

PharmaPOST full study

This project summarizes the intended conduct of a MTO-programme research study at Astra Hässle during a period of 20 calendar months, 010598-311299. The project is an up-scale of a pilot study conducted during the first months of 1998, and its content is based on the results of the pilot study, as well as research needs expressed by the industrial partner.

Background

The pharmaceutical industry is undergoing substantial changes. Despite high profit margins in many companies, a wave of mergers and acquisitions is taking place internationally. Also, authorities have increased their requirements for product documentation, and many companies are struggling with improving their processes in order to introduce new and improved products, while at the same time reducing cycle times in their R&D processes, thus shortening time-to-market.

Also Astra Hässle, a research company in the Astra group, is coping with cycle time reduction and R&D process improvement. During the past years, several projects have been conducted in order to exploit the opportunities delivered by emerging technologies, and to overhaul business processes and organizational structures. One of the projects, FASTRAC (Fastest And Smartest To Registration And Commercialization), conducted during 1995-96, was aiming at the clinical trial process at Astra Hässle. The investigational phase of the project delivered a set of critical success factors and areas for improvement that were targetted for further action. These areas included organizational issues, as well as technological solutions.

As part of NUTEK's MTO-research programme, a pilot study was conducted at Astra Hässle, investigating the outcome of one of the actions taken, namely the introduction of a semi-RDC system for the collection of data during clinical trials.

Summary of intermediate results

The results of the pilot study reveal, that the introduction of new technology, combined with new work processes and content is not only crucial, but can be highly critical to the conduct of clinical trials. The rigidity of organizational procedures and the design and use of technology are thus important aspects to consider when engaging in change and improvement activities.

For analyzing the impact of organizational and technological *inscription*, i.e. the predescription of how to use technology and how to comply with organizational procedures, a theoretical framework was developed.

Also, based on observations made during the case study, aspects of project management were initially explored. More specifically, the self-reinforcement of projects has been

briefly discussed, and will be further developed in the paper in progress. Apparently, the *Leitbild* of a project can have a significant influence on the conduct of the project, and can subsequently replace the original project objectives, thus becoming a goal in itself.

A draft of the project report in form of a paper to be published is attached to the project application document.

Cooperation aspects

The pilot study did not only serve as a research project, aiming at the identification of further research needs. It also was considered as an explorative effort of cooperation between academia and corporate world. An initial evaluation of this cooperation effort is currently in progress, but promising results are anticipated

- The cooperation between company members and researchers has been without friction, and the contact person at Astra Hässle will dedicate a significant share of his time to the future project.
- The case study has revealed research questions, being relevant for Astra Hässle, but also for other companies and the research community.
- The project has, through its relation with the InfraGlobe research project, become a link between two research networks.
- Initial results show a good potential for also contributing to theory development.
- The pilot study report will be published as a book-chapter in an anthology comprising a set of case studies from various companies and industries.

Project outline

Based on the results of the pilot, a longitudinal study is planned, starting May 1, 1998. The study will closely observe the way of Astra Hässle into the next millenium with regard to aspects of organizational change and IT-use. Especially aspects of infrastructure will be investigated due to the significant importance for the company.

Research areas

The following research areas will be addressed in the full study. Each area is one partial project, which will be conducted independently, but logically related, to the other parts. The deliverable for each partial project is an article/report to be published at a relevant international conference. In the following, we will briefly outline the major characteristics of the partial projects and the most significant questions to be addressed and discussed.

The deliverables for the partial projects are outlined in the dissemination section below.

Investigation of infrastructure literature

The idea of infrastructure originally stems from warfare and comprises a country's transportation system, manufacturing capabilities, and other requirements for efficient warfare. In the IT field, infrastructure is often described in terms of Wide-area networks (WAN), communication systems, and global accounting systems (such as SAP).

However, when looking into companies it is apparent that also organizational processes and structures, as well as norms, values and beliefs play a role similar to that of the technical infrastructure. In order to make sense of the terminology, a careful investigation of current literature must be conducted.

The initial part of the full study will consist of a thorough investigation of the literature in the infrastructure field, and a summary of the major problems being identified. This investigation will take place in the light of the theoretical model being developed during the pilot study.

Questions/Aspects

- What is state-of-the-art in infrastructure theory and practice?
- Which are the most important issues being discussed?
- Which are the most important areas to be addressed for further research?

Exploration of organizational dynamics

The employment of IT is virtually always, also at Astra Hässle, justified with arguments regarding improved efficiency, shorter cycle-times, or cost reduction in business operations. At the same time, the introduction of new technology, often combined with new forms and contents of work as well as efforts aiming at organizational restructuring, may result in unexpected organizational dynamics, resulting in increasing complexity, rather than improved performance. Previous research by the project group has indicated that investments in IT infrastructure not necessarily must result in improved coordination and cooperation but that, in fact, IT can have a negative impact on organizational performance.

Questions/Aspects

- Is there a *diseconomy of scale* in IT implementation and diffusion processes?
- Can a break-point be identified? *and* How can it be identified, if at all?
- Are the indicators or models that would allow a break-point determination?

Knowledge development and management

Companies such as Astra Hässle are highly depending on various forms of knowledge management in their organization. While this has been rather actively utilized in the company's traditional core activities, e.g. chemical synthesis and pharmaceutical research, it is not obvious to what extent similar mechanisms are used in the IT-area. Also, the possible effects and gainable momentum from actively employing information technology in the knowledge management processes will be taken into consideration.

Questions/Aspects

- Are there mechanisms for knowledge management in the IT-area?
- How does the knowledge management (collection, dissemination, etc.) look like?
- Which measures can be taken to enable an active utilization of the KM process?

Bounded rationality in IT and change implementation and diffusion

Classic theory in the management field, but also current theorists, often claim that decision taking is a merely rational process, where alternative options are evaluated and the most appropriate solution is chosen and implemented. However, at the same time, the rapid pace of environmental changes, as well as bounded rationality, politics and other factors influence decisions of large magnitude and serious consequences for an organization and its business. Therefore, it is apparently important to investigate the rationals behind decisions made regarding organizational change measures and information technology.

Questions/Aspects

- Which rationals govern the decision making process for change and IT-implementation processes?
- On which basis can/should decisions in this area been taken, and are there general indicators which could guide the decision process?

Research setting

As the pilot study, the full study will be conducted in cooperation with Astra Hässle, and to a major extent also with a focus on this particular company. Where necessary, the scope of the project will be enlarged to also include issues on Astra corporate level being important to the project.

The main cooperation partner within the company is Elof Dimenäs, formerly director of clinical IT and data management, now responsible for strategic change in the clinical unit of the company. Also, Pehr Johansson, responsible for process development in clinical IT, as well as other staff will be involved on a temporary basis. The involvement of 2 industrial PhD-students, Astra Hässle employees participating in a postgraduate education at the Viktoria Institute, is currently discussed.

Method

The primary methods being applied in the project are based on the principles of action research, i.e. researchers actively participate in the company processes, rather than playing an observing role. This allows a deeper analysis of company internal issues and can, in line with the MTO programme objectives, also result in sustainable results.

Since a significant amount of the project is conducted as an empirical study, i.e. that interviews with organizational members are conducted at various places and action research plays an important role, it is necessary to ensure that certain competencies are available. While the management and information technology aspects are covered within

the project group, competence in the behavioural science field has been connected to the project through the involvement of ethnographic competence. Magnus Bergquist, PhD in ethnography, will assist the project in maintaining a high relevance with respect to the "M"-element of the project.

Company contribution

Astra Hässle's annual financial contribution to the project will primarily be accounted in terms of working hours of company personnel. For the below calculation, a flat fee has been applied for hourly costs. The calculation is also based on the lowest expected contribution and time spending.



Contribution to MTO-programme objectives

The PharmaPOST study comprises aspects regarding individuals and their work, technology and organizational issues, thus covering the full range of areas within the programme. According to the MTO programme statement, research projects participating in the programme should deliver a substantial contribution to the improvement of change conducts and technology implementation. Both of these areas are well covered in the PharmaPOST project.

The project will also be reviewed on an ongoing basis. This proceeding will take place in part through discussions with the MTO-steering group, but also by direct concertation meetings between company and research staff.

Dissemination of results

The results of the research being conducted within the project is primarily disseminated in the form of conference and journal articles. Also the MTO concertation meetings, as part of the synthesis programme, play an important role for spreading results to corporations and the research community. More specifically, the following reports/scientific deliverables are planned for the project period.

Deliverable 1

A paper investigating current literature. The paper will also discuss the limitations of traditional management approaches in dealing with dynamic aspects of organizational and information infrastructure.

Deliverable 2

A paper discussing "diseconomy of scale" in technology investment and implementation. (Submitted in May 98 to ICIS - International Conference on Information Systems - December 98)

Deliverable 3

A paper discussing the divergence between the envisioned organization, processes and technology, and the actual outcome of the change and implementation exercise.

Deliverable 4

A paper on the impact of the technology on the organizational knowledge management processes.

Deliverable 5

A paper further outlining the concept of organization and technology inscription and the consequences for IOI implementation and use.

Since detailed information regarding the internal and external MTO programme activities has not been available at the date of submission of this project description, these activities were not included in the list. However, further planned dissemination activities are:

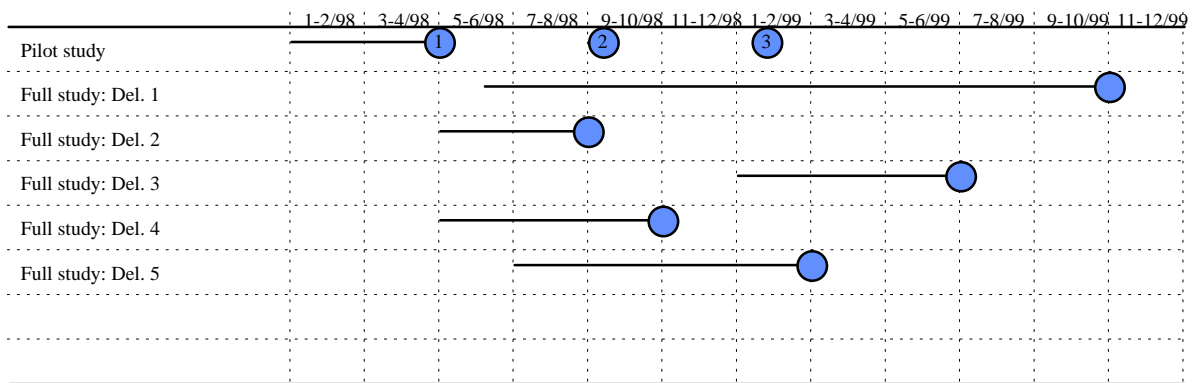
- **August 1998:** Workshop at the Scandinavian IT-research conference IRIS in Denmark
- **September 1998:** Launch of the Italian book version containing the pilot study (published by IBM Research Foundation) in Bologna
- **Early 1999:** Launch of the English book version containing the pilot study

Also, the project results will be made available through a WWW-site. Information about the pilot study has already been made available through this channel. The current site has the following address:

<http://www.viktoria.informatik.gu.se/groups/manageit>

Time scale

The project has an initial planning period of 2 years, including the pilot study. The following Gantt-chart outlines the activities being planned for this period. Further envisioned, but not actually fully planned activities are not included.



- ① • Application for full study
• Pilot study report submitted to NUTEK
- ② • Italian book version of pilot study report
- ③ • English book version of pilot study report