspects, also shows that FASTRAC had a long-term ambition in establishing a value system beyond the primary aim of performance improvement.

Tools. The tool-set comprised time-oriented analysis tools and modeling approaches, but the limited experience of the project participants also resulted in some experimentation. In general, however, there was no clear strategy for the use of tools or methods for data collection, analysis and documentation and the tool set being practically used was a mixture of different approaches, partially developed or known within the company, partially brought in by the consultants. A clear categorization of these tools in accordance with the forecast/crisis criteria is not possible.

Role of IT. The forecast/crisis categorization suggests that forecast initiatives should have a strategic focus on the role of IT, whereas crisis projects would focus on cost and time efficiency. In the FASTRAC case, both propositions hold true. The focus of the applications being developed, e.g. for Remote Data Capture, had a clear intention to cut time in the clinical R&D process. On the other hand, the outcome of the initiative was expected to have a strategic impact on the company through its potential impact to significantly reduce time-to-market.

The fact that the rationale governing the decision for initializing FASTRAC contains characteristics that provide arguments for labeling FASTRAC a crisis, as well as a forecast project suggests, that there is no simple way of defining clear-cut

categories for improvement initiatives. Also the CANDELA project, the corporate-wide process improvement initiative within Astra, has a similar dual nature and can not be clearly sorted into either category.

3.4 FASTRAC description

In order to find a goal and purpose for the FASTRAC initiative to strive for, the project steering group started its work with identifying a vision for the clinical R&D organization:

> **Vision:** To be considered as the leading company in clinical research and the development of innovative therapies.

The vision was accompanies by two mission statements with the purpose of making the vision more concrete and touchable.

> **Mission statement 1:** To create knowledge in the clinical area for the development, adequate use, and support for commercialization of our products during their entire life cycle.

> **Mission statement 2:** To create medical and methodological knowledge to achieve our primary mission and to actively contribute to Astra Hässle's strategy.

Looking at these statements we can conclude that they are relevant and valid, but hardly revolutionary. Similar statements can be found in virtually all companies and leadership, best practice and innovation are frequently occurring terms in corporate visions and missions.[16] However, for the members of

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[16] **Novartis:** Novartis is a global leader in the life sciences, committed to improving health and well-being through innovative products and services. **Glaxo Wellcome:** Glaxo Wellcome is a research-based company whose people are committed to fighting disease by bringing innovative medicines

the clinical R&D department it was an important experience to be able to define the statements and to implement them. They were also considered as being a valuable common point of reference for the FASTRAC project. During an internal meeting of the project team it was obvious, that many participants considered the vision as a source of inspiration for their contribution to the project.

The common mission statement, being valid for the whole unit, was also seen as a first and important step to create a common identity, or esprit de corps, as Henri Fayol called it in the beginning of the last century. Given the fact that the FASTRAC-initiative was sanctioned, but not actively driven by Astra Hässle's senior management, the unit's vision also served as a form of replacement for management participation and functioned as an icon for the project. The important role of the vision statement became obvious during several meetings, which were opened with a reference to the vision.

The lack of active participation from senior management can be interpreted as being contrary to the requirement of top-management sponsorship, as required for successful change in the organization. On the other hand, the CEO and other executives kept themselves frequently updated about the initiative's progress and also supported the project team when problems occurred, e.g. by supplying the necessary financial resources for increasing the share of time being dedicated to the project by key personnel.

This observation points at a dilemma that senior management in organizations undergoing major change initiatives seems to face, namely the necessary level of support and participation in the project. Through commitment and participation, management can contribute to the success of a project when it demonstrates the importance of the initiative and provides legitimacy to the change team. On the other hand, management cannot take an active role without the risk of

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and services to patients throughout the world and to the healthcare providers who serve them.

hampering the creativity and performance of the change team and the feasible range of involvement is therefore limited.

The FASTRAC project was inspired by successful BPR-style projects in other pharmaceutical companies. Several of these had managed to reduce time-to-market significantly by introducing new business processes and organizational and technical infrastructures for supporting R&D.

Early adopters of process oriented change methodologies in the industry had actually demonstrated that cycle-time reductions of 30-50% within research & development could be achieved without compromising quality and safety, but with substantial cost savings. Glaxo Wellcome, a company that Astra considered as a main competitor in several of its therapy areas, had already initiated a similar initiative and many other companies were in the preparation or starting phase of re-engineering projects.

The FASTRAC project took off by identifying three major processes to be scrutinized: Drug acquisition, clinical trials and Market support & Safety. Of these, the clinical trial process attracted most attention, since it was considered to be the most resource consuming, but also the one that contained the highest improvement potential due to its major impact on overall R&D cycle time.

The objective and strategic intent of the initiative was clearly defined: Reduction of cycle time from Investigational New Drug to New Drug Application by at least 50%, from an average of +8 to 4 years. The targeted improvement was met with ambivalent feelings in the clinical unit. Some people expressed their skepticism, mainly stemming from the belief that the current process could not be so inefficient, that a 50% time reduction was a realistic target. Others, following the arguments in the BPR literature and the propositions of most methodological approaches believed that the objective should be set at an even more ambitious level. Finally, however, the 50% target was generally accepted.

Since drug development is not only a lengthy, but also considerably expensive process with an average cost of $ 60-250

million, or even more, in the clinical phase, also financial aspects played an important role and the project team considered the achievable benefits of cutting time and cost in clinical trials as significant and important for sustained and improved competitive advantage. Despite the consideration of cost aspects, however, time compression was the dominant objective and cost savings were expected to be realized indirectly.

It is also interesting to note that personnel reduction, often being an important element of BPR initiatives, never appeared on the FASTRAC agenda and several project participants expressed that the absence of a downsizing threat also increased individuals' ability to identify themselves with the project and that the mere existence of such a possibility would have raised barriers against the FASTRAC initiative that would have been hard to overcome.

The analysis of the clinical trial process focused on three major areas - planning and reporting, data handling, and operating values. After that vision, mission, major processes and focus areas had been identified, these initial results were presented to all members of the clinical R&D group during June 1995. From this point on, the project was transferred to the clinical unit. Members of the clinical unit then performed all further project activities, including the selection of project management and process teams.

For each of the identified areas, a project group with members from the involved departments of the clinical unit was assembled. Membership in the project groups was voluntary, since it was considered important that all members of the project team would be highly committed to the project. Of the more than 100 organizational members volunteering for participation in the project, about 30 were chosen and assigned to the three groups. The selection criteria were based on the requirement that all parts of the clinical unit should be represented and that a high number of competence areas should be covered. The latter requirement, however, only referred to the clinical area and did not include knowledge in the areas of organization or change

management, since this knowledge and experience was rarely present in the organization.

The three main project groups, now broken up into nine smaller groups, started their work during the summer of 1995 and were supposed to deliver their analysis of the current process and their conclusions and recommendations by the beginning of 1996.

The project group members were assigned to the project with 20% of their working time, while group leaders were assigned with 50%. Despite the intention of reducing day-to-day workload from their functional occupations, the regular work of the people participating in the project wasn't reduced with the 20%, respectively 50% or working time, that had been assigned to the reengineering effort and many project participants, especially group leaders, considered themselves as being overwhelmed with additional tasks. In November 1995, the work-overload had become critical to the time plan of the project and in order to maintain the original schedule, measures had to be taken. In the project master plan, a period of 6 months had been foreseen for delivering feasible proposals for improvement, and the group leaders were now allowed to dedicate 100% of their time to the project.

Lack of time, and consequently effort, that can be invested into a change effort is a critical success factor. Being unable to dedicate themselves to the initiative, people might reduce their commitment and the early momentum gains might be lost. In the Astra case, a variant of slack resources, in accordance with the design strategies proposed by Galbraith (1977) were used in order to resolve this problem, in addition to the self-containment of tasks that had been achieved through the division of the project groups into nine task forces. However, it is interesting to note that this decision was taken on an intuitive basis by the FASTRAC steering group, rather than following Galbraith's strategies deliberately.

The reporting date was set for February 1 and the teams for the different sub-projects actually managed to finalize their work and presented their results according to schedule. The

following 10-week period, from early February to the middle of April was dedicated to developing a project implementation plan. For this purpose, a group under the name of FIST - Fastrac Implementation Steering Team - was formed and given the task to develop an implementation plan to be realized until fall 1997. The implementation team started its work by developing time schedules for the implementation of the new overall process structure and its different parts. An important aspect of this process is to manage the transition, without loosing efficiency in the currently on-going operational activities. The company had several important projects in the research pipeline and it was made clear, that these projects could not be disrupted in any way in order to keep the market introduction schedule. This issue, however, never had to be resolved. Senior management at corporate level decided to initiate a group-wide reengineering effort, CANDELA, and the implementation of other change measures was put on hold in order to await the CANDELA results, which were expected to contain general organizational structures and standardized processes and IT-portfolios.

3.5 Summary of FASTRAC outcome

The project group delivered its report on time in February 1996. In accordance with the project directives, the report contained a description and analysis of the current clinical trial processes, a new process design proposal and recommendations for infrastructure deployment. It also outlined several shortcomings with respect to the current organizational structures, processes and use of information technology.

- **Insufficient planning and prioritization**: The planning and prioritization does not utilize the existing resources in the most efficient way.

- **Insufficient document management**: The documents within the study are not handled in the most time saving

way. This refers especially to the handling of CRFs, which is based on a manual process.

- **Lack of standards**: Documents, such as the protocol, are not based on standards, but are developed for each study.

- **Work is mainly performed sequentially**: Instead of performing activities with low or no interdependence in parallel, they are carried out sequentially, thus increasing overall cycle time and creating wait-states within the process.

- **Lack of cooperation**: Line- and project-organization are cooperating in a limited way. As a consequence, resources are used sub-optimally.

As a consequence of the above factors, clinical studies were considered as being too time-consuming and expensive. The report indicated nine areas for potential improvement of the clinical trial process, falling into three main categories: managerial, organizational and cultural. In addition, a set of actions for achieving the change was defined. The use of more advanced IT-infrastructures, especially for data collection, was identified as one of the major enablers for improvement, but no direct suggestions were made regarding specific technologies, or how they should be developed, implemented and deployed and consequently, different solutions had to be explored.

3.5.1 Management and control

In order to focus the available, yet limited, R&D resources on the most promising areas, adequate mechanisms for project planning, assessment and prioritization were considered critical and had to be developed and adopted. So far, too many projects had been conducted with highest priority, resulting in internal competition for resources. While this problem was experienced throughout the organization, the FASTRAC team could not easily propose measures to address it. Project priority decisions were,

and are, taken at senior management level and the mandate of the project did not include the propositions of solutions outside the clinical unit. Consequently, the observation was passed on to senior management for further consideration. This phenomenon also points at the problems that are associated with driving process improvement projects within limited parts of the organization, instead of addressing the entire organization. Problems, or solutions, that are related to other organizational parts cannot be easily addressed, or resolved.

Another important issue was the management of documents throughout the clinical process. While clinical R&D very often is perceived as a primarily research oriented process, document management is, in fact, critical to its efficiency. In order to shorten the drug approval time required by regulatory authorities, the preparation, compilation and management of drug documentation can be an important area for focused improvement efforts.

A third aspect that was conceived crucial was the application of common standards and coordination mechanisms. Due to the highly decentralized structure of the Astra group, a wide variety of terms, systems, standards and protocols have been in use for different purposes. The coordination of different activities and processes enabled and facilitated by the use of common standards and terminology can contribute to a more efficient coordination within and among different parts of the organization. Also here, the problem with global aspects of local improvement efforts became evident. The terminology issue not only affects the clinical unit within Astra Hässle, but involves the other local units, but also other parts of the Astra organization that are involved in clinical R&D, such as the market companies. In order to make the development of a common terminology relevant and useful, compliance from all units would be required and achieving it is a matter of negotiation.

3.5.2 Structures and processes

The clinical trial process, with its average cycle-time of more than eight years, was generally considered as being too time-intensive. Paralleling work, improving coordination and cooperation between line and project were identified as the major organizational factors for time reduction, optimized resource allocation and training and competence development for study participants.

Also, the conduct of various work processes, especially phase I-III studies, was primarily sequential, awaiting completed results before initiating the sub-sequent process. Using a parallel approach to planning and conduct allows non-critical activities to overlap and thus reduce wait-states in the process.

The implementation and deployment of a new IT-infrastructure was considered as a pre-requisite for achieving the targeted improvements of processes and the underlying organization.

3.5.3 Culture and values

The spirit and informal ways of doing things, considered as an important part of the organizational culture, plays an important role as informal guidelines. It can be effectively used as replacements for formalized chains of commands and bureaucratic structures, and thus reduce the need for managerial control. The re-establishment of Astra Hässle's operating values, which had become less prominent during the period of rapid growth, was therefore seen as an important instrument for facilitating direct communication and an information-sharing environment. These values and beliefs, which had a significant importance for making Astra Hässle a successful R&D company, should also be shared by temporary employees and consultants, which are used in a variety of areas, from medical research to systems development, helpdesk and systems maintenance. Incorporating temporary members of the organization into the social context of work can improve work

satisfaction as well as enhance cooperation between permanent and temporary staff.

3.5.4 Action for change

Within the areas that were targeted for improvement, a set of measures was identified in order to assess their potential and define concrete actions, which could be initiated and performed under coordination of the implementation steering committee. These actions comprised technical solutions, operational process improvements and structural changes, as well as guidelines for the re-establishment of the organizational value system. Following the steps of the clinical trial process, project planning and documentation were the first areas to be changed. The action to be taken included the introduction of clear targets for project prioritization, funding and resource allocation, as well as the development of a master plan for all activities from the investigation of a new drug (IND) to final product. Additional steps should be taken to align project documentation with requirements imposed by regulatory authorities. For making internal and external document and data management as efficient as possible, new IT-infrastructures had to be explored and introduced. Special attention was paid to remote data capture (RDC) within clinical trials and all clinical projects were urged to initiate RDC projects.

The sequential way of performing clinical R&D activities was perceived as a major time-consumer and in the new process design, it was attempted to overcome this performance limitation. Rather than running project activities in sequence, sub-processes should be conducted in parallel, thus reducing wait-states and waste of time between different activities. In addition, all clinical R&D activities were supposed to be concentrated within clinical research projects. Instead of conducting small-scale clinical studies, comparable to Phase I studies, in pre-clinical research projects, all field trials were moved into the clinical phase and conducted in accordance with the new process design. The idea behind this measure was to

increase efficiency by running all clinical R&D activities within the same organization, using a standardized process design.

Together with new business process and organizational structure, a process of cultural re-establishment was initiated. As the FASTRAC report stated, the cultural awareness initiative was promoting

"respect for each others competence and work, clear goals, and leadership that facilitates the implementation and acceptance of the process."

While these goals must be seen as important for the success of the change initiative, it was not clear how the actual awareness creating process should look like and what activities it should include. Due to the urge for improved operational effectiveness, the cultural issues were not actually paid a high level of attention in the implementation phase and the FIST-team did not develop an action plan within that area. Nevertheless, many employees at Astra in Mölndal have declared that the FASTRAC project actually influenced their cultural perception and opened their eyes for the need of change.

As part of its outcome,

Activity	Current time (days)	Target time (days)
Recruitment	484	250
Clean file work	176	45
Preparation of statistical report	358	15
Preparation of AE report	403	15
Preparation of clinical report	200	60

Table 4: Current average and future targeted cycle times in clinical projects

The targeted time reductions within the different phases of clinical projects naturally required a re-design of the involved sub-processes. The following measures were introduced.

- **Wait-state reduction**: Reduction of wait-states within and between processes, i.e. that the finalization of one phase instantly triggers the sub-sequent activity.

- **Parallelism**: Sub-processes with limited or no inter-dependencies are performed in parallel, instead of sequence. This is relevant for the preparation activities (preparation of study protocol, Case Report Form, database and report) and the ongoing-validation and control of data being collected within the study.

- **Monitoring**: In order to monitor projects' performance and their impact on overall R&D efficiency, a set of quantitative measures, aligned with the new overall process, was introduced.

- **Continuous improvement**: The continuous evaluation of projects conducted in accordance with the new process design is used to inform the change team and prepare for further improvement.

Design Engaging Large Areas - in spring 1996. CANDELA was promoted internally as "the key to our vision" and as the "project to take Astra into the next millenium" and ambitious goals were set and communicated throughout the Astra organization when the project was presented:

> "The objective of the project is to position Astra as one of the top three pharmaceutical companies, as measured by speed of product development, adherence to goals, efficient use of resources, methodology and quality of clinical documentation."

Together with the vision, a set of objectives and guiding principles was developed and announced. These additional statements were aimed at clarifying additional project objectives and means to achieve them.

> **Objective 1: Optimizing key clinical R&D processes.** The key processes for clinical research and development were under scrutiny also in the CANDELA project. For these processes, a standard design and operating model was to be developed and implemented in all Astra research companies.

> **Objective 2: Maximizing return on marketing investment.** Marketing investments are considerable for new product introductions in the pharmaceutical industry. Increasing ROI in marketing was seen as an important measure for improving the financial performance of Astra.

> **Objective 3: Prolonging the protected time of products.** Extending patent protection can be achieved in two ways, (1) by shortening time from IND to NDA and (2) by developing improved versions of a product, e.g. by changing delivery mechanism or prolonging other patents than those for the chemical entity itself. The CANDELA project, with its focus on process improvement, had the first option on its target list, whereas the second one was considered as being an issue for pre-clinical R&D.

Principle 1: Clarity in all processes. In order to avoid misinterpretations of how work should be conducted, all processes must be described in an unambiguous way. This includes not only operating procedures and workflow, but also clear lines of authority and decision making.

Principle 2: Simple solutions to complex problems. For most problems, solutions with varying levels of complexity can be found. For the CANDELA project, simplicity was an outspoken goal. This aim included straightforward process descriptions, decision taking mechanisms and execution of tasks.

Principle 3: Individual responsibility for implementing continuous improvement. While large-scale and radical process elevation, such as targeted in the CANDELA project, continuous and incremental improvement of daily operations was considered as being an individual responsibility for all employees.

Principle 4: Transparency in prioritization, allocation of resources, and decision-making. In order to direct peoples' efforts into the most important directions, it was seen as necessary to make the basis for project prioritization and the subsequent allocation of resources clear and transparent.

A project organization, consisting of the project sponsor Håkan Mogren, a steering committee comprising representatives from all product companies and senior executives, and 9 project area managers for key R&D and support processes was formed. An overall project plan with a total time frame of 3 years (1996-1998) for the project was developed.

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                    │     Project sponsor     │
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│ Core R&D processes                                                      │
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│  │ Portfolio ││Product life-cycle││  NDA    ││              │            │
│  │management ││  management    ││ process  ││ Clinical trial│            │
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│ Supporting processes                                                    │
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│  │Standardized││Human safety││Implementation││Information and│        │   │
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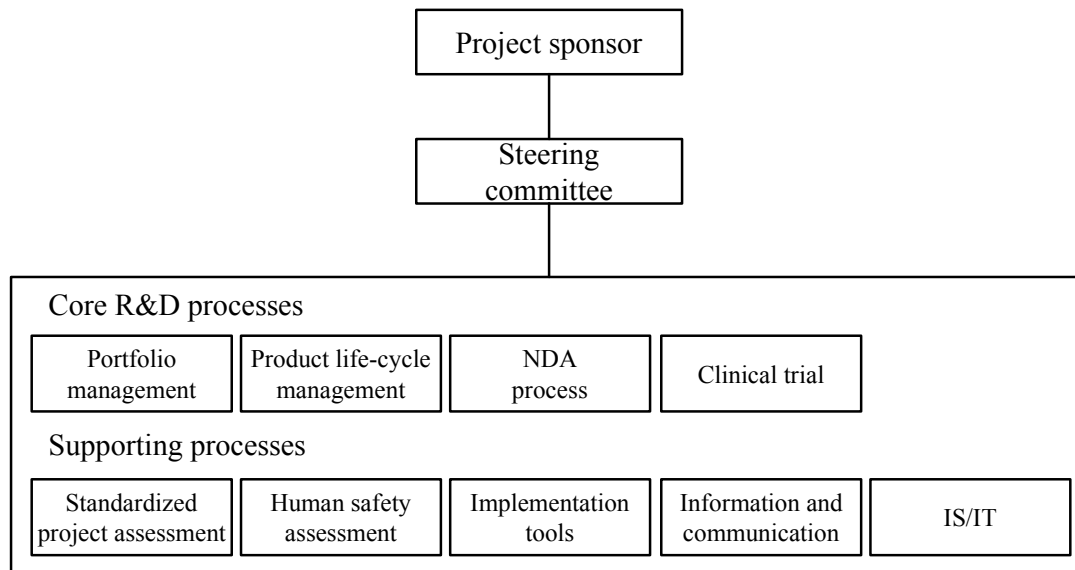
Figure 3-4: CANDELA project organization

The methodological approach for the CANDELA project followed the traditional model for BPR-projects, with an initial analysis and assessment of the current operations and their performance, followed by a design phase, and concluded by an implementation phase with re-assessment, fine-tuning and continuous improvement. In order to ensure that the methodological steps were performed in accordance with the intentions of a reengineering project, a group of consultants was contracted to assist the project management team from Astra. Initially, the consultants were contracted individually from a variety of companies. First later on, larger consulting teams from McKinsey and Andersen Consulting were brought into the project in order to perform specific parts of the analysis and design phases.

The CANDELA initiative was divided into nine sub-projects, of which four were as the core due to their impact on performance improvement. The following table outlines the partial projects and their responsibilities.

Partial project	Responsibility
Systems (core)	Portfolio Management and coordination of sub-projects under the CANDELA umbrella.

Partial project	Responsibility
Product Life Cycle Mgmt. (core)	Documentation of first indication, registration, pricing, market growth of products, market peak sales, endurance of sales and market retraction.
New Drug Application (core)	Reducing time required from Candidate Drug to New Drug Application.
Clinical Trials (core)	Reducing time for performing and concluding clinical trials. The goal was to achieve a median duration of 235 days, excluding the duration of treatment and authority approval: • Protocol completion: 30 days • Study preparation (to FPI–first patient in): 30 days • Recruitment (FPI to LPO-last patient out): 120 days • Data Management (LPO-clean file): 10 days • Reporting (clean file – report): 45 days
Human Safety	Efficiency (time/quality) within the safety area by ensuring the development and use of common methods, processes and IT systems.
Project Assessment	Development of instruments and mechanisms for prioritization of projects.
Information	Dissemination of activities and results of CANDELA within the initiative and to members of the Astra group.
IS/IT	Definition of a technology portfolio for R&D within the Astra group, including systems evaluation and selection.
Implementation	Development of implementation guidelines and procedures, as well as change management efforts to support implementation.

At an early stage, several critical success factors for change programs were identified and also communicated in the Astra organization.

- **Poor communication.** It was early realized, that poor communication constitutes a serious threat to the buy-in of all members of the organization. Frequent communication was therefore considered as a high-priority took place via information over the intranet, and a news-bulletin.

- **Poor implementation of change.** The CANDELA team also realized, that change programs are not only a matter of sound analysis and consistent and good design of solutions. Implementing the designed processes, organizational structures and IT solutions is actually as important as design itself.

- **Inadequate resources.** In the FASTRAC project, the initial lack of time resources jeopardized the project time schedule until this problem was resolved by additional time assigned to the project. Intending to avoid this situation, and others that could be referred back to lack of resources, the CANDELA project was well financed. Another reason for the generous resource provisioning was the fact that CANDELA was considered as the Astra-group's flagship change project and that a lot of prestige had been invested in it.

- **Poor follow-up.** A change initiative does not end with implementation. The introduction and roll-out of new processes must be followed by an on-going evaluation of results and a program for continuous improvement.

It was also pointed out that the CANDELA project was proactive and future oriented and not intended to be a fix to current problems. As a counter-example to CANDELA, the FTTM (Faster Time To Market) project at Ciba-Geigy (now Novartis) was used. The Ciba project realized a 63% increase of productivity in clinical development and a significant cycle-time reduction was achieved. If, it was argued, Ciba could achieve these dramatic results despite the shortcomings of the project set-up and

conduct, it should be possible to realize even higher gains through CANDELA, which was described as being superior in terms of approach and project set-up and management. Especially it was pointed out that CANDELA used a bottom-up approach as opposed to the top-down analysis and design employed in the Ciba case.

The Ciba-Geigy case has also been described briefly in a report from consulting firm Coopers & Lybrand (now merged with Price Waterhouse to PWC) (PriceWaterhouseCoopers, 1997), that had been involved in the project. Despite the fact that the provided description must be seen as a marketing instrument, it still reveals some interesting aspects of the Ciba project. The FTTM-project was clearly intended to be a time and cost control initiative and did not have the primary ambition to be a full scale BPR-project. The goal was to reduce annual R&D expenditure with 10% and to establish a management control structure for the R&D process. The employed methods, activity analysis and financial analysis, are typical top-down approaches. Considering the different levels of ambition and scope of FTTM and CANDELA, it was clear that the methods being used by Ciba-Geigy could not be used at Astra and the comparison was therefore somewhat irrelevant. On the other hand, it provided an instrument for pointing at the superiority of CANDELA and boosting motivation in the Astra organization.

3.7   The CANDELA approach to process improvement

The CANDELA project continued with the development of a high-level process map, showing the core and support processes and their sequence on a general level. This overall sketch was submitted to the steering committee and approved as the basis for analysis and solution development. The sub-sequent work was assigned to sub-process task forces and coordinated by a project management team.
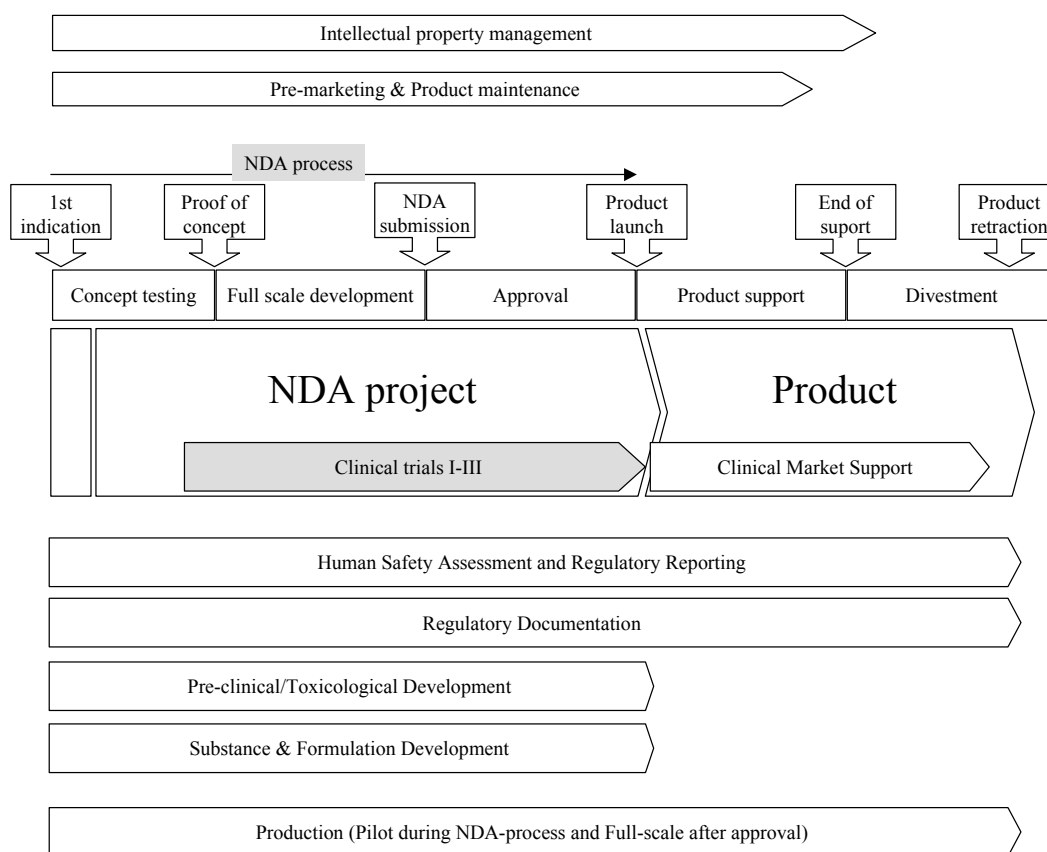
Figure 3-5: CANDELA overall product life-cycle scheme

At that point, the consulting team from McKinsey & Co. was brought into the project in order to assist the internal project management team. Individual consultants from different consulting firms had been participating in the project since its beginning, but the McKinsey team was assigned in order to provide methodological support for the development and implementation of a master plan for the implementation of change measures and to provide administrative assistance to the CANDELA management team with regard to planning, co-ordination of the sub-teams and the identification of resource requirements. It was rather clear, that the external consultants would play an assisting role, but not being the ones driving the project forward.

The McKinsey team conducted its work in compliance with the methodological approach previously described. Initially, the existing processes were mapped and described with regard to

their shortcomings. In the next step, the existing processes were integrated with new design ideas and a projection of potential benefits and problems was developed. In several iterations, alternative process designs were developed, rejected, or modified, until a final design was agreed upon and approved by the CANDELA management team and steering committee.

On the basis of the new process design, a list of the prioritized changes was compiled and also this list had to pass the approval process. Once the list had been approved, a master plan for implementing the change action was developed, including a sequential description of the different steps to be conducted in order to ensure a migration to the new processes without disrupting the current operations. The master plan also included a set of tollgates and mechanisms for measuring implementation progress, based on the delivery plan and critical path.

3.7.1 The NDA-process

One of the most important processes within clinical R&D is the New Drug Application. The NDA contains all documentation of the new drug, including a description of its chemical composition, its indication, and the results and analysis of the clinical trials. Since regulatory authorities take their decisions regarding the approval of a new product mainly based on this application document and the supporting documentation, the NDA is the critical delivery within the clinical R&D process.

When CANDELA was initiated, Astra was considered as being an "average performer" with regard to managing time efficiently in the process from Candidate Drug to New Drug Application. The average Astra project had a total lead-time of 8.8 years, with an industry average of 8.7 years and this was far too much for a place in the top-performer list of the industry. The CANDELA steering committee approved a proposal comprising three main areas.

- **Process analysis and description.** The analysis and description part of the project should focus on the description of an overall NDA-process and its sub-process, including definitions and terminology, optimum lead-times, risk assessment and management and critical success factors and milestones.

- **Toolbox.** The toolbox part was supposed to develop a common set of tools and principles for managing the NDA-process efficiently, including measurements and measure points, monitoring mechanisms and performance data collection.

- **Roles and competencies.** The third and last part of the NDA improvement initiative was investigating the required competencies and roles for managing the NDA process and its continuous improvement.

The task groups for these areas worked with a common set of long-term objectives for the new NDA-process, of which the time-related one was most important. Other goals referred to performance criteria and requirements for efficient process management and continuous improvement. The NDA project team also identified and outlined a set of critical success factors for the timely delivery of New Drug Applications. These factors involved not only the clinical organization, but stretched over a variety of areas within and outside the company as a cross-functional process.

Adequate planning of the entire NDA-process was considered as the primary success factor. Planning, in this context, does not only mean that the content and sequence of activities are pre-defined, but that a target date for the finalization of the NDA is set upon initiation of the NDA-process after authority approval of a Candidate Drug. Proactivity towards regulatory authorities was another aspect being taken into consideration.

IND- (Investigational New Drug) and NDA-files had been following a standardized pattern, often resulting in "over-delivery" of documentation, i.e. that more documentation than required was submitted together with the application for approval. Since the authorities could neither reject, nor ignore, the additional information, its evaluation extended the cycle-time for authority approval. A pro-active attitude towards regulatory authorities was considered as an effective instrument for preventing this form of ineffective behavior. Engaging in a dialogue with regulatory authorities could reduce the volume of documentation submitted, thus lowering the workload for Astra, as well as for the authorities and resulting in a faster handling of the NDA.

It was also understood, that the planning and conduct of the NDA-process is not only a matter for R&D functions, but affecting a variety of units within the company and cooperation partners, such as contracting organizations for clinical trials, chemical and pharmaceutical units and the marketing organization in various countries. As a consequence, all these entities being involved in the process were considered in the planning phase in order to run the process in an integrated environment and paralleling activities when possible.

Early participation of other part of the Astra organization, such as Health Economics, Quality of Life, Epidemiology and Marketing was not only seen as a way of improving the quality of clinical studies, but as a means for ensuring that product pricing and reimbursement strategies could be taken into account already in the planning phase of clinical R&D. In order to enable this cooperation across organizational borders within the organization and with regard to external partners, it was necessary to develop a common terminology, that would cover all aspects of clinical R&D and that would become a part of the process model, common tools and standard operating procedures that comprised all activities within the process.
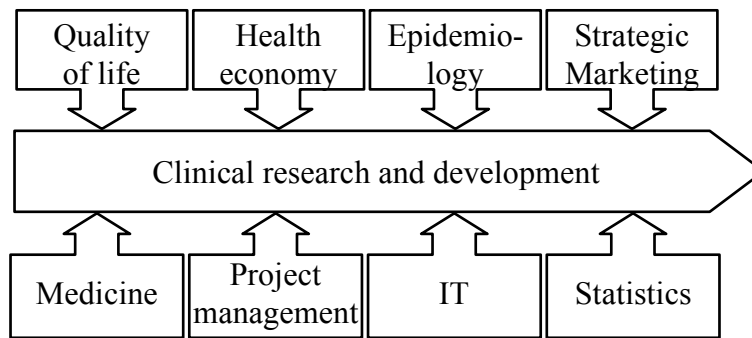
Figure 3-6: Competencies needed in clinical R&D

All these requirements imposed on a new NDA made it imperative to have an elaborate and consistent model for planning and running the process. The planning model must include aspects such as the availability of internal and external resources, a funding model being independent from the annual budgeting of the functional organization and roles, responsibilities and accountability for project progress. In addition, it must contain milestones and delivery and decision points. In order to bring all these aspects together, a task force was formed to develop a project management model that would allow to run and control the NDA-process efficiently, without hampering flexibility and problem solving.

We can also conclude, that CANDELA affected more parts of the organization than R&D functions and that the project became a truly global initiative not only in terms of the corporate-wide implementation of its results within R&D, but also with regard to its impact on different functional parts of the organization.

3.7.2 Clinical trials

Since clinical trials are the most time-consuming part of clinical R&D, this area was considered as being the most promising one with respect to cycle-time reduction. For the new clinical trial process, an average cycle-time of 235 days, excluding authority approval was assumed to be an achievable objective. The

investigation was conducted in seven task groups, each being responsible for one area.

- **Process description,** being responsible for developing a new model and description of the new clinical trial process. The new model should take into account the CANDELA objectives, but also be built on the best practices to be identified within Astra and other companies.

- **Planning, monitoring and reviewing** emphasized the planning aspects of clinical trial management and had to develop tools and procedures for setting up, monitoring and following up trials.

- **Performance management** focused efficiency aspects of clinical trial management and had the task of identifying performance measures and benchmarks and mechanisms for implementing them in the process.

- **Protocol and report approval** looked at procedures and tools for designing case report forms and study protocols. In addition, tasks, roles and responsibilities for approval of these documents were investigated.

- **Recruitment.** Clinical trials involve the recruitment of investigators and patients. Since patient recruitment usually consumes a considerable portion of overall trial time, fast recruitment and the avoidance of over-recruiting was considered as a high-prospect time saver. The task of this group included the design of recruiting principles and performance measurement for recruitment by investigators.

- **Remote Data Capture** (RDC) was analyzing how information technology could be used for reducing the time and effort required for patient data collection and transfer from the study center into the Astra information systems. The task of the group also included the

assessment of the value-adding potential of RDC technology and the investigation of commercially available systems.

- **Data management** is the process of handling data from clinical trials for analysis and report writing. The working group was given the assignment to develop new procedures for data management, including clean-file.

The different working groups were supposed to deliver a result report within a few months, in order to allow the implementation of the new clinical trial process for all new R&D project under 1999. The aggregated results were used as a basis for a new process design and documentation, which was used as input for the overall design and integration by the management team.

4. IT aspects of the BPR initiatives

In both projects, information technology was considered as a key to improving business process performance in two ways. (1) Information technology could accelerate process performance by reducing transaction cost and time and (2) it could enable process designs that were impossible to consider without IT. This reciprocal relationship was a red thread in both projects, but was more prominent in the late phase of FASTRAC, whereas CANDELA had a stronger focus on the supportive functions of IT.

4.1 IT aspects of CANDELA

Since the CANDELA project was aiming at redesigning R&D at corporate level, a very wide perspective was taken with regard to the technical support systems. For the IT-aspects of CANDELA, a team from Andersen Consulting was brought into the project. The task of the consultants was to assist the project management team in the selection and assessment of products that could be considered for the global IT-portfolio and to test and evaluate the different portfolio options in a business simulation.

The CANDELA-team developed several portfolio options, comprising different combinations of standard products. The portfolios included systems for supporting multiple aspects of clinical R&D: Analysis & Reporting (A&R), Data Management, Electronic (Remote) Data Capture (EDC/RDC), Product Life Cycle Management, Project Management, Safety and Study Management.

Safety	Data Management
4 alternative products, all packaged solutions	4 alternative products, of which one internal
Project Management	Study Management
3 alternative products, all packaged solutions	2 alternative products, all packaged solutions

Figure 4-1: Alternatives for the product portfolio[17]

The products to be included into the portfolio options were selected upon a set of weighted measures, where strategic fit, product quality and supplier quality were the main evaluation criteria. After some further discussions in the project management group, however, these original criteria were complemented with some additional measures - functional fit, product integration and cost - in order to better reflect purchasing and deployment aspects. Of all evaluation criteria, functional fit was considered as being the most important one, with a relative weight of 32%.

The products being considered for the corporate standard portfolio were then analyzed with regard to their functionality and ability to be used together in projects. This selection process resulted in the final selection of a subset of the products being included in the first list. Among the remaining products, clear preference was given to one alternative in the areas Safety and Study Management and of the three options for Project Management, only one remained after the first evaluation round. The final recommendation included four alternative portfolios, of which two were considered as preferred choices.

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[17] Product names have been removed due to confidentiality reasons.

Safety	Data Management
2 alternative products, all packaged solutions	3 alternative products, of which one internal
Project Management	Study Management
1 product, packaged solution	2 alternative products, all packaged solutions

Figure 4-2: Final selections for the product portfolio

In parallel, the different products were analyzed with regard to their costs and benefits. The cost analysis included software purchase, configuration and maintenance, required internal and external implementation resources, data conversion, training and system support. Direct costs for software licenses were gathered from the respective vendors, whereas additional costs were estimated upon the experience from the internal IT-department and the Andersen Consultants. The benefits were estimated indirectly by calculating the projected timesavings and opportunity costs. The first estimation resulted in a total cost of 170-290 MSEK, depending on the chosen products and including software, training, implementation and data conversion. Additional 11-21 MSEK cost for maintenance on an annual basis were added.

The recommended portfolio options were developed in early 1998. For the business simulation phase, a period of six months was projected in order to implement and test the different solutions. This time plan was aligned with the overall schedule for CANDELA, in which the final decisions regarding the new process design were projected for the end of 1998. With a beginning in early 1999, the implementation and roll-out phase was supposed to be initiated.

4.2 Critical IT-issues in CANDELA

The build-vs.-buy-vs.-partner debate was extensive in the project and from within the Astra organization, many comments regarding this issue were received by the CANDELA team. It was decided at an early stage of the project, that packaged solutions should be considered in the first place, rather than looking into the possibility of developing systems in-house, or partnering with an external vendor of systems development services. This decision was justified with the argument that is was essential to free resources from developing basic systems in-house to concentrate instead on systems that have more specific functionality and provide more benefit to the R&D process. According to the management team, this would not mean to compromise with functionality and usability of the systems to be selected. Furthermore, it was pointed out that this policy would not apply to all existing systems, but primarily to new ones and those that had to be replaced at the end of their life-cycle.

With regard to the relation between the local and global project it can be concluded that the CANDELA goal to use packaged solutions was not totally in line with the intentions of FASTRAC, where no such limitation was found. The technology options of FASTRAC included the internal systems that were already in use within Astra Hässle and did not exclude the possibility of developing in-house systems, since many of the standard system available on the market were considered as being insufficient in terms of functionality and long-term deployment.

Another issue that was raised during the project was the competitive advantage that technology could provide. The following critical issues were brought up:

- The IT-portfolios that were defined and used in the business simulation phase did not address several strategically relevant issues.

- The portfolios would not be flexible enough to be adaptable to changing processes as a result of environmental changes or continuous improvement.

- The portfolios would not cover all aspects of the clinical trial process and only support a sub-set of all activities, which would lead to sub-optimization in the process.

- The same packaged solutions and portfolio could be purchased by any competitor to Astra and that it would be impossible to realize advantages relative to Astra's competition, if the system portfolio was based on standard solutions.

- Some of the systems being part of the portfolio options were not state-of-the-art technology, but based on a concept of clinical trials that had become obsolete. Especially the use of Internet-technology, or rather the lack thereof, was criticized, since a system for on-line data collection had already been developed locally at Astra Hässle.

The project management team responded to this criticism with the following clarification:

> This (the replacement policy) does not mean that...

> ...we blindly select packages and sacrifice functionality that is necessary for our business. The objective therefore, is to free scarce resources to work on solutions that will radically change the way we do business and not just core functionality which may already be available in packaged solutions.

> ...we immediately replace all custom built systems that exist within Astra today. When these custom systems reach the end of their life, they will be replaced where possible by package solutions.

When looking at these responses we can conclude that they do not actually address the critical issues that were brought up from within the organization. In fact, it is hard to see in hat way any of the proposed portfolios would enable the radically new ways of working that CANDELA was aiming for.

The successive replacement of custom-built systems, based on their life-cycle, must also be seen as a serious barrier to the implementation of CANDELA recommendations. According to its time schedule, the project was supposed to deliver its results by the end of 1997 and implementation should be finalized by the end of 1998. Obviously, the successive replacement of systems was not compliant with the projected time schedule.

The CANDELA project was discontinued in January 1999 as a result of the merger between Astra and Zeneca. Only a small fraction of the proposed changes were actually implemented.

4.3   IT aspects of FASTRAC

It was obvious to the FASTRAC team, that the employment of current and relevant IT could deliver a major leap forward for implementation of the proposed change agenda. Consequently, serious efforts were made to investigate possible IT infrastructures for providing support to clinical trial projects. As a measure to improve performance in clinical data handling, special attention was put on RDC (Remote Data Capture), i.e. the collection and transfer of clinical data by means of technology. The use of RDC based technological infrastructures was seen as a way of satisfying organizational and technological needs of the new process design. As the result of the identified need to improve data collection and management, six projects employing different technologies were initiated. Of the technological solutions being chosen, some were based on packaged solutions, which were adapted to fit the clinical project in which they were supposed to be used, whereas other solutions were in-house developed systems.

- **Apple Newton.** For a quality-of-life study, a system for data entry by patients was developed and implemented on 130 Newton PDAs (Personal Digital Assistants). The PDAs were distributed to the investigators in the study, but data entry was actually conducted by the patients in the study. The data collection was based on multiple choice lists and ticking boxes and was well received by the users. Since the study involved patients with a wide age variety, it is notable that mainly positive comments were received from users.

- **Internet.** Using the Internet as carrier for remotely collected data is currently explored, and a first trial application has been in use since April 1998 with promising results. Medical personnel at the test center enter the clinical data directly into the central database at Astra Hässle through a Web-interface. This RDC-system, termed COOL (Clinical Operations On-Line) uses the in-house developed AMOS-system for data management and is basically a WWW-technology based data entry interface.

- **Bedside continuous data collection.** Collecting data directly from bedside medical equipment is a way to collect highly accurate patient data without interfering with the treatment of the patient. It also makes the manual collection and transfer of data obsolete, but is only feasible for a limited category of patients. For trials with patient not being stationary treated in a hospital, this technology is not feasible.

- **Datafax/OCR (Optical Character Recognition).** For studies with low reporting frequency and standardized measures, i.e. handwritten notes are not used, the transfer of data via fax with subsequent optical character recognition is a low-cost, yet sufficiently efficient, way of collecting data.

- **AMOS C/S client/server) on WAN (Wide Area Network).** AMOS is a study and data management system developed internally by Astra Hässle. In its client/server version it consists of a proprietary client for data entry and access and a database. The AMOS system had been in use at Astra Hässle for some time and its proprietary interface was commonly used for data entry in most clinical projects where paper CRFs (Case Report Forms) were entered into the system at Astra Hässle. It was considered technically possible to provide investigators or local marketing companies in other countries with a client-version of the software for direct data entry into the AMOS-system, but the concept never reached full-scale implementation.

- **SCODA: Semi-RDC.** The SCODA system used a 2-tier client/server architecture for data entry and storage. The client module contained an electronic version of the paper CRF, being able to save and handle multiple records. The transfer between client and server module is achieved through a modem-connection to a private network. This system is conceptually close to the AMOS C/S solution, but included the possibility to store patient records locally in the client module.

The solutions being investigated for managing data collection in clinical trials more efficiently ranged from traditional forms of data capture, over client/server based architectures to Internet-based RDC. In parallel to the development of the various technological infrastructures, a new process for clinical trials was developed in the FASTRAC-project. The strategic intent of the reengineering initiative was, of course, to align the business process and its procedures with the use of an IT-infrastructure for data collection. However, the in-depth analysis of the deployment process of one of the technical solutions, SCODA, indicated that there was a discrepancy between the globally

designed business process and the procedures for working and technology deployment developed at the local level.

4.4 SCODA - a FASTRAC IT project

The FASTRAC and CANDELA projects both included an overhaul of the data collection process in clinical trials. Considering that clinical trials regularly involve thousands of patients and that they are conducted on an international basis, it is obvious that managing patient data accurately and efficiently has a substantial impact on overall performance of the clinical trial process. The options for Remote Data Capture (RDC) technology that had been considered in the FASTRAC project included SCODA[18], a 2-tier client/server system, developed and marketed by an independent software company.

The SCODA-system was, on the other side, not part of the product portfolio options being developed within CANDELA. However, since some of the systems being investigated within the CANDELA project were similar to the technology used in SCODA in terms of functionality and technical architecture, SCODA can be said to be representative for the basic approach to RDC in CANDELA. We have therefore chosen the SCODA-system for a more detailed study and analysis of the data collection process and the relation between organizational and technological aspects in the deployment process of a business process and an IT-infrastructure.

The implementation and deployment process of SCODA was studied during a period of one year. During this period, a series of interviews was conducted in different countries participating in the SCOPE-study, where the SCODA system was used. The clinical project that we have followed during the research project was a relatively large study, conducted at 500 centers in 12 countries and comprising 4.000 patients, and can

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[18] SCODA was the Astra-internal name of the product.

therefore be considered as being representative for clinical projects in general.

The reason for choosing study monitors as primary interviewees can be found in the set-up of the study. During most other studies a central unit at Astra Hässle performs data entry. However, in this study data entry was supposed to be performed by the study monitors participating in the project. In addition to the interviews, a close dialogue with the Clinical IT and Data Management department within the clinical unit at Astra Hässle was maintained during the entire analysis. Especially the head of Clinical IT and Data Management at this time, Elof Dimenäs, was part of a frequent dialogue. It was obvious from the beginning of the study, that the implementation and deployment of an IT-infrastructure is not an organizational and technological issue alone and that these aspects cannot be investigated and considered independent from each other. An important role is played by the dynamics between these factors; dynamics resulting in tension between global and local aspects of the company's organization and processes. Consequently, we have chosen to focus our analysis on the tension between global and local organizational procedures and technological flexibility.

Country	# of interviews	Roles of interviewees
Sweden	3	1 Study Monitor 1 SCOPE Data Manager 1 SCODA IT Manager
Germany	2	2 Study Monitors
Spain	2	2 Study Monitors
Unites States	1	1 Study Monitor

Table 5: Interviews for SCODA analysis

As the project revealed, the actual outcome of the deployment process is different from the anticipated use of technology and the globally designed organizational procedures are subjected to modifications and work-arounds. The infrastructure in use is, in

fact, the result of the interaction between business processes and the use of information technology, rather than a result of a deliberate planning process and management control mechanisms. The case study also shows, that the design and introduction of global standardized processes and technologies certainly contains a significant improvement potential, but that disregarding the aspect of local adaptation puts limits to the understanding and deployment of the infrastructure in use.

4.5 The SCODA-system

SCODA is a data capture application for collecting and entering patient data in clinical studies. It is part of a product suite offered by the vending firm, comprising components for study design, data entry and management, communication and data analysis. The technical solution is based on a client/server system, consisting of a data entry support application running on a laptop-computer, and a central server component for data aggregation and analysis. The connection between clients and server is established through modem links over a commercial global network.

The SCODA application interface represents a digital version of the traditional paper-based case report form (CRF) that is used by the investigators for the first step of the data collection process. The study monitors, being responsible for data entry, use this electronic CRF for transferring patient data into the computer-based system. Most of the collected data consists of numbers, describing the status of various medical variables, such as blood pressure, etc. If additional information regarding the patient or the treatment is annotated by the doctor, the monitor can open normally hidden fields in the electronic form with a simple mouse-click and enter the supporting information.

At a first glance, the interface gives a user-friendly impression, but it lacks of some fundamental functions that are crucial for supporting a clinical study as a whole. It is basically

the reproduction of the paper folders, i.e. it does not provide support for study management, which is the other important task of monitors. The monitors cannot easily access the state of work, the status of recruitment for the study and for individual study centers. The study management capability is basically limited to individual patient records, but doesn't include the collation of results. Editing and monitoring is limited to one patient record at a time. Upon submitting CRFs via modem to Astra Hässle, requests for further specifications or error notifications can be received in return. In this case, the problem is checked locally by the monitor, eventually corrected and the record re-submitted to the central database. The work process for using the system is strictly sequential – data entry cannot take place disregarding the structure and sequence of data entry fields pre-scribed by the electronic case report form – and empty fields are not accepted by the system.

The data handling at Astra Hässle took place in the in-in-house developed AMOS database system. The AMOS-system is basically a relational database system that was developed locally, with the help of an IT-consulting firm, by Astra Hässle, resulting from the lack of a corporate-wide portfolio and the limitations of packaged solutions that were considered as being insufficient for supporting the needs and requirements for clinical R&D at Astra Hässle. Other R&D units within the Astra group had chosen other solutions, either self-developed or standard packages, but AMOS could match most of these systems in terms of functionality and was also considered for the global IT portfolio during the CANDELA project's portfolio selection.

4.6   The data collection process

The choice of the new organization and technological infrastructure was based on the rationale of supporting clinical studies with a time-saving tool for data collection and transfer into the central database for data analysis and the development

of supportive documentation for the New Drug Application. It was also anticipated, that data quality would increase due to shorter feedback cycles between study monitor and the investigating and documenting personnel, doctors and study nurses, at the study centers. Since data cleaning, i.e. the consistency check and validation of clinical data, has a considerable impact on the time being required for the clean-file procedure, i.e. the correction or removal of errors in the database, further time savings were anticipated for the overall clinical trial process.
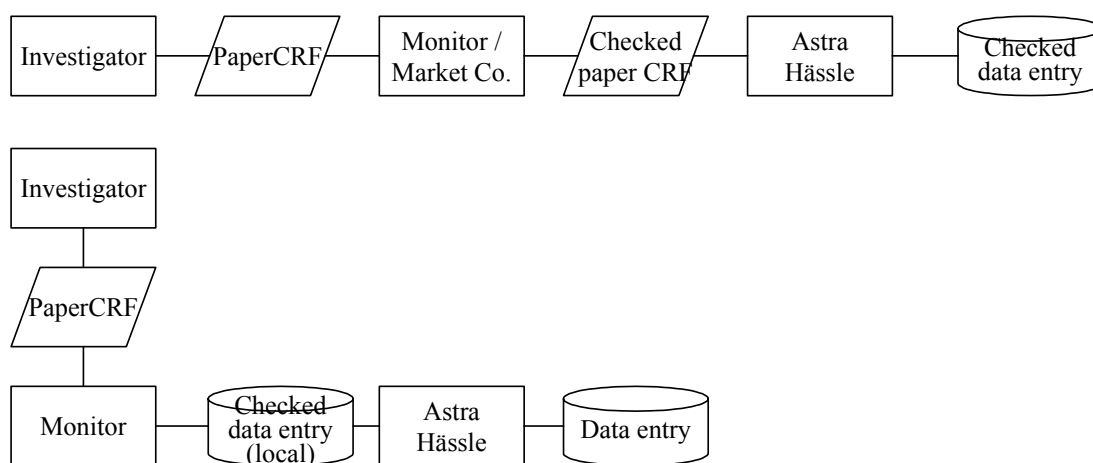

Figure 4-3: Old and SCODA data collection process

The new process was aiming at bringing data collection and quality control together at the study center and for this purpose, the traditional roles and responsibilities in clinical studies were modified. In most previous studies, data collection was conducted by investigators on paper-based CRFs, that upon completition were sent to a central data entry facility, in most cases AstraZeneca in Mölndal, that maintained a special group of people being occupied with keying clinical data into the database systems for cleaning and analysis. For this clinical project, this process was changed in the way that investigators still would collect data on paper CRFs, but data entry into the electronic system became a task for the study monitors.

Study monitors are a group of well-educated specialists being occupied with supporting investigators during the studies and managing clinical projects locally in their countries. In order to realize the intention of reducing the time needed for data cleaning and the handling of clarifications, the role of monitors was changed. From primarily being concerned with data cleaning and local study management, the content of their work spanned over a wider part of the process, including the actual data entry into the computer system that is considerably time-consuming.

The monitors reacted in a differentiated way to this change of their work. While they realized that there was a potential timesaving that could be exploited by moving data entry to the study sites, they had two basic objections. Firstly, monitors consider themselves as being primarily local study managers and not data entry personnel. The new process was thus to some extent conflicting with the professional pride that monitors have in their work and competence. Secondly, several practical factors were mentioned that would hamper the actual implementation of the process in the form it was designed.

4.7   SCODA case analysis

The final report resulting from the FASTRAC initiative contained an analysis of the existing organizational and technical clinical trial infrastructure and recommendations for a new process design and other areas for improvement. However, the project outcome did not include a specific recommendation with regard to technological solutions or implementation strategies for either new organizational or technological infrastructures. While it was stated that Remote Data Capture would have a significant potential for reducing cycle-time in the data collection process, no concrete decisions were taken regarding which solutions that should be chosen and implemented and consequently, clinical project leaders were facing the responsibility for introducing project-specific RDC-infrastructures. This phenomenon was also observed in other projects and the development of organizational

and technical infrastructures specifically for each project can be said to be the typical, yet non-deliberately chosen, strategy for setting up and conducting clinical R&D projects.

The technology to be used for facilitating remote data collection was chosen locally for each clinical project, based on knowledge about available systems in the Clinical IT department, where several alternatives had been initially investigated for future consideration in clinical projects. At the same time, the clinical IT department did not have the mandate to propose and develop a common systems portfolio that could be used in all clinical projects within Astra Hässle and therefore, the decisions regarding choice and implementation of RDC-systems had to be taken by clinical project managers.

Also in the SCODA project, the system selection followed the same rationale. The system was chosen as the result of discussions between the project leader and the Clinical IT department. It had been developed by a small development company that specializes in systems supporting RDC. Moreover, it had recently been purchased and implemented at large scale by another pharmaceutical company, Glaxo Wellcome, and was therefore considered as a safe choice.

However, the system was not originally developed for being used by study monitors, but for data entry by investigators, and the data entry process embedded in the system followed this design rationale. Accordingly, the system was highly functional for data collection, but lacked substantial functionality for monitors' main task: study management. The lack of functionality in the study management area was also mentioned as the major source of dissatisfaction by all monitors that were interviewed during the research project.

4.7.1 System implementation and training

The SCODA system was used for a study of considerable size, 4000 patients in several hundred centers located in 12 countries. Implementing and deploying organizational and technological infrastructures for large-scale studies on a global

basis is neither simple nor intuitive. Astra Hässle had learned this lesson during previous projects and consequently, the SCODA implementation process was planned thoroughly.

The RDC-software, used as the technological component of the new infrastructure, had not previously been used within Astra Hässle. It was also employed for the first time for use by study monitors in a combination of data entry and study management, instead of being used for data entry by investigators only, for which the system had been developed originally. In this way, the deployment at Astra Hässle also differed from the use of the system at Glaxo Wellcome, where the use of SCODA had been limited to data collection by investigators, whereas study management was conducted with the help of a different technological solution.

Due to the limited experience with the software within Astra Hässle and its intended use by study monitors, training was considered as an important issue for successful deployment of the new technology. All study monitors received a 2-day hands-on training. Despite these efforts, the training period was considered insufficient due to several reasons.

- The training was actually based on a beta version of the product that was not fully functional.

- Some specific new functions, required by Astra Hässle in order to adapt the system to the use by monitors instead of investigators, were not part of the version used for training.

- When the system was delivered in its final version, the monitors had to adapt to this version before it could be put into production.

4.7.2 Work procedures

Together with the new technological infrastructure, the organizational procedures for clinical trials were overhauled in order to fit with the new way of technology deployment. Instead

of collecting paper copies of medical records, which then would be shipped to Astra Hässle for data entry, monitors were supposed to stay on-site at the study center and enter the clinical data into the SCODA system. According to the new process, some pre-cleaning of the clinical data should take place in conjunction with the data entry and the monitors were supposed to discuss unclear data on the paper-based CRF and other problems with the investigator directly on-site, and then transcribe the data into the SCODA system for transfer into the central AMOS database at Astra Hässle. However, interviews and discussions with monitors being involved in the project revealed, that the actual process in use deviated from the theoretical design and several reasons were given.

- **Time limitation:** Depending on the number of test centers for monitoring, their geographical distribution throughout the country and the time required for study management and data entry, excessive travel could be required in order to follow the procedure.

- **Budget constraints:** The project budget is negotiated between Astra Hässle and the local market companies in each country in advance of the project. Consequently, when more traveling than anticipated is required, the result is a conflict between the requirements imposed by the global process design and budget constraints.

- **Inadequate facilities:** The study centers were not considered during the process design and were often unprepared for hosting monitors. They were often unable to provide the necessary physical office space and investigators were not prepared to spend the necessary time with the monitors.

As a result of these tensions between the global process design and the locally imposed constraints, several varying instances of the process could be found in the different countries that

participated in the clinical study. In these cases, the monitors tinkered the process in order to manage the contingent requirements. A typical situation is that monitors obtained a copy of the paper-based CRF and did data entry at home or in their own office at the local Astra subsidiary, rather than spending time at the study center.

4.7.3 Project management and "serious adverse events"

As mentioned, the SCODA-system was originally designed for supporting investigators at local study centers in their data entry. The main focus of the system was therefore to enable a structured and sequential data entry process. Considering the work of study monitors, we find that process and content are rather different. Data is entered at different times and in varying sequences, and data entry and study management are interwoven activities. However, the monitors were expected to comply with the rather strict and sequential process design developed around the use of the SCODA system.

In order to reduce the time required for data entry and cleaning, i.e. the checking of data for consistency and completeness, the procedure requires monitors to stay at study centers. The rationale behind this design is the opportunity to discuss eventual problems directly an immediately with the responsible investigator. However, in practice it is impossible to interrupt the investigator's ordinary work for every occurring question. Alternatively, the monitor might enter all data without interruption and then discuss deviations and problems with the investigator. This alternative procedure is not facilitated by the system.

Study monitors also maintain responsibility for study management at local level. In order to facilitate effective study management, a computer system would need to contain additional functionality, such as accumulated recruitment figures and patient status information. The system does not fulfill these requirements and monitors had to use an inductive

procedure through the CRFs for obtaining study management information.

An important aspect of clinical studies is the handling of so-called serious adverse events, e.g. side effects of the investigated drug or other unexpected events, such as suddenly increasing mortality of patients in the study. When these events occur, regulatory authorities require that them to be reported to the study management within 24 hours. Due to the asynchronicity of the system, i.e. data is collected and delivered with delay and not immediately available at Astra Hässle, it is impossible to include the handling of serious adverse events into the system. As a consequence a manual procedure, based on phone and fax communication, has to be set-up in parallel with the computer based data collection process.

A second aspect related to system asynchronicity, and common for all client/server systems with local data storage and manipulation, is that information is not available centrally before it has been transferred from the client application to the server. Considering the complexity of the architecture and the movement of the client system between different sites, it is obviously difficult to ensure a smooth and continuous data flow. Also, data may be stocked in client applications, e.g. as a result of technical problems, which might result in over-recruiting of patients into the study. Consequently, central study management and data analysis at Astra Hässle is heavily depending on the functioning of local client systems.

4.7.4 System choice and implementation

During the SCODA project, a considerable discrepancy emerged between the needs being experienced and expressed by the study monitors and the organizational and technological support provided to them. This was not clear and obvious from the beginning of the study, but emerged during the roll-out of the technical solution and the implementation of the organizational procedures. The main source for dissatisfaction was found in the

job enlargement of the study monitors that was not accompanied by appropriate organizational and technological support.

Data collection is, in most pharmaceutical companies, not a task that normally is conducted by study monitors, but by specialized personnel. In the SCODA project, monitors were expected to handle their regular tasks - local study management and providing assistance to the investigators at study centers - but also data collection was included. The work of monitors has also been characterized by different timely and spatial constraints that are imposed by the design of a clinical research project, the goals being set for local market companies and the resources being assigned to the study.

Obviously, the objectives and performance of these tasks are partially in conflict with each other and this tension is influencing the organizational and technical infrastructure of the project. The infrastructure deployed in the SCODA project was primarily chosen to support and increase performance in the data collection activity. The rationale and design idea was that the use of a common computerized platform, used for data cleaning with help of the investigators and digital transmission, would enable a faster, more accurate collection of all data required for analysis and the sub-sequent drug registration. Following the intentions of the FASTRAC project, driven as a typical BPR-project, time reduction was the dominant implication for choosing the SCODA system, as time consumption in clinical trials was identified as one of the most important factors for long time-to-market.

As a result of this strict time focus, other aspects of data collection and study management, such as a user-friendly administration of study centers, had to stand back. The need for supporting effective local study management by monitors, their timely constraints and the lack of space at study centers were considered as subordinated factors in relation to the time savings that could be achieved by a fast deployment of the RDC-system without major adaptations. As a result, the tension between the different rationales governing the SCODA project at different levels had a considerable impact on the infrastructure

deployment, i.e. the way of using the system and complying with the organizational procedures that were designed around it. Understanding the different rationales and intentions of the project at global and local level and the tension that was resulting from them is therefore imperative for improving the performance of future projects.

Looking back at the outcome of FASTRAC, it was obvious that momentum was too important to be lost in long-term evaluations of different options and the development of a set of business processes and a standardized IT-portfolio that would support and improve all aspects of clinical trials. Including the previous re-organization of the Astra Hässle organization, almost four years had been spent on organization and process analysis and visible results were needed for justifying the project and maintaining confidence in the capabilities of the company. Within the Astra Hässle organization, the project advertisement had also created a sense of urgency and expectation and many employees were anticipating considerable changes and improvement. In this sense, the SCODA project was not a failure. Despite the shortcomings of the technical component, the deployment of SCODA and the other RDC-infrastructures was well in line with the FASTRAC results contributed to developing a change awareness in the organization.

The initiation of the six RDC-projects can, at least partly, be seen as the consequence of these expectations and the requirements for improvement. Clinical project leaders realized situations where they felt obliged to chose FASTRAC compliant technological and organizational infrastructures for their projects, but also to conduct the clinical tests within given time and budget frames. Since FASTRAC did not include detailed selection or implementation guidelines, the systems were chosen and implemented in accordance with decisions taken by clinical project leaders or the technical responsible in the projects. In the case of SCODA, the system was purchased from an external software company that took care of implementing the software as well as system maintenance. The system provider was also furnishing the network supporting the data transfer.

Consequently, a division of competencies for project support to monitors took place. Technical aspects were taken care of by the software company, and content or study related problems by Astra Hässle's project helpdesk. Several monitors, however, expressed doubts about this division, since the borderline between technical and content related problems was not clear to them, or to the help-desk staff. Before contacting the help-desk, the monitors had to determine whether the encountered problem is related to the study itself or to the technology employed, a question that often was considered as difficult to answer. Moreover, simple technical problems, that could have been fixed easily by the local IT support staff, had to be solved by the system provider in the Netherlands. A monitor in the USA described a situation where the laptop-computer had to be sent to the system provider in Europe for repair and re-installation and configuration of the RDC-client software. This proceeding was part of the contractual agreement between Astra Hässle and the software provider and related to warranty issues, but the monitors experienced this situation as time-consuming and frustrating.

Summarizing the results of the analysis, the SCODA deployment reveals the presence of different, and partially conflicting, rationales behind the decisions governing the selection, implementation and deployment of the RDC-infrastructure. On one hand, providing an appropriate infrastructure to support monitors' work was considered as important for improving overall performance in the clinical trial process. On the other hand, the chosen solutions had to be simultaneously compliant with the FASTRAC recommendations, i.e. to reduce cycle-time in the clinical trial process, which caused a dilemma when systems had to be selected. The monitors' working situation and experienced problems, related to local conditions in the countries participating in the study, are highlighting issues that can't be solved by implementing a system and process that primarily follows the rationale of cutting time and does not take into account the local circumstances under which it is used.

Considering the implemented solutions for all clinical projects, and the different rationales governing the underlying decisions, one can conclude that there was a significant amount of patchwork in the system selection and implementation process. While these aspects did not affect the performance and outcome of most studies, the SCODA project experience has revealed several factors that need to be taken into consideration.

The system was chosen and implemented to reduce cycle-time in data collection, while monitors' expectations included functionality for study management. In addition, the system came bundled with a process design and organizational procedures, i.e. that the project infrastructure for SCODA was a combination of information technology and organizational elements, partly conflicting with local objectives and environmental constraints. Consequently, the monitors were tinkering the infrastructure they had been provided with in order to adapt it to their local conditions, while still complying with the objectives of the SCODA project.

5. Results from the case study

5.1   SCODA as an infrastructure

In the SCODA project, the underlying foundation has been the design and use of a global business process, supported by high-end, standardized technology. The aim of this infrastructure, which actually can be considered as a bundle of a computerized system and organizational procedures, has been to achieve compliance with the strategic intent of the FASTRAC project.

Consequently, the selection of the SCODA infrastructure was not the result of cultivation (Dahlbom and Janlert 1996) or evolutionary processes in the organization, but stemmed from a single point of reference: The FASTRAC recommendations. Considering the span of FASTRAC, including new business process design and organizational change as well as cultural aspects, the SCODA project not only concerned the implementation of a computer system, but implicitly addresses the problem of interaction between technology and organization.

5.1.1   Change and drift

When analyzing the design and use of infrastructures, especially in large and multi-national organizations, it is crucial to understand the dynamics that occur as a result of the change process. Firstly, we have to consider the interplay between technology and the organizational structures and processes that surround it. Secondly, the tension between global and local, between design and inscription on the one hand, and local use and adaptation on the other hand, need to be considered. Distinguishing between global and local aspects also allows us to refer to the magnitude of the change process. Change at

infrastructure level does not only concern new forms of performing certain organizational tasks. It actually means to redefine their underlying foundation, the skeleton around which operational activities are built.

The FASTRAC project at Astra Hässle was conceptually based on the idea of radical and disruptive change and followed the steps being required for change initiatives under the label of Business Process Reengineering. The implementation of new technical infrastructures is a standard element of BPR efforts and in this sense, the SCODA project is not different from other initiatives. The BPR literature frequently pinpoints the mutual relationship between processes and technology and IT is considered as a supporter, as well as enabler of new organizational forms and procedures. However, when looking at the BPR-approaches previously presented and considering the conduct of BPR projects, the enabling concept often falls short. Instead, an in-depth analysis and detailed design of business processes is used as the point of departure for the IT-related aspects of the initiative, resulting in customized support systems for new process designs.

A perspective of the relation between IT and organization being similar to the one advocated in the BPR literature, though from an academic and more theoretical perspective, is promoted in the Strategic Alignment Model (SAM) (Henderson and Venkatraman, 1993). The SAM is pushing the idea of matching organizational structure and information technology to achieve an inherently dynamic fit between external and internal domains, comprising business strategy, IT-strategy, organizational infrastructure and processes, and IT-infrastructure and processes (Henderson and Venkatraman, 1993). The role of infrastructure is generally regarded as being an enabler for new pre-defined organizational forms and procedures. The SAM model's attempt to bring together multiple facets of the organization is, however, a difficult undertaking as, Charles O'Reilly, professor at Stanford University has noted:

> When we say organization what we mean is an alignment, and one of the reasons changing an organization is hard to do is that they are aligned in multiple dimensions and just getting one or two dimensions newly aligned doesn't work. (Source: Consulting Magazine, issue 4, 2000)

Both approaches are based on the assumption, that organizational and process change initiatives and the implementation of infrastructural changes are fully planable and predictable in their outcome. However, the study of SCODA suggests something different, namely that changes processes are dynamic and not fully predictable and that the implementation of new organizational procedures and IT-infrastructures are an inseparable element of this processes. Consequently, the outcome of the implementation of a new infrastructure is not fully predictable and the infrastructure in use is different from the ex-ante design.

Ciborra (2000) refers to this process as drifting, but does not necessarily consider it as being negative. On the contrary, drifting can be a way of balancing the bounded rationality of top-level decision makers, which are unaware of the aspects that influence the local units of the organization. In the SCODA case, this top level is represented by the process and systems designers at Astra Hässle, whereas the monitors are representing the local organizations that drift in their use of the centrally designed procedures and technology support.

A similar argumentation lies behind the use of divisionalized organizational structures. The bounded rationality, i.e. the cognitive limits, within top management is balanced by the introduction of operational divisions. Williamson (1975) has pointed out, that the decentralization of decision making that comes along with this organizational form also contributes to balancing the opportunistic behavior of middle management, since it facilitates a stronger identification with corporate objectives and reduces the favorizing of local goals at the expense of the central ones.

In the context of SCODA, it was clear that the local adaptations of the global process and the resulting work-arounds were opportunistic, but not necessarily in the sense that global goals were disregarded. The opportunistic behavior of monitors can rather be considered as a way of maintaining focus on the global goals under the limitations being imposed by local circumstances. Consequently, we might be able to speak about this behavior in terms of altruistic opportunism.

5.1.2 Global and local aspects

The change management and infrastructure literature uses several assumptions that, at a first glance, are rather clear and obvious. However, when taking a closer look, they appear to be somewhat simplified. A typical claim is that introducing new IT in institutionalized organizational procedures will enable strategically defined positive externalities. This claim is expressed for example by Broadbent, Weill & Clair (1995), but is also part of the strategic alignment concept and other proposals for business renewal, such Tapscott and Caston's (1993). In these contexts, the role of IT-infrastructure is clearly defined: It is an engine for business globalization and standardization of procedures throughout the global enterprise.

The analytical model normally employed in projects aiming at strategic change and following the reengineering and alignment philosophy is based on a description of business processes, the rational evaluation of change options, and the identification and implementation of the best innovative technologies and procedures to improve organizational performance from a given and well-defined point of departure. The position of infrastructure in this context is to enable and accelerate the defined business processes on a global level, where it is implicit that global means uniform. Shared databases and common sets of organizational procedures, often combined with workflow technology, are frequently proposed as measures to cope with diversity, which is considered as a disturbing factor

in the process of creating a global organization and implementing standardized business processes.

Consequently, the role of the infrastructure becomes more complex. Instead of being a means for supporting and improving business performance, it also becomes an engine for reducing variation and diversity in organizational processes. As Lévy (1996) puts it: The organization is striving for "universality with totality". Following this argumentation, globalization is not perceived as the process of organizing and doing business worldwide, but as a way of constituting a global institution, and thus to a large extent a process of standardization. Through standardization, local characteristics are homogenized to the global, predefined ones. The result is thus uniformity and conformity to a single standard design, rather than globalization in the sense that local circumstances are taken in to account in the design, implementation and use process.

A major imperative for the implementation of change based on the concept of standardization is the alignment of organizational structure and processes on one hand, and IT-infrastructure and its deployment on the other hand. The alignment concept suggests, that multiple organizational dimensions - strategy, culture, IT, structure - can be managed in a coherent way. Consequently, each form of misalignment or variation in the adoption process is considered as an organizational pathology, rather than an effect of local adaptation in the implementation process, and must consequently be removed or re-aligned in accordance to the pre-defined business process or action plan.

While the idea of alignment has gained wide diffusion in the management and IT field, there can also be raised some critique. Ciborra (1997) has argued that, despite the long existence of strategic IT plans, many organizations fail to realize alignment and that many examples of successful alignment seem to be ex-post rationalizations. In sum, alignment appears to be hard to achieve and is not the result of a purposeful process, but rather the outcome of a process of tinkering with IT applications.

Also the SCODA case reveals, that local adaptation of the globally defined infrastructure, variations in organizational procedures, and differences in the use of IT are characteristic elements of infrastructure implementation and deployment processes. Otherwise, globalization would be nothing more than the upscale of a local implementation process, and the global organization a larger extension of the local one. In this case, the process of globalization that many companies are struggling with would be relatively simple. To organize world-wide, however, means to deal with local circumstances and dynamics, without loosing perspective on the common goals of the global organization.

Summarizing the result of the case study we can conclude, that infrastructure implementation and deployment is highly situated. Situatedness derives from specific organizational needs, but is also strongly influenced by the dynamics of the change process, such as global and local organizational politics and power games. Instead of creating a single infrastructure, alternative systems were implemented to comply with the FASTRAC recommendations, partly for investigating different technological threads, partly due to a heterogeneous image of the planned change. Analyzing the specific infrastructure used in the SCODA project. an approach to change based on different levels of tinkering and improvisation was used, rather than reengineering and strategic alignment. (Ciborra 1997)

5.2 The relation between organization and technology

The relation between global and local aspects of an infrastructure, which we have found to be an endogenous element of its implementation and deployment process, can be analyzed through the concept of inscription (Akrich 1992). Using this approach, we can describe the world as being defined by the reciprocal interaction between objects and subjects. "Objects are defined by subjects and subjects by objects" (ibid., p 222), i.e.

that the world is inscribed in the object and the object is described in its placement.

This concept of reciprocity in the relationship between two phenomena lies at the core of the analysis of the relation between technological and organizational inscription with regard to local and global dynamics in infrastructure implementation. Taking this point of departure, we can describe how inscription occurs at technology and organizational level and what impact it has on the relation between IT and organization.

- **Technology inscription** can be defined as the rigidity of the technology in constraining the users in the way they are related to the technical object. In other words, it refers to the way technological systems can be used within or outside their design and which forms of work-arounds the system allows or prevents.

- **Organizational inscription**, on the other hand, reflects the level of freedom or rigidity in organizational procedures or, in other words, the extent to which organizational agents are allowed to reshape the ways in which the technical object are used with respect to organizational rules.

As a consequence of this relationship, organization and technology interact and reciprocally shape the organizational context that is resulting from their interaction. Technology is providing a platform for performing organizational activities, and the way of using the technology in the organization "situates" technology itself. Consequently, organization and technology can not be considered as separate entities, but must be seen as "flip-sides" of the same coin. Looking at organizational improvement initiatives, the reciprocal relation between IT and organization leads us to the conclusion, that it is impossible to isolate and improve either of these aspects without taking into account the other one.

Figure 5-1: The framework for analysis

The two-entry schema provides a combination of alternative scenarios based on different inscription levels in its two dimensions - organization and technology - and allows the characterization of different ways of conceiving infrastructure and its deployment. In this context, the term infrastructure refers to the combination of organization, processes and technology that is used within a company. The entries in the table represent four alternative infrastructure implementation contexts.

5.2.1.1 Strict alignment

In this case, the design of organizational procedures leaves no room for local adaptation. At the same time, technology is rigid: There is no option for use outside the defined context. Standardization of technology and organizational procedures and strict alignment between these elements typically characterize the infrastructure. In most process improvement initiatives, the aim is to develop and implement a strictly aligned organizational and technical infrastructure, following a pre-defined process design and using information systems that are supporting this design efficiently. Both improvement initiatives at Astra that have been investigated previously also had this intention.

5.2.1.2 Rigid Technology

Organizational procedures are open for local adaptation, while technology does not permit changes in use. Infrastructure is characterized by tensions between global and local organization procedures aiming at satisfying the same objectives, but differing in the means for their achievement. Despite the original intention to develop a strictly aligned infrastructure, the SCODA case falls into this context. The reason can be found in the lack of control that was exercised with regard to process compliance. It was assumed that all monitors would comply with the globally designed process and senior management was not aware of the local adaptations that took place.

5.2.1.3 Loose coupling

Organizational procedures and technology use can be redefined and adapted locally. The infrastructure allows adaptation to internal and environmental dynamics and is typical of knowledge intensive organizations. During the FASTRAC project, some voices already claimed that the company should aim at developing an infrastructure that would allow local adaptations and combine standardization with flexibility. During 1998, some middle managers in the clinical unit started to develop a framework that was less rigid than the BPR-track that had been followed in the FASTRAC project and also governed the CANDELA initiative. At that time, also some senior managers had adopted a more open view and advocated a loosely coupled infrastructure concept. However, the concept was never actually implemented, since the merger with Zeneca stopped all local initiatives of this kind and the sub-sequent efforts to integrate the two organizations are based on re-enforced hierarchical structures and creating centralized control mechanisms, rather than facilitating local initiatives and adaptability.

5.2.1.4 Rigid organization

In this context, organizational procedures are strictly defined at global level, while technology is open for modifications. The infrastructure is characterized by tensions between different technologies adopted at local level, or local variations in

technology use. This context is typical for a post-merger situation, where the merging firms are aiming at developing a common and standardized set of organizational procedures, but maintain their individual technical infrastructures. The AstraZeneca organization can be seen as an example of this setting. Since the design of the global IT-portfolio for the new organization is not decided, but still in the design phase, the technological level of inscription cannot be easily determined. The organizational changes having taken place since the merger, however, suggest that the company will aim at developing a highly standardized infrastructure and this makes the strict alignment scenario the most probable one.

Obviously, the four contexts presented here cannot serve as a prescriptive model for selecting the best possible infrastructure for a given organizational setting, or for optimizing an organization using a specific technology. Rather, they can be considered as an explanatory model to understand possible interactions between organization and technology and to outline the characteristics of the infrastructure in use in these two dimensions.

5.2.2   SCODA - a rigid infrastructure example

The infrastructure adoption process at local level can define or redefine the infrastructure in use. When this redefinition takes place, the actually deployed infrastructure differs from the globally defined organizational procedures, or prescriptions regarding the use of technology.

In the case of Astra Hässle, the infrastructure in use in the SCODA project is resulting from different local organizational adaptations due to the low level of organizational inscription. The monitors use different procedures, developed on the basis of a local organizational context, to fulfill their task, e.g. data entry is not always done on-site in the study center, as prescribed in the global process design. At the same time, technology inscription is high, the IT-system does not allow a local customization.

While standardized technology can be used for achieving a high inscription in the technology dimension, local factors can have a considerable influence on the implementation of organizational procedures and therefore, subsequently, on the infrastructure in use. In the Astra Hässle case, the different local adaptations of the global organizational process has created local, modified instances of the globally defined infrastructure and therefore it affecting and re-shaped it. To the designers, who were unaware of the adaptations taking place at local level, the infrastructure appeared to be homogeneous and global, but in fact, it was a conglomerate of locally adapted processes, supported by the same technological system.

Following the argumentation above, the SCODA infrastructure is not only constituted by the used technology and its highly inscribed characteristics, but is a result of the reciprocal relation and interaction between two dimensions, the organizational and technological. Limiting the analysis of infrastructure to either one of these dimensions, without taking into account the other, would provide an image of reality that is considerably different from what has been found in the case study.

The analysis of the technological dimension alone would lead to the conclusion that the infrastructure in fact is standardizing organizational procedures and resulting in globalization in terms of uniformity. Looking solely at the organizational dimension, we would find a non-articulated and uncoordinated puzzle of locally defined activities. In order to understand the scenario in which the organization is situated, as well as its implications for the infrastructure in use, it is thus important to take into account the organizational and technological dimensions and their level of inscription.

5.2.3 Global and local aspects of infrastructures

The analysis of the case study at Astra Hässle allows us to identify some critical factors for the introduction and implementation of a new infrastructure for the clinical trial

process within the AstraZeneca organization. Even though the lessons learned stem from a specific case, they can be applied in a wide variety of organizations.

It was observed that there is a divergence between the originally designed and anticipated way of working and the actual local work procedures being applied in the project. At the same time, the study of the technological infrastructure being employed for data collection and entry has revealed two major shortcomings.

- The technology only supports a sub-set of the tasks to be conducted by monitors in the project.

- The technology in its organizational context does not facilitate organizational processes to be fully compliant with the recommendations of the FASTRAC change initiative.

The infrastructure in use is thus the result of a deliberate planning process regarding the design of organizational procedures and the selection, implementation and use of information technology, intertwined with dynamic and unpredictable elements due to non-anticipated local adaptations.

In order to comply with legal and other requirements, clinical trial processes require certain rigidity, and thus a minimal general level of specification. As shown in the case study, a process definition and general rules for IT-use have been introduced through the FASTRAC framework: the global level of organizational inscription. However, IT-use was characterized by adaptation into its local organizational context: users actions took place at local level. Consequently, global design and inscription are only one element in the infrastructure adoption processes. Local adaptation and the unfolding of local inscription are other factors that influence the emerging work process and infrastructure use. In this case, the traditional managerial approach to study infrastructure deployment is not

fully sufficient to describe and understand the infrastructure in use and the global and local dynamics influencing it.

5.2.4 Misfit resolution strategies

Soh et. al. (2000) have identified four resolution strategies for handling the misfit been organizational and technological aspects of a change process. Their work is concerned with the implementation and deployment packaged software solutions, but the strategies they outline can be applied also to the deployment of infrastructures in a wider sense.
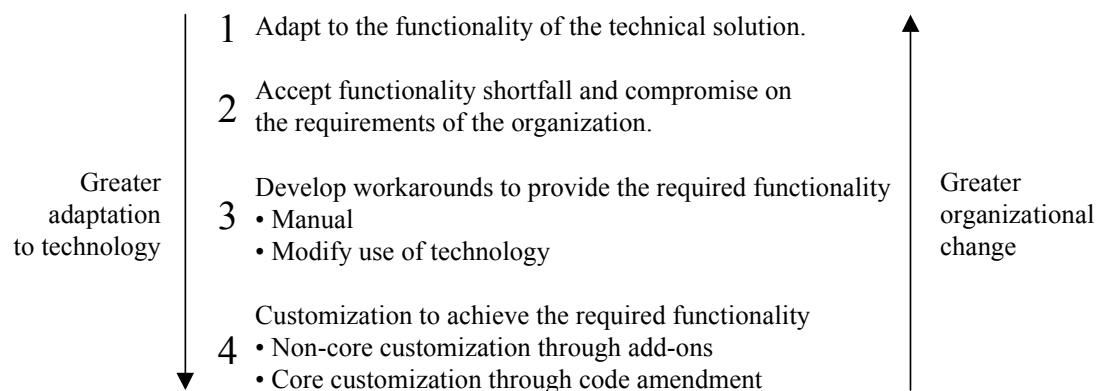

Figure 5-2: Misfit resolution strategies

The analysis provided by Soh et. al (ibid.) does not explicitly discuss global and local aspects of implementation and deployment, but they address the issue of implementing "best-practice" processes together with the technical solution, that do not fit the organizational requirements of the user organization. A similar point has been made by Brynjolfsson (1993). He used the term "productivity paradox" to describe the phenomenon that increasing investments in IT often only provide marginal performance improvements. and identified the lack of congruence between organizational requirements and IT-functionality as an important reason. The research results being presented by Soh et. al. and Brynjolfsson, even though stemming from a different technology application area, are congruent with

the results of the study presented here and leads to the following conclusion.

Infrastructure deployment has to be considered as the outcome of the interaction between global design and inscription and local adoption, rather than as the result of a deliberate and straightforward planning and implementation process. Local adoption processes regularly result in adaptation of global specifications and the development of locally situated technological use and organizational procedures. Different contexts of interaction can be identified, depending on the selected organization and technology: rigid organization; rigid technology; strict alignment; loose coupling.

5.3   Methodological aspects

The process improvement initiatives conducted locally at Astra Hässle (FASTRAC) and corporate-wide (CANDELA) both followed the Business Process Reengineering concept in a close way. Re-engineering, in virtually all of its incarnations, is based on the idea of designing global business processes, supported by standardized IT-solutions that are adapted to fit and follow the process design. However, as we have seen in the detailed analysis of one of the implementation projects of the FASTRAC recommendations, there is no guarantee that methodology compliance actually ensures success.

The approaches to process improvement being used in practice, of which two have been described and compared previously, also support this interpretation of how BPR initiatives are actually implemented: Organizational processes can be designed in a rational way, the best technology can be chosen and a global and standardized infrastructure, consisting of a set of business processes and IT-solutions, can be implemented and deployed. All deviations from the standardized design are considered as pathologies that must be removed and the process re-aligned with the original design. The implementation then follows the model described in Figure 5-3.
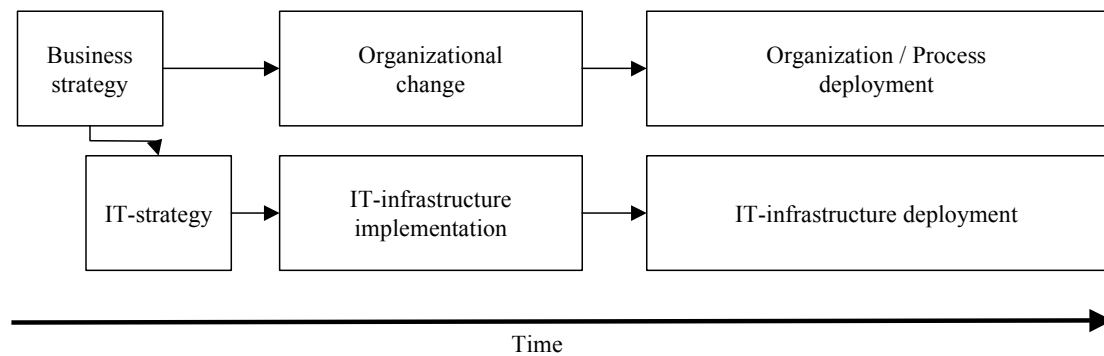
Figure 5-3: Traditional model for change implementation

While this linear model is appealing from a design and implementation perspective, there are two barriers to its implementation.

- The model does not consider "drift", i.e. the development of shortcuts and modifications of processes and the use of information technology.

- The model does not consider the different cycles times in pharmaceutical R&D and change initiatives.

5.3.1 The drift phenomenon

The FASTRAC project followed the dominating rationale for BPR-style projects. The development of the clinical trial process and the technological support system was governed by a linear approach based on the stages analysis, design and implementation under the assumption that a general process can be implemented and deployed. However, as the case study revealed, the local instances of the global data collection process showed deviations from the ex-ante design. These differences were the result of local process adaptations that were not anticipated by the designers.

It is important to note, that this phenomenon of "drift" (Ciborra, 2000) in the use of IT and the non-compliance with organizational process definitions did not emerge as a result of insubordination, but as an attempt to handle the incompatibility

of globally defined goals and locally imposed constraints. The "drift" phenomenon also passed by the internal check-mechanisms without being discovered. In other words, the designers of the process, located at Astra Hässle in Sweden, were unaware of the local adaptation that had been taking place in various countries. In fact, when they were revealed through the case study, design group participants were surprised and admitted that this had not been known.

The process re-engineering approach that was used for designing the clinical trial process being used in FASTRAC did not contain any element for addressing the issue of drift. Also the process improvement approaches being previously described in chapter do not cover the issue. Instead, the idea of top-down design is governing the methodologies, assuming that local deviations and adaptations can be avoided by inscribing certain behavior into the process. While these methods often contain an element of how to manage open resistance to the change process and the implementation of new technology, the issue of more subtle local adaptation, especially when it does not occur as a result of open and direct rejection, is not covered in the methodological frameworks.

The results of the case study suggest, that the aspects of global and local should be included into the methodological framework for process improvement in order to capture and address the dynamics that influence the organizational and technological adoption process. An alternative methodological model for implementing organizational and technological change could look like following.
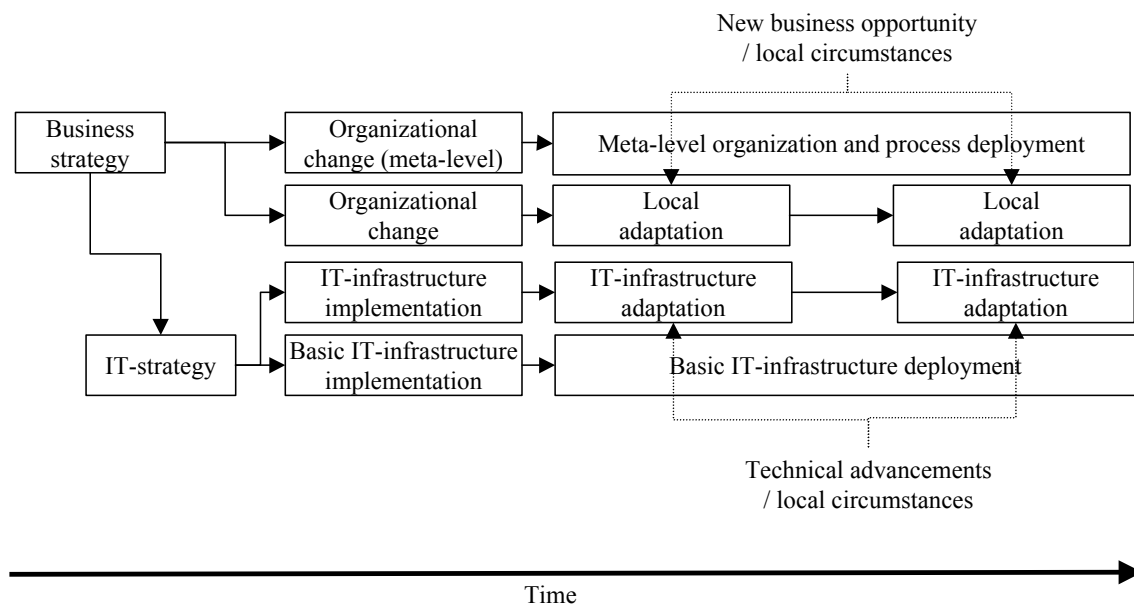
Figure 5-4: Alternative model for change implementation

The alternative methodological model suggests that design and implementation of new organizations, processes and IT-infrastructures should follow a layered-approach. It can be described by the following characteristics.

- **Organizational meta-level.** This layer represents the basic requirements being necessary to perform the process. In the pharmaceutical industry, this layer contains the organizational and process requirements imposed by regulatory authorities, which incarnate in mandatory Standard Operating Procedures. In addition, the meta-level contains the overall structural framework of the organization and business processes.

- **Organizational local adaptation layer.** The local adaptation layer contains the organizational and process elements that are open for changes at local level. These changes can become necessary as a result of specific circumstances in the local environment, as described in the SCODA case, or due to occurring business opportunities that require quick responses.

- **Basic IT-infrastructure layer.** The basic IT-layer constitutes the available portfolio of IT-systems that can be used for supporting a specific business process. In the case of clinical R&D at AstraZeneca, it contains the underlying systems for data collection and analysis, clinical trial management and SAE-reporting.

- **IT-infrastructure adaptation layer.** In this layer, we find the elements of the infrastructure that can be changed as a result of local circumstances or technical advancements that can be implemented without interference with the basic infrastructure levels.

The relation between adaptations at organizational or process level and the technical infrastructures is reciprocal and can be initiated from either direction.
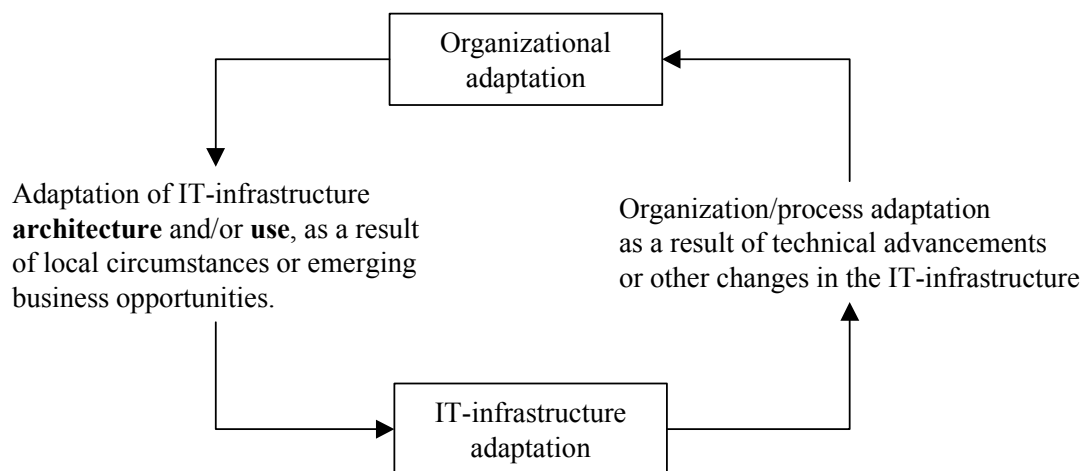

Figure 5-5: Relation between organizational and technical adaptation

Taking this issue into account when developing process improvement approaches, the following consequences are emerging for the organizational and process design stage.

- The local adaptation of business processes requires that the process design is open for modifications without compromising the overall architectural integrity.

- Process designs must be open to changes as a result of changes in the IT-infrastructure.

Both issues can be handled by the abundance of highly detailed process maps, thus allowing organizational members to create their own procedures locally. For the design of the IT-infrastructure, the following consequences are relevant.

- The use of the IT-infrastructure must be adaptable to changes in the business process they support.

- The architecture of the infrastructure must be flexible in order to allow local adaptations.

The first issue is related to the existence of highly detailed and prescriptive process descriptions. Designing infrastructures for processes with a high specification level and prescriptive activities almost necessarily fosters inflexibility. Maintaining architectural flexibility, on the other hand, requires certain technical requirements - modularity, standard based, multiple layers - to be satisfied.

5.3.2 Unsynchronized cycles

Within the pharmaceutical industry, the product development life cycle is typically very long, ranging from 8-12 years. The projects FASTRAC and CANDELA were initiated to reduce development time to an average of 4 years. At the same time, organizational and process improvement initiatives have a much shorter life cycle - it is not uncommon to embark on a change initiative every second year - and adopting a new organizational structure and/or business process in ongoing R&D projects is considerably difficult.
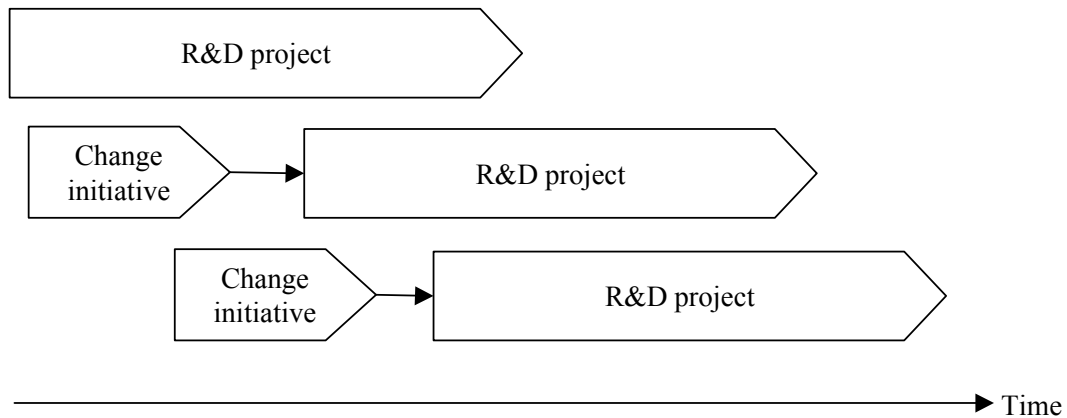
Figure 5-6: Life cycle of R&D projects and change initiatives

Consequently, change initiatives and R&D projects exist in parallel and in an unsynchronized way. This inability to synchronize results in the following effects:

- Change initiatives have a limited or no impact on projects that have been initiated before its conclusion. This was also evident in the FASTRAC project, where projects in progress were not supposed to adapt their organization and process structure or their use of IT. Instead, the FASTRAC results were supposed to be applied on new projects.

- As a result of the first effect, processes exist in different flavors, depending on the time the project in which they are deployed has been initiated.

It can also be concluded that the BPR approaches that have been investigated previously do not contain mechanisms to handle these effects.

5.4   The role of consultants

When the FASTRAC project was initiated, the knowledge about process orientation and how to initiate and run a BPR project

was rather limited within the Astra Hässle organization. It was obvious that external guidance from consultants would be necessary to run the FASTRAC project successfully. However, the criteria for which firm that should be selected were more diffuse.

The company had been working with consultants within the IS/IT area for a considerable time, but the FASTRAC-project clearly required competencies that were significantly different from systems development services. A formal list of requirement or competencies for the consultants did not exist and the choice was finally made upon the basis of personal chemistry between Astra Hässle's senior management and the senior representatives from the consulting firm. The argument was that personal fit was more important than formal aspects and that there were no substantial differences between the methodological approaches being offered by different consulting firms. The similarities between the different approaches described in chapter 2.7 support this claim and suggest, that the choice of consulting support on the basis of methodology only has a limited impact on a change project.

The selection process of the different consultants for the CANDELA project was based on a slightly different rationale. The consultants participating initially and serving as direct advisors to the project management team were selected on the same premises as the ones in the FASTRAC project. In fact, at least one of them was part of both projects, even though several projects participants were critical to his role in FASTRAC, especially regarding the level of commitment and quality of the work that the less experienced members of his firm delivered. However, the CANDELA project manager disregarded the critique and assigned the consultant to the project, again on the basis of personal chemistry. The supporting consultants from McKinsey and Andersen Consulting were brought into the project on the basis of an informal investigation, performed by the previously recruited consultants and the CANDELA project management team. Representatives from the consulting companies were

invited in order to present their methodological approaches and demonstrate their ability to perform the required tasks.

As a result of his investigation of the role that methods used by management consultants play for organizational change initiatives, Werr (1999) has claimed that methods serve the purpose of supporting consultants in their work and their interaction with clients. The primary use is to provide structures, concepts, checklist and roadmaps for analysis and design, and to provide a language that can be used for establishing common perspectives and a trustful client relation. However, he does not address the issue of their relevance as determinants for choosing a specific consulting firm.

Working with a consulting firm is not only a financial issue. The competence that consultants bring into a project, or the lack thereof, can contribute significantly to a project's success or failure. When considering the cooperation with a consulting firm, a company must consider several aspects, of which the completeness of concept and the ability to execute are the most important ones. For many consulting clients, it is also difficult to find the appropriate selection criteria when consulting firms are brought into projects, since they lack experience in buying professional services. On the other hand, competence itself is not sufficient and personal chemistry plays a role just as important as the formal competencies. The following aspects provide a compilation of factors that are relevant for the consultant selection process in the two categories concept and execution.

It also became obvious during the project that the personal fit between the consultants and Astra Hässle's senior management, which did not actively participate in the project, was not considered a sufficient selection criterion by all members of the project organization. Members of the FASTRAC team and the Astra Hässle organization frequently expressed dissatisfaction with the work the management consultants delivered. The critique included a perceived lack of understanding of company specific aspects, but also insufficient

content of project reports and resultless interviews and meetings.

However, as discussions with Astra employees reveal, this was not primarily a critique of the consulting firm in question, but also an expression of the general skepticism against consultants that could, and still can, be found in the Astra Hässle organization. The consultants from McKinsey and Andersen Consulting, participating in the corporate-wide BPR-project CANDELA, were met with the same skepticism and in personal discussions, many employees at Astra claim to be "tired" of consultants. In order to draw scientifically valid general conclusions from this phenomenon it would be necessary to conduct studies in additional organizations, but the Astra case could indicate that there is a correlation between the level of education and knowledge in an organization and the attitude its members have towards consultants. The Mölndal site is a R&D organization with hundreds of advanced degree holders - professors, MDs, PhDs - and for many people it can be considerably difficult to accept that external consultants, without knowledge of the company, tell them "how to do things around here". This observation was also made by Christer Mohlin, who was the responsible partner at Andersen Consulting for the CANDELA project.

6. Beyond BPR – Towards ...

6.1   A new model for clinical R&D

The traditional hierarchical models for organizing have been proven to be inadequate for coping with the challenges the pharmaceutical industry is facing. The need for shorter product development cycles and new discovery and development strategies require other organizational structures than those imposed by the bureaucratic paradigm of the early industrial era, which was targeted at the mass production of standardized goods.

In order to adapt their organizations, processes and IT-solutions to the changing environment and competitive situation, many pharmaceutical companies have embarked on large-scale improvement efforts, following the dominating change approach of the 1990s, Business Process Reengineering. However, as the results of the Astra Hässle case study have shown, that the BPR concept, as described in the literature and applied in practice, does not include the consideration of local implementation and adaptation issues in a way that allows to address them in a satisfying manner. Within BPR it is generally assumed that processes can be globally designed and implemented, and that organizational members comply with this process. As the case study indicated, organizational members actually adapt the global process to their local conditions, which might not have been appropriately considered during the design of the process. In other words, this "misbehavior" is no organizational or individual pathology that necessarily must be removed or subjected to change management action, but can be seen as a way to create efficient local instances of the global process.

In the same way, the rigid approach to considering IT and process infrastructures and deviations from the pre-defined design did not seem to fit the clinical trial process at Astra Hässle. Consequently, it became necessary to develop a new organizational model that would allow the local adaptation of business processes and technology use, without compromising operational efficiency. Together with members of the Astra Hässle organization, a model based on three building blocks - process, project, and center of excellence - was developed.
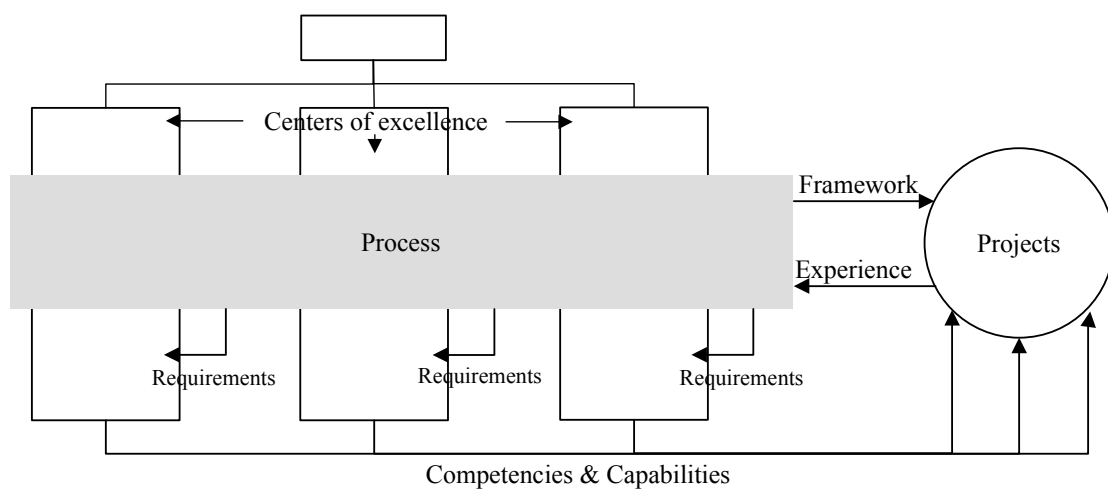

Figure 6-1: A new model for clinical R&D

The application of this model allows the company to establish clear responsibilities for each of the components and relationships between them and to overcome the deficiencies of the previously used models - hierarchy and business processes with a high level of specification and prescription of behavior.

Process. The process represents a conceptual framework for clinical projects. It contains a collection of the practices, methods and tools being required for conducting clinical research in an efficient way. The process is developed and managed by a process owner, i.e. a person being responsible for the improvement of the elements being part of the process, such as organizational procedures and IT-infrastructure. Process development, in this context, means to include the experience and knowledge gained from previous projects, but also to

consider external developments, such as emerging technologies and developments in other firms. The content of the process also describes the competencies and capabilities to be provisioned from the competence areas to the clinical projects. While the concept of process ownership is similar to the one proposed in the business process improvement literature and methodologies, the term process has a different meaning. Instead of being a detailed prescription of work procedures, it must be seen as a collection of best practices, recommendations and experience, supported by Standard Operating Procedures only where regulatory authorities require them. In this sense, the meaning of the term "process" follows the definition of a conceptual framework for integration, rather than work methodology.

> "A conceptual framework [...] is a meta-level model through which a range of concepts, models, techniques, methodologies can either be clarified, compared, categorized, evaluated and/or integrated." (Jayaratna 1994)

For non-regulated activities, the process leaves room for local adaptation and improvement in the clinical projects.

Projects. Today, clinical R&D is generally performed in project form, rather than by combining the activities of functional units within the line organization. A project is the instance of a process, where the methods and tools are deployed in a "real-world" setting, i.e. it contains the clinical research for an actual substance. Within a project, the framework provided by the process is used together with the competencies and capabilities provided by the organizational competence areas. The provisioning of services from competence areas to projects takes place on the basis of a market model. From the projects, experience gained is brought back into the process, which can be improved continuously according to the feedback provided. Projects are run by a project manager, who is assigned on a temporary basis for the duration of the project.

Centers of excellence and competence pools. Competencies and capabilities are provisioned to projects from

centers of excellence or competence areas, which are based on the functional units of the "traditional" organization. Competence areas can also be described as defined communities of practice within their functional areas. The members of these communities constitute a competence-pool, from which move into projects on a temporary basis. In this setting, the role of functional managers changes from supervisor to coach. In the coaching role, the continuous development of functional expertise plays an important role and must be matched against process requirements.

The above presented model also represents a way to overcome the limitations of a sequential change model and the lack of synchronization between change initiatives and R&D projects that has been pointed out in chapter 5.3.2 due to the following factors:

- A process does not represent a strict and normative way of prescribing the sequence and content of activities, but as a collection of experiences and tools.

- Process changes are not performed within dedicated initiatives, but are a continuous activity.

Consequently, there is no requirement for aiming at the design of a single, global process - a best way.

6.2   The extended enterprise

The use of Internet-based technical platforms for clinical trials allows the development of radically new organizational models for clinical R&D. Internet technology has a potential impact on several areas:

- **Community building around specific indications.** This concept has been proven successfully by other pharmaceutical companies, such as Roche in the field of
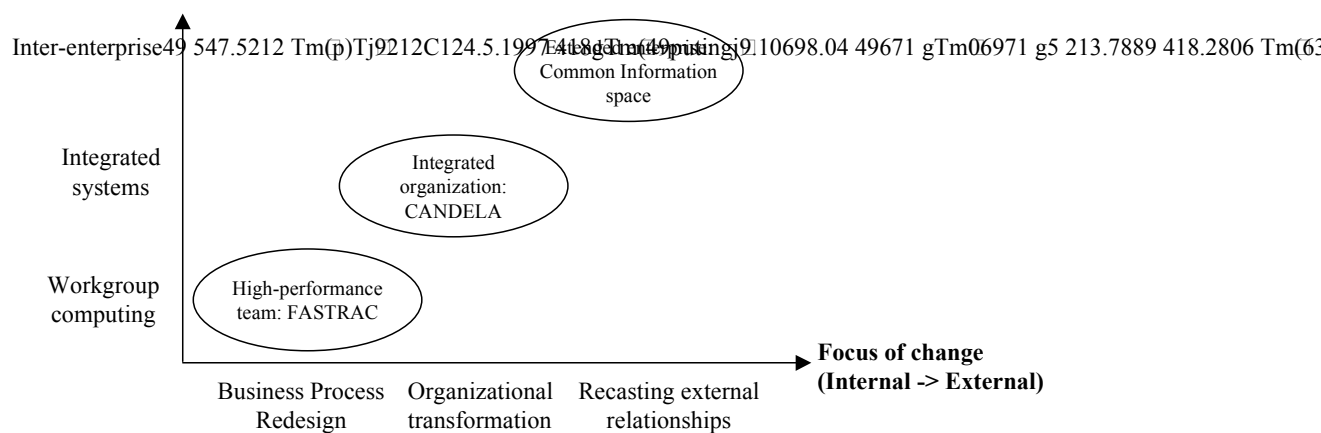
HIV. The development of communities allows the pharmaceutical company to maintain contact with patients and other interest groups, such as doctors, and individuals. A second aspect is that the pharmaceutical company can establish a certain level of control over the discussions taking place within the community, or at least take part in these discussions.

- **Patient recruiting for clinical studies.** Having contact with patients allows the pharmaceutical company to recruit patients for clinical studies directly from the target group for a new product, instead of using doctors as recruiters of patients. This direct contact to the recruiting base allows the reduction of the time for finding study participants and thus the overall cycle time of the clinical R&D process.

- **Inclusion of various stakeholders in clinical R&D.** As described in the previous section, the use of Internet-technology, more specifically a Common Information Space or Clinical R&D Portal, allows the pharmaceutical company to grant access to studies to different stakeholders, such as regulatory authorities, CROs, and patients.

All three areas named above share an increasing focus on the external parties being involved in clinical R&D. Instead of supporting internal processes and information handling, which has been the common approach in the past, the clinical R&D process becomes more transparent to all stakeholders, including those who have been largely excluded from the information flow. This means, that the organizational borders that exist between the different actors in clinical studies become less obvious. Instead, the process is extended beyond organizational borders and the enterprise is extended to include the external actors.

The sequence of improvement initiatives at Astra, including the future implementation of a new model supported

by a common information space demonstrates a shift with regard to the primary focus of change. Tapscott and Caston (1993) have developed a three-level model that describes the migration process from individual work and use of IT to the extended enterprise, with inter-organizational collaboration and computing under consideration of enabling technologies and the focus of change at each level. Each of these levels can characterize the aim of one change initiative at Astra.

Inter-enterprise49 547.5212 Tm(p)Tj9212C124.5.19971E4t8gdmt49prsingj9.10698.04 49671 gTm06971 g5 213.7889 418.2806 Tm(63

Common Information space

Integrated systems

Integrated organization: CANDELA

Workgroup computing

High-performance team: FASTRAC

Focus of change (Internal -> External)

Business Process Redesign

Organizational transformation

Recasting external relationships

a common global IS-portfolio, based on a set of integrated standard systems, was the major objective.

Clinical R&D Portal. The Clinical R&D Portal extends the Astra organization to include external participants in clinical studies. Investigators become an actor in Astra's clinical trial process not only by the manual collection of data that is handed over to Astra personnel, but by entering patient data into the system, participating in discussions and becoming a virtual member of the project group and the Astra organization is thus extended to include all participants during the duration of a study. The enabling technology also aims at including external actors under basically the same conditions as internal participants. The COOL-system, despite its current limitations, can be seen as a first step towards the implementation of a Clinical R&D Portal.

6.3   A clinical R&D portal

The use of Internet-technology within clinical R&D is a relatively immature field. A recent survey (Andersen Consulting, 2000) among 50 R&D managers in pharmaceutical companies revealed, that only 10% are using the Internet for patient recruiting. However, a majority of the respondents stated that they expect a significant increase of this figure within the next three years. A majority of the respondents (80%) also expected significant cycle time reductions and cost savings (68%), as well as new forms of cooperation between the different actors being involved in clinical R&D, such as NDA-filing (68%). These figures are also supported by the results of a questionnaire among the participating investigators in the studies supported by COOL, where 71% of the respondents declared, that the use of the Internet-based application was a clear advantage compared to other alternatives.

However, in order to reap these potential benefits, it becomes necessary to deconstruct the tight coupling between organizational structures, process models and technological

systems. At Astra Hässle, the development and use of COOL (Clinical Operations On-Line), an Internet-based system for clinical data collection, was a first step into this direction.

6.3.1 The history of COOL

COOL was initiated as a response to the shortcomings of the sequential, batch-oriented data-collection and –management systems that Astra had been using, such as the already discussed SCODA. A first discussion in the Clinical IT-department resulted in the development of a prototype as proof-of-concept, a demonstrator of the technical feasibility that was finalized during the second half of 1997.

The first version was focused on study management by supporting the collection of administrative study data, rather than clinical information from Case Report Forms (CRFs). The reason was simply that patient data handling requires a high level of confidentiality and security in the collection and transmission process and was not considered as feasible for a prototype. The working prototype was presented to the management of the clinical unit of Astra Hässle, and at the same time, a non-critical project was chosen for practical demonstration of the prototype. Since the demonstration was largely successful, the COOL-initiative gained support from the clinical unit's management and the development of a production system was initiated in the middle of 1998 and, with full functionality, used in a clinical study at the end of the year.

At the same time when the COOL idea and concept was developed, the Astra group's top management had initiated CANDELA (see chapter 3.6), aiming at a group-wide standardization of R&D processes and systems, for the latter selecting commercial products wherever possible. Despite this requirement, COOL could be developed further, due its successful demonstration. However, in the middle of 1998 the technology steering group of CANDELA decided that the development of COOL should be discontinued.

Since the decision regarding the new standardized IT-portfolio had not been taken yet at that time, the local Astra Hässle management decided to use COOL in another clinical study. When the results of using COOL for data collection in the first studies were analyzed in 1999, the work of the standardization group was discontinued since it was proven, that none of the, at that time, commercially available products could match COOL in terms of functionality and performance. The final recommendation of the IT standardization group was to advocate the further development of COOL into the standard tool for data collection in clinical trials.

6.3.2 The use of COOL in clinical studies

The use of COOL in clinical studies was a local decision, taken at Astra Hässle by the management group of the clinical unit. At the time of the decision, the system had been tested, but it was not clear, whether it would actually provide substantial benefits compared to the technical solutions already in place. Consequently, the studies did not only serve as a technical testing ground, but had to demonstrate the business benefits that, so far, had been assumed to be realizable, but not been demonstrated.

The first study comprised 440 patients; spread over 40 centers in Canada, Denmark, France, Germany, Spain and Sweden. The second study involved an identical number of patients and centers, but the centers were located in the Czech Republic, Hungary and Poland.

Since COOL was not only another application used to support an already existing and proven process, but also represented a different kind of thinking about clinical trials, training became an important issue in the preparation and implementation phase, not only for the staff at the study centers, but also for the study monitors and other Astra personnel.

6.3.3 The benefits of COOL

The COOL-system does not require specific persons - investigators, study nurses, or monitors - to enter the clinical data. Instead, any person that has authority to log on to the system, i.e. can take on the role of data entry, can perform this activity, independent from his/her organizational belonging. In other words, the data collection process is no longer prescribing who is supposed to perform a certain task; instead it provides technical support for performing it, based on a role model for the collection process. The local implementation of the process and its roles can thus be delegated to the locally responsible managers for the study.
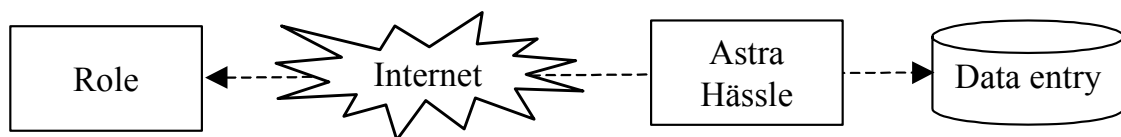

Figure 6-3: Data collection process with the COOL-system

In addition, the COOL-system uses the AMOS clinical database system directly, i.e. that data is entered directly into the central system, without intermediate storage in a client system. Also piled CRFs in the client, as it occurred in the SCODA project, can be avoided and consequently, over-recruiting is reduced through the on-line availability of project status information to the central study management.

In addition, the direct attachment of COOL on top of the already existing data management system protected the previous investments, since it did not require the replacement of any of the existing systems.

Metric	Study 1	Study 2
Recruitment (FPI to LPI) in days	175	128
% of visits entered within 2 days	69	54
% of queries resolved within 2 days	23	24
% of queries resolved within 7 days	45	55

Metric	Study 1	Study 2
Final locking in days	8	5
Final data checking in days	6	7
Last patient out to Clean File in days	14	20

Table 6: COOL data collection process metrics (adapted from Dimenäs et.al. 2001)

The use of COOL actually resulted in a substantial reduction of cycle-time in data collection, going far beyond what could be achieved through process improvement initiatives and the associated infrastructures for clinical data collection that followed a pre-designed business process. The following table describes the cycle times for some of the core metrics of the data collection process.
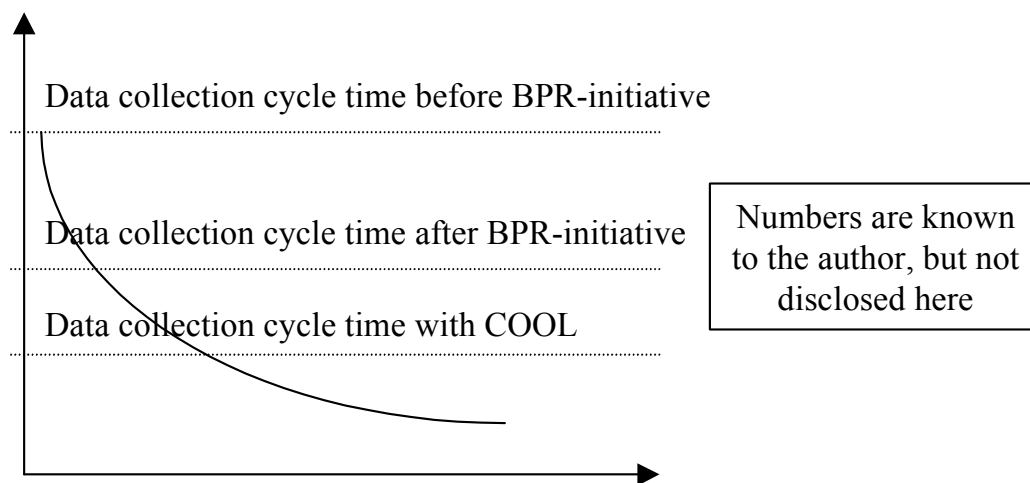

Figure 6-4: Cycle-time reduction in clinical trials

The development of COOL was the result of a local initiative in Mölndal, taken by some developers and the head of the clinical IT department. In its current form, COOL is primarily a tool for data collection, but it also represents a different concept for the organization of clinical R&D.

Following the model described in Figure 6-1, COOL is a part of the process element of the organization, but it does not

include a process prescription and leaves the form of its use to the project in which it is used. In this sense, COOL represents an example for the "loose coupling" infrastructure implementation context.

COOL, as an application, is also only a first step towards the development and implementation of an infrastructure that ties together all relevant stakeholders in clinical R&D - investigators, monitors, project managers, data managers, regulatory authorities, patient communities - through one single entrance point. This common information space, or Clinical R&D Portal, allows the instant delivery and exchange of information in clinical R&D projects and provides accurate and timely information to its users. Besides further improvements of clinical trial management, for example through on-line availability of patient recruitment status information and on-line monitoring of Case Report Forms (CRFs), the portal also facilitates cooperation within and between different communities that are participating in the research project, or have other interests in it, such as patient organizations and regulatory authorities.
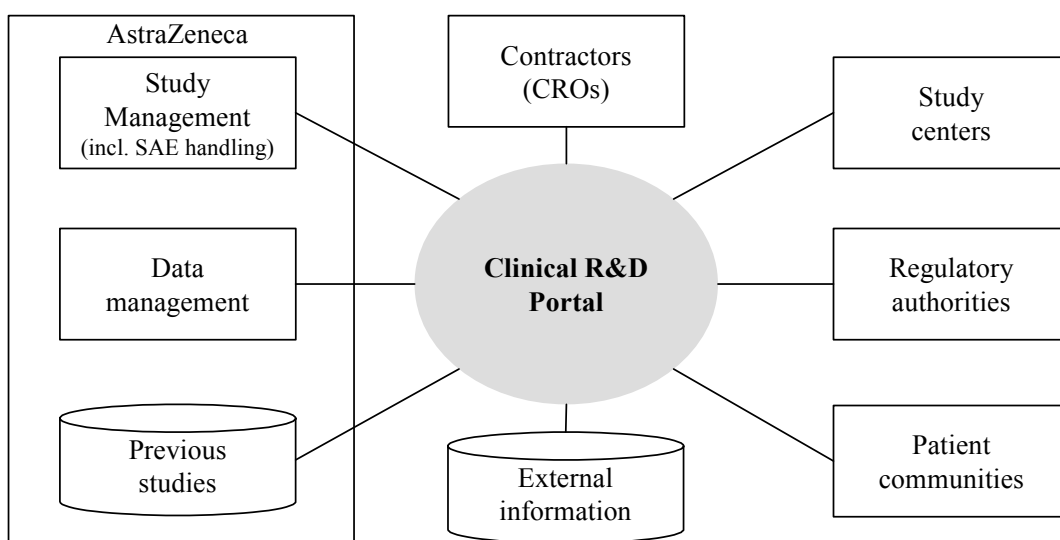

Figure 6-5: The Clinical R&D Portal concept

The current version of COOL has a simple form of cooperation functionality, but does not allow the categorization of users in different communities, since it focuses on one user segment: investigators. In order to establish a Common Information

Space, Introducing discussion areas for different stakeholder communities is a way of providing added value to users, but also to create loyalty among investigators, who can engage in research oriented discourses and "chat" with other participants on a global basis. Also, the handling of SAEs (serious adverse events) can be improved significantly. In the current version of COOL, there is some functionality for publishing announcements and notifications, while the actual SAE handling still is based on a manual side-process. Within the portal, SAE-related information can be distributed instantly and, if desired, regulatory authorities can be linked directly into the SAE-process.

The creation of patient communities, based on specific indications, is also an important issue in the context of creating customer loyalty. Today, many patients are no longer passive recipients of medical treatment and medication. Instead, they use different sources, most notably health-focused web-sites on the Internet, to actively search information about indications and possible treatments and medications. These sites are typically developed by patient organizations, health-care organizations and pharmaceutical companies. They provide advice about the treatment of diseases, product information, and several also offer on-line discussions with doctors and other patients.

Even though the purpose and intentions of the different sites varies, mainly depending on the provider of the service, they provide a significant marketing potential for the pharmaceutical industry, if used properly. On the other hand, they also constitute a threat, if the provided information and statements express a negative attitude towards products or specific pharmaceutical companies. Consequently, pharma-companies have an interest in offering these services themselves and maintaining a certain control over the information being exchanged and discussions taking place. Considering the customer bases of the pharmaceutical industry, the service should target two main user groups – physicians and patients.

The following benefits can be identified for users, but also the pharmaceutical company offering the service.

Stakeholder	Benefits
Patients	• Customized information about specific indications, their treatment and products. • Access to current research that patients normally do not have access to, such as research reports and results from clinical studies. • Contact with physicians. • Offering of free treatment during clinical trials in which they participate.
Physicians	• Better informed patients. • Access to current research and clinical studies. • Possibility to take part in clinical studies. • Positioning as informed treatment provider for patients.
Pharmaceutical company	• Access to patient information through patient inquiries and the logging of user behavior. • Easy access to recruitment base for clinical trials, i.e. direct contact with relevant study participants and faster recruitment. • Information about the perception of the company and its products in the patient community and by physicians.

Table 7: User groups and benefits

6.4   Spinning off Clinical R&D

Traditionally, pharmaceutical companies have performed clinical studies internally. For the operational work, local doctors in different countries were recruited and data collection was partially managed by the companies' local market organizations,

but project management and overall coordination was performed by the Clinical R&D department of the company. The SCOPE study was no exception to that rule and the COOL-system was intended to support the extended enterprise concept, but not to change the organizational structures and belongings within Astra.

Over the past years, pharmaceutical companies have increased their cooperation with Contract Research Organizations (CROs), thus outsourcing many of the previously internally managed activities to an outside organization. Activities performed by CROs might range from patient recruiting and data collection to actually managing entire studies, including protocol writing and even submitting the New Drug Application. There are several reasons that lie behind the outsourcing of clinical studies:

- Through specialization on a specific part of the overall R&D process, CROs gain a high level of experience and develop and deploy efficient and effective processes.

- Through higher efficiency, CROs can perform a clinical study at lower cost and the pharmaceutical company does not have to maintain a large-scale clinical R&D organization.

- Many pharmaceutical companies do not consider the operational elements of clinical R&D as a core competence and by outsourcing them to CROs, they can concentrate on a limited number of core activities and develop their capabilities within these fields.

The level of outsourcing of clinical R&D activities varies between different pharmaceutical companies. While some use CROs as an extension of their internal clinical R&D departments in case of utilization peaks, others take a more radical approach. Aventis, for example, has decided to spinout the entire clinical R&D unit, including the clinical IT department. The new company has a

three-year guarantee for assignments from Aventis, but after this period it is subjected to competition on the market and considered as any other CRO. Ulrich Nickel, head of the new company states:

> "Yes, it will be tough for us and there is a considerable need for business process improvement in our organization in order to become a top-tier CRO. On the other hand, we can now develop our organization, processes and technology without interference and we actually believe, that we will be able to perform higher and also to motivate our people better than before, when we were part of a big company."

7. Final remarks

The promise of BPR, to deliver order-of-magnitude improvements in cost and time reduction, without compromising the strict demands for quality that surround drug development and testing, has been an appealing concept to many senior executives in the pharmaceutical industry, including Astra and its R&D subsidiary Astra Hässle. During a period from 1994 to 1998, management at Astra Hässle and Astra's corporate level initiated several organizational and process improvement efforts. A re-organization of Astra Hässle, focusing on improvements within the existing functional areas, took place in 1994. In the following year, a BPR project was launched and in 1997, corporate management initiated a group-wide re-engineering effort. These initiatives resulted in the introduction of new business process designs, organizational structures and new IT systems. The outcome also resulted in a two-digit reduction of cycle time in clinical R&D and allowed the company to reduce their costs, but at the same time, these savings were only to some part the result of an intentional analysis, design and development of business processes and IT-systems. Elements of adaptation and drift also influenced the actual outcome of the change projects.

In this thesis, a history of the change initiatives that have been taken at Astra Hässle (now AstraZeneca) and the impact of these initiatives on clinical research & development has been provided. In order to provide the reader with a framework for the reasoning in this thesis, a review of the history of organization theory, from classic theory to process-based organizations, has been offered and the described theories have been discussed and briefly criticized.

The concept of process-based organizations and Business Process Reengineering has been taken into special consideration, since it governed the change initiatives at Astra Hässle, and a

detailed description of process improvement approaches being used by different consulting firms, has been included. Two of these firms have been actively involved in the projects at Astra.

During the case study it became evident, that global and local issues played an important role in the implementation of organizational and technological infrastructures. The tension between globally designed processes and IT-tools and their local deployment was found to re-shape the designed infrastructure in ways that were not anticipated. This issue was discussed as part of the analysis of a project-specific infrastructure for remote data collection and a model for identifying different infrastructure implementation issues was developed.

Finally, a new organizational model for considering clinical R&D, developed by the researcher and AstraZeneca personnel, has been outlined. This model, currently in an initial and tentative form, offers a more suitable rationale for designing clinical R&D at AstraZeneca. Future research will be dedicated to developing this model and following its use.

The new organizational model also required a new concept for the design of IT-infrastructures that does not prescribe or require certain organizational structures or processes. The common information space, or clinical R&D information portal, based on the COOL-system that was developed at Astra, seems to be a feasible solution to the issue of handling the relationship between organizational and technical aspects of the clinical R&D infrastructure and global and local aspects of the implementation and deployment process. Summarizing the results being presented in this thesis in brief, we can compile the following list:

- The process improvement approaches being used by management consulting firms are similar with respect to scope and methodological steps. Consequently, the subsequent discussion of the FASTRAC and CANDELA initiatives is not specifically related to one specific way of conducting BPR-projects.

- Conducting BPR-style change initiatives, following the general methodological approach to BPR, in a company such as Astra Hässle is not the most efficient way to improvement, since aspects that are crucial to the efficient implementation and deployment of organizational infrastructures are not taken into consideration.

- The fit, or mis-fit, of organizational and technical aspects is a critical success factor for corporate change initiatives. High levels of organizational and/or technical inscription may result in work-arounds that modify the global design of processes and IT-use and re-shape the infrastructure in use.

- New organizational approaches and forms of technological support are required to improve operational performance in clinical R&D at Astra. A first step into this direction, proposing process, projects and centers of excellence as organizational building blocks, has been taken and a first version of an on-line system for clinical trials has been developed and successfully deployed.

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