

# Infrastructure deployment: Global intent and local adoption

Antonio Cordella & Kai A Simon

Viktorias Research Institute  
Göteborg

## 1 Introduction

After World War II, the pharmaceutical industry developed to become one of the most profitable business sectors. The development of new drugs against so far intractable diseases (about 1.000 new products were registered in the 1950s) resulted in the emergence of large scale pharmaceutical companies, that often had their roots in the chemical industry.

The pharmaceutical market is also very different from other 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.

During the past few years, however, significant changes have taken place in the pharmaceutical industry. New drug indications and niche products, in combination with higher demands for documentation and drug safety<sup>1</sup> by regulatory organizations (US

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<sup>1</sup> The sleeping pill Thalomid, 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.

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 reduced profitability. Despite the fact that profits still are high, these developments have forced pharmaceutical companies to rethink their business and to redesign their way of developing, testing and marketing products. A 1995 article in Information Week stated that

*”the pharmaceuticals industry faces a radically shifting client base and revised business economics that have put a squeeze on profits. As a result, drug-makers have had to downsize, consolidate, and reorganize during the past years. In an industry, where a product’s life cycle rarely lasts more than a dozen years, and profits are no longer guaranteed, efficiency has taken on a new urgency. (Information Week, Sept 18, 1995)*

Also Astra Hässle, a research company in the Swedish Astra group, has found itself in the position of needing to improve its organizational processes, in order to sustain its position as a successful research company with products accounting for a considerable share of Astra group sales. Since the early 1990s, multiple change projects have been conducted under a variety of labels.

These projects basically reached their aim in terms of creating a more efficient functional organization and also succeeded in delivering some operational improvements. The development of new organization infrastructures has taken place as at corporate level as well as at branch level. More important, this consideration of the company infrastructure has also resulted in an increasing awareness that a more general overhaul of Astra Hässle’s business processes would be required in order to ensure that time-to-market for future products could be reduced significantly. Especially the clinical trial process infrastructure, which has a considerable impact on R&D cycle time, has been attracting attention as a potential area for major improvement, as several competitors have already developed and established clinical trial processes allowing them to reduce time-to-market by several years.

Being aware of this situation, Astra Hässle started a large-scale infrastructure reengineering style change effort under the name of FASTRAC in 1995. The strategic

intent of this initiative was cutting time from *Investigational New Drug* to *New Drug Application* by half, from an average of +8 to 4 years. The achievable benefits of reducing cycle time in clinical trials were considered significant in terms of cost savings and competitive advantage.

*Traditional drug development is lengthy (6-12 years) and expensive (\$60-240 million). When combined with the limited duration of patent protection, any delay or misdirected development costs only increase the charge to the patient for effective pharmaceuticals.* (Program Statement: Center for Imaging and Pharmaceutical Research, Massachusetts General Hospital)

The project was finalized in early 1996, and the report contained a set of recommendations, aiming at organizational change, the development of new IT infrastructures for clinical trials, and the re-establishment of the “Hässle spirit”

The FASTRAC-project was aiming at a complete overhaul of the clinical trial process, including the re-consideration of the Information and Organization Infrastructure. In the spirit of reengineering and related concepts, such as time-based management, there was a strict business process and cycle-time focus. Also, information technology was conceived as one of the major enabler of a new, streamlined and time-compressed clinical trial process. Special attention was paid to Remote Data Capture (RDC) as a technological infrastructure component that would allow a faster and more accurate handling of information during clinical trials.

The analysis of this case is taking its departure in one of the six RDC-implementation projects that were initiated for providing a technological infrastructure for clinical studies. It shows that the actual implementation and use of the infrastructure is not fully aligned with the strategic intent of the FASTRAC reengineering initiative. The local adoptions of organization procedures and the technology for supporting them have been influenced by the tension between local and global dynamics that were not considered in advance.

## 2 Company setting

Astra Hässle is a research company within the Swedish Astra group, focusing on the development of pharmaceuticals for cardiovascular and gastro-intestinal diseases. The company employs about 1.400 people at three sites: Mölndal and Umeå in Sweden, and

Boston (MA) in the United States. The company has a line/staff organizational structure, consisting of four operational and four staff units. The current organizational structure derives from a restructuring project conducted in 1994.

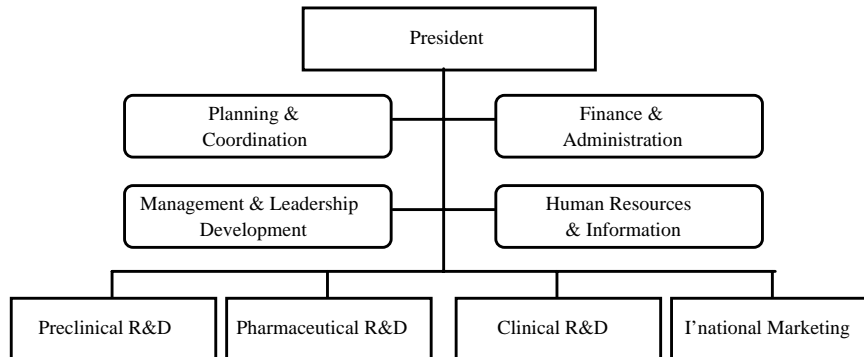


Figure 1: Astra Hässle organizational structure

In 1997, the Astra group achieved a total sales volume of 44,9 billion SEK, of which products originating from Astra Hässle accounted for more than 80%. The Astra group's main product, Omeprazole, accounted for about half of the group's sales, including licensed products, thus making it the best selling drug world-wide, but also creating a significant dependency from a single product.

The core competencies of Astra Hässle have traditionally been 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 become 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 considered as a major enabling factor for successfully re-designing the clinical trial process, thus reducing the time and resources required for testing new drugs and contributing to an increased return-on-investment.

### ***2.1 The clinical trial process***

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 sub-sequent sub-processes. Traditionally, the three phases within the clinical trial period have also been conducted in sequence, and a major aim of the current change initiatives is to parallel the planning, conduct and analysis of multiple trials within the same study.

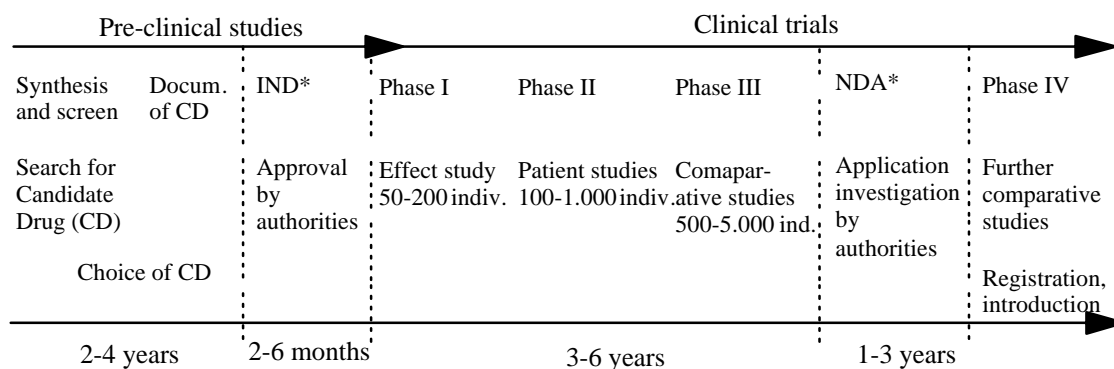


Figure 2: The drug development process

### **Chemical synthesis**

In this stage, 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 return-on-investment (ROI).

### **Pharmaceutical research**

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 trial

Clinical trials comprise a series of different tests, where a new drug is tested on different patient groups. The purpose of these tests is to find the optimum dose, detect side effects, and study the drugs treating effect. These tests are conducted at different clinics in various countries. The results of the clinical trial phase, extensively documented and analyzed, is the basis for the application for approval to the respective authorities in different countries. 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 FASTRAC: Reengineering at Astra Hässle

In order to cope with the need for improved efficiency and effectiveness in the clinical unit, a reorganization project was conducted in 1994, resulting in the current organizational structure and putting more emphasis on the use of project organizations around certain products or candidate drugs.

While the pathologies being detected in the organizational structure were handled rather successfully, the project was not taking a business process perspective. At the same time, the need for cycle-time reduction in the clinical trial process became apparent and consequently, a major initiative, devoted at redesigning the Information and Organization Infrastructure in clinical trial process, was launched in 1995. The major aim of the FASTRAC-project (*Fastest and Smartest to Registration and Commercialization*) was squeezing time out of the clinical trial process and establishing new work practices. The FASTRAC project was also considered as a major leap forward to the achievement of the strategic intent of the company.

*Astra Hässle has set four main targets, which 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. (Astra Hässle WWW-pages)*

While the new research area, biochemistry, is currently established and a research facility in Boston has been opened, the objective in the area of drug development was

considered to require an in-depth redefinition of the company's business processes and infrastructure in order to be feasible.

Four processes were considered as being of major importance for achieving the strategic intent: Drug acquisition, clinical trial, market support and safety—of which clinical trial was conceived as the one offering the highest potential for improvement due to its time and resource consuming structure.

The FASTRAC project was set out with a limited number of objectives that were stressing the importance of a general overhaul of work procedures and establishment of “Hässle spirit” in the clinical trial process. Additional emphasis was put on the use of IT for enabling new organizational forms and work processes. The projected targeted three main areas:

- Clinical Data Handling
- Planning and Reporting
- Hässle spirit

For each of these areas a project group, consisting of members from the involved units, 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.

To support the groups in their work, third party assistance was contracted. A team of five consultants of an international management-consulting firm was assigned to the project.

The FASTRAC project was planned during spring 1995, and presented to the members of the unit during June. The project groups started their work during the summer, 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 project groups leaders were assigned with 50%. Due to the overall time

frame and the request to deliver results after 6 months, group leaders were allowed to dedicate 100% of their time to the project by November 1995.

The reporting date was followed by a 10-week period dedicated to develop an implementation plan to be realized until fall 1997. For conducting these final stages, a group called FIST (Fastrac Implementation Steering Team) was formed.

### **3.1 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. In summary, the report indicated the following areas for potential improvement of the clinical trial process.

#### **Project planning and prioritization**

In order to focus the available, yet limited, R&D resources on the most promising areas, adequate mechanisms for project planning, assessment and prioritization must be developed and adopted. So far, too many projects are conducted with highest priority, thus resulting in internal competition for resources.

#### **Document management**

While clinical R&D very often is perceived as a primarily research oriented process, document management is, in fact, critical to process 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.

#### **Use 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 are 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.

### **Process cycle-time**

The clinical trial process was generally considered as being too time-consuming. Paralleling work, improved coordination and cooperation between line and project organization and the implementation and use of a more efficient IT-infrastructure are identified as the major enabling factors for time reduction.

### **Sequential and parallel work processes**

The conduct of various work processes, especially Phase I-III studies, has often been 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-stated in the process.

### **Improved cooperation between line organization and projects**

The interaction of line and project organization is crucial for the proper allocation of resources to projects, training and development of staff and appropriate decision taking. Improving the cooperation between these two organizational structures contributes to a more appropriate project management.

### **Establishment of “Hässle spirit” as encompassing guidelines**

Hässle spirit, often considered as part of the organizational culture, play 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.

### **Integration of temporary staff into the organization**

Besides its directly employed staff, Astra Hässle uses consultants 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.

In order to attack the identified problems and access the improvement potential, a set of measures was identified, ranging from the introduction of new technical infrastructures

for clinical projects, over operational improvements, to changes in the organizational value system.

- Planning and document management is simplified
- Parallel sub-processes are introduced
- The clinical part of pre-studies will be shortened
- Data retrieval and handling is simplified
- Mechanisms for measuring project and process impact are developed
- “Hässle spirit” are used as the basis for the new process

The development of new IT-infrastructure for clinical projects was considered as an important contributing factor for the targeted achievements. Consequently, a variety of projects, tied to clinical trials, was initiated.

### ***3.2 Six IT-infrastructure projects***

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 for investigating possible infrastructures for providing support to clinical trial projects. As a measure to improve performance in clinical data handling, special attention was put on RDC, i.e. the collection and transfer of clinical data by means of technology. The use of an RDC based infrastructure was seen as a way of satisfying organizational and technological needs of the new process design. Six projects, employing different technologies, were initiated:

#### **Apple Newton**

For a quality-of-life study, a system for data entry by patients was developed and implemented on 130 Newton PDAs. The system was based on multiple choice lists and ticking boxes and was accepted by people with a wide age variety.

### **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. Medical personnel at the test center enter the clinical data directly into the central database at Astra Hässle through a WWW-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.

### **Datafax/OCR**

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 considered as a cost-effective technology.

### **SCODA: Semi-RDC**

Instead of employing direct data entry, the SCODA system consists of a data entry client and a server module. The transfer between client and server application is achieved through a modem-connection through a private network.

### **AMOS C/S on WAN**

AMOS is a study and data management system developed internally by Astra. In its client/server version it consists of a proprietary client for data entry and access and a database.

The tested solutions range from traditional forms of data capture, over client/server based architectures to Internet-based RDC. In what follows, object of study is the semi-RDC approach based on client/server technology: SCODA.

## **4 The SCODA project**

SCODA is a data capture application for clinical projects conducted at 500 centers in 12 countries, and comprising 4.000 patients.

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 choice of the new organization and technologic infrastructure was based on the rationale of supporting the clinical study with a timesaving tool for data collection. At the same time it was anticipated, that data quality would increase due to shorter feedback cycles between study monitor and the medical personnel at the study centers.

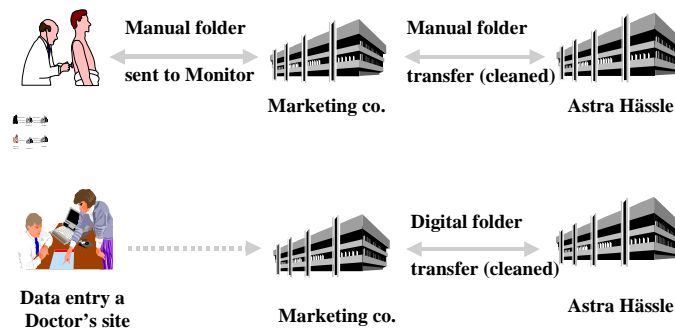


Figure 3. Old and new process design

The new process is aiming at bringing data collection and quality control together at the study center. Data entry is moved from a central center to the study monitors and data cleaning and entry is supposed to take place on-site in cooperation between monitor and center personnel. This new process design has changed the work content of study monitors to a large extent. From primarily being concerned with data cleaning and local study management, their work now spans over wider part of the process, including the actual data entry into the computer systems.

## **5 The SCODA Case Analysis**

The report resulting from the FASTRAC project contained an analysis of the existing clinical trial infrastructure and recommendations for a new process design and other areas for improvement. However, the delivered recommendations did not include a specific implementation strategy. The decision to use RDC, and consequently for

introducing a new project-specific infrastructure, was delegated to the clinical project leaders.

The technology to be used for supporting RDC was chosen locally for each project, based on knowledge about available systems existing in the Clinical IT department. Also in the SCODA project, the choice followed the same rationale. The system under concern, provided by Technilogix, supported RDC functionality and had recently been purchased and implemented at large scale by another pharmaceutical company, Glaxo Wellcome. However, the system was not originally developed for being used by study monitors, but for data entry by doctors, and was thus lacking functionality for study management.

### ***5.1 The SCODA implementation process***

Implementing infrastructure and organizational processes is neither simple nor intuitive. The SCODA implementation process has revealed several aspects to be considered in the context of introducing infrastructure.

#### **Software training**

The Technilogix software, used as the technological component of the new infrastructure, had not previously been used within Astra Hässle. Also, it was employed for the first time for being used by study monitors, instead of being used directly by doctors. Consequently, training was an important issue. The study monitors of the system received a 2-day training. However, the training period was considered insufficient. Also, the training was not conducted on the final version of the software, but on a version that was still under development in order to include some additional functionality requested by Astra Hässle. This caused a delay in use, when the monitors first had to adapt to the final version.

#### **Work procedures**

Together with the use of the infrastructure, new organizational procedures were introduced. Instead of collecting paper copies of medical records, which then would be shipped to Astra for data entry, monitors were supposed to stay at the test site and enter the cleaned medical data into the SCODA-system. The case study revealed, that there was no full compliance with this procedure, for which the following reasons were found:

- Time limitation: Depending on the number of test centers for monitoring, and their geographical distribution it is not always possible to follow the rule without excessive travel time.
- Budget constraints: The project budget is negotiated between Astra Hässle and the local market companies in advance of the project. Consequently, when more traveling than anticipated is required, the result is a conflict between study rules and budget constraints.

As a result of these problems, we found situations where the process was applied in accordance to its design, but the monitor conducted the actual data entry at home or at the company office, rather than on-site at the test center.

### **Project management and “serious events”**

As mentioned, the Technilogix system was originally developed for supporting doctors in their data entry. The main focus of the system was therefore to enable a structured and sequential data entry process. Considering the work conducted by monitors, the work setting was rather different: Data is entered at different times and in varying sequences. Also, the monitor’s job includes being the local manager of the project. In order to facilitate effective management, the system would need to contain additional functionality for supporting management requirements, which was not available.

An important aspect of clinical studies is the handling of so called *serious events*, e.g. side effects or other unexpected occurrences. In case of their occurrence, they are to be reported immediately to Astra Hässle. Due to the asynchronicity of the system, it is impossible to include serious events handling. As a consequence, a manual procedure based on phone and fax communication is used instead in parallel with the computer based data collection process.

A second aspect related to system asynchronicity, and common for all client/server systems, 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, together with 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. Consequently, central study

management and data analysis at Astra Hässle is heavily depending on the functioning of local client systems

### **System choice and implementation**

During the case study a considerable discrepancy emerged between the monitors' needs and the organizational and technological support provided to them. In order to improve the conduct and performance of future projects, it is therefore important to understand the underlying rationales and intentions that influence the choice of technology and organizational procedures in clinical projects.

Considering the outcome of FASTRAC, it was obvious that momentum was too important to be lost in long-term evaluations of different options. The initiation of six RDC-projects can be seen as the consequence of the need to achieve fast and tangible results in the FASTRAC implementation phase.

Clinical project leaders realized situations where they were 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 implementation guidelines, the systems were chosen and implemented in accordance with decisions taken by clinical project leaders or the technical responsables in the projects.

The Technilogix-system chosen to support the SCODA-project was implemented and maintained by the vendor, who also provided the infrastructure for data transfer. The help-desk function in the project was thus divided between technical aspects, taken care of by Technilogix, and content or study related problems, supported by Astra Hässle. Several monitors, however, expressed doubts about this division, since the borderline between technical and content related problems was not clear to them, and to the help desk-staff.

Summarizing the results of the analysis, the SCODA deployment reveals the presence of different, and partially conflicting, rationales behind the decisions taken. On one hand, providing appropriate IT-support for clinical projects was considered as important for improving overall performance in clinical trial process. On the other hand, the chosen solutions had to be simultaneously compliant with the FASTRAC recommendations, which caused a dilemma when systems had to be selected.

Considering the implemented solutions for all projects, one can conclude that there is a significant amount of patchwork in the system selection and implementation process.

## 6 Discussion

Webster's New World dictionary (1988) defines infrastructure as

*"a structure or underlying foundation; the basic installation and facilities on which the continuance and growth of a community, state, etc. depends, as roads, schools, power plants, transportation and communication system etc."*

In the SCODA project, the underlying foundation is found in the design of a global business process, supported by standardized technology. The aim of this organizational and technological infrastructure is to achieve compliance with the strategic intent for the FASTRAC project. Consequently, the selection of the SCODA infrastructure is not the result of cultivation (Dahlbom and Janlert 1996) or evolutionary processes in the organization, but stems from a single point of reference: The FASTRAC recommendations. Considering the span of FASTRAC, ranging from organizational change to technological solutions, the SCODA project not only concerns the implementation of a computer system, but implicitly addresses the problem of the interaction between technology and organization.

When analyzing infrastructure redesign processes, the understanding of global and local dynamics and the occurring tensions are crucial. Distinguishing these two levels of change, we can refer to the depth and magnitude of the change process. Changing infrastructure means to redefine the underlying foundation, the skeleton on which operational activities are based.

The FASTRAC project at Astra Hässle was conceptually based on the idea of radical and disruptive change, as promoted in the literature addressing Business Process Reengineering, and also used in the Strategic Alignment Model (SAM).

The SAM is pushing the idea of matching organizational structure and information technology to achieve the inherently dynamic fit between external and internal domains, such as business processes and information technology (Henderson, Venkatraman, 1993). The role of infrastructure is often regarded as an enabler for new pre-defined

organizational forms and procedures rather than being a non-separable element in a dynamic and not fully predictable change process. Accordingly, the use of simplified assumptions, e.g. that introducing new IT in institutionalized organizational procedures will enable strategically defined effects, is a common conclusion in the infrastructure related literature (see, Broadbent, Weill & Clair, 1995). Moreover, IT infrastructure is conceived as an engine for business globalization and standardization of procedures throughout the global enterprise.

This analytical model is based on a description of business processes within the organization, the rational evaluation of change options, and the identification and implementation of the best innovative technologies and procedures to improve organizational performance.

Looking at how infrastructure and its implementation and diffusion are discussed in the managerial literature, it is implicit that global means uniform. Consequently, the infrastructure 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.

A major imperative for the implementation of standardized change is the alignment of organizational structure and processes on the one hand, and information technology infrastructure and use on the other hand. 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 be removed or re-aligned in accordance to the pre-defined business process or action plan.

The case reveals that local adaptation of globally defined structures, variations in organizational processes, and differences in the use of IT are characteristic elements of infrastructure implementation. 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. To organize world wide, however, means to deal with local circumstances and dynamics, without losing perspective on the common goals of the global organization.

In sum, infrastructure implementation is a highly situated. Situatedness derives from specific organizational needs, but is also strongly influenced by the dynamics of the change process, such as local and global organizational politics and power games.

The case study shows that alternative systems have been implemented, partly for investigating different technological threads, partly due to a non-homogeneous image of the planned change. Despite the strategic intent of designing and implementing a common infrastructure, this reflects an approach to change based on different levels of tinkering and improvising, rather than reengineering and strategic alignment. (Ciborra 1997)

### ***6.1 Organization and technology: reciprocal inscriptions***

The relation between global and local aspects of infrastructure can be analyzed through the concept of inscription (Akrich 1992).

Akrich points out that "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 infrastructure implementation.

*Technology inscription* refers to the rigidity of the technology in constraining the users in the way they are related to the technical object. *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 following the organizational rules.

Organization and technology interact and reciprocally shape the organizational context which 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.

Organization Inscription	H	Rigid Organization	Strict Alignement
	L	Loose Coupling	Rigid Infrastructure
		L	H
		Technology Inscription	

Figure 4: The framework for analysis

The two-entry table in fig.4 provides a combination of alternative scenarios based on different inscription levels, and allows the characterization of different ways of conceiving infrastructure and its deployment. The entries in the table represent four alternative infrastructure implementation contexts.

**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. Infrastructure is typically characterized by standardization and strict alignment.

**Rigid infrastructure**

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.

**Loose coupling**

Organizational procedures and technology use can be redefined and adapted locally. The infrastructure allows adaptation to environmental dynamics and is typical of knowledge intensive organizations.(see the Chapter on the Roche case)

**Rigid organization**

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.

Obviously, the four contexts presented here can not serve as a prescriptive model for selecting the best possible infrastructure for a given organizational setting. Rather, they can be considered as an explanatory model to understand possible interactions between organization and technology and to define the infrastructure in use.

The local adoption process can define or redefine the infrastructure in use. 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 organization 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 at the doctor's place as defined in the global procedure. At the same time, technology inscription is high, i.e. the IT-system does not allow a local customization.

While standardized technology can be deployed to achieve a high technological inscription, local factors can have a considerable influence on the implementation of organizational procedures and thus on the infrastructure in use. On the other side, highly inscribed organization procedures can be affected by local adaptations of low inscribed technology. Local adaptations are thus a critical factor in defining the infrastructure in use.

## 7 Conclusion

The analysis of the case study allows the identification of some critical factors influencing the introduction and implementation of a new infrastructure into the clinical trial process at Astra Hässle. Though these lessons stem from a specific case, they may be applicable 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 infrastructure being used in the data collection and entry process has shown that it is not fully sufficient to support the study monitors' job. Also, it does not allow the use of an organizational process fully compliant with the recommendations of the FASTRAC change initiative.

The infrastructure in use is thus a consequence 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 inscription. However, IT-use was characterized by adaptation into its local organizational context: inscription also took place at local level.

Global design and inscription is thus only one phase in the adoption process of infrastructures. Local adaptation and the unfolding of local inscription are other factors that influence the emerging work process and use of infrastructure. In this case, the traditional managerial approach to study the infrastructure deployment is not fully sufficient to describe the infrastructure in use. This approach leaves the analysis at the surface.

Studying the deployment of infrastructures in global organizations means to study the infrastructure in use, not only on the surface. The case study has shown that raising the awareness of the tensions between global and local design and adoption is important.

Infrastructure deployment has to be considered as the outcome of the interaction between global design and inscription, and local adoption. Local adoption processes regularly result in adaptation of global specifications and the development of local inscription mechanisms. Different contexts of interaction can be identified, depending on the selected organization and technology. Limiting the analysis to the identification of mis-alignments may not allow the full comprehension of the dynamics of change.

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## Bibliography

- Akrich M., The description of technical objects, In: W. Biker, J. Law (Eds.) *Shaping technology/building society*, MIT Press, pp.205-224, 1992
- Broadbent, Weill & Clair, *The role of information technology infrastructure in business process redesign*, CISR WP. No. 278, Sloan WP no. 3824, Center for information systems research, Sloan School of Management, 1995
- Ciborra C., De profundis? Deconstructing the concept of strategic alignment, *Scandinavian Journal of information System*, 9 (1): 67 - 81:1997
- Dahlbom, B. and Janlert, S. Computer Future, Mimeo, Department of Informatics, University of Göteborg, 1996.
- Henderson, J.C. and Venkatram, N., Strategic alignment: leaving information technology for transforming organization, *IBM Systems Journal*, 32, 1:4-16, 1993
- Lévy, P., Essai sur le cyberculture: l'universel sans totalité. DiversCité Langues. En ligne. Vol. 1 1996-1997. Available at URL <http://www.uquebec.ca/diverscite>