A BUSINESS PROCESS FRAMEWORK
for
GENERATING BUSINESS VALUE
through
INFORMATION TECHNOLOGY
in
PHARMACEUTICAL DEVELOPMENT

- A WHITE PAPER -

INTRODUCTION

Though many efforts have been made to build business cases for Information Systems investments, and to determine their ROI, information systems investments are still among the least well understood by companies in most every industry. While numerous formulas and approaches exist to calculate the amortization of manufacturing equipment, the business cases developed for information systems are rather weak in comparison. Phrases like “drastic improvement”, “strong reduction” and others are used to describe a perceived value that can rarely be quantified.

In fact, information systems are hardly ever measured against their return on investment. Systems projects generally end with a simple user acceptance test of the installed hardware and software. User acceptance, however, does not demonstrate whether the system has actually improved the bottom line of the business making the investment.

Amortization formulas focus mainly on the purely financial return of an investment. On the other hand, Information Systems generally impact all three dimensions of business performance: Quality, Cost and Timing.

This paper explores the issues behind this problem, and describes a methodology that has been used successfully in almost every aspect of pharmaceutical development to

- define information systems,
- design information systems, and
- evaluate proposed systems solutions

In a way that makes it possible to understand and quantify their contribution toward achieving the business objectives set for the organization.

And though there is no single/simple equation that provides the answer to how well systems themselves contribute to the achievement of business objectives, there is a way to ensure that a company’s systems development or selection projects do so. This can become particularly important in today’s environment where multiple systems projects generally withdraw significant amounts of resources from the organization. When this happens, they cannot be utilized to pursue the core business activity of developing, submitting and marketing drugs.

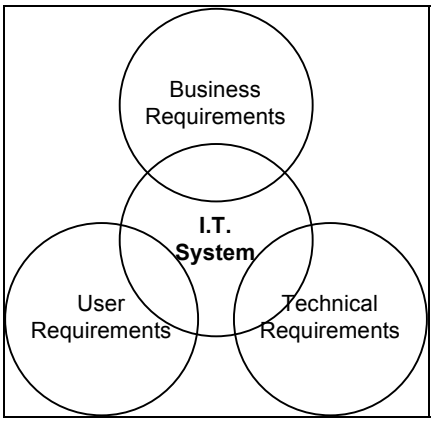
While consuming minimal resources from the user community, the approach described in this paper has shown to speed up systems projects in all stages of the Systems Development Life Cycle. This is basically achieved by focusing and validating every step and decision along the systems development or selection process around one objective: to deliver measureable Business Value to the organization.

Some History

In the early days of the computer, the user basically had to make do with what the programmers delivered. And because programmers generally had a fairly low level of understanding of the users business, the solutions - often helpful, sometimes fancy gadgets - did not generally meet the users' real needs.

It took years for software developers to create and respect formal procedures that included the structured assessment of users' needs. And, for a long time, technology itself put significant restrictions on the programmer's ability to meet those needs. Even today, we can witness numerous systems projects where technical limitations are used as (more or less valid) excuses for not completely meeting user requirements. Though technology has made quantum-leap-like progress in the last few years, particularly when it comes to systems integration issues, technical limitations still dictate the possibilities given/offered to users.

For an executive, leader or manager, systems development projects are usually driven by the need to make the organization more efficient, or to make it leaner, or to make products of a higher quality or at a lower cost. Thus, while there is a set of business requirements, they are usually neither of a technical nature, nor can they always be expressed by the individual users of a system.

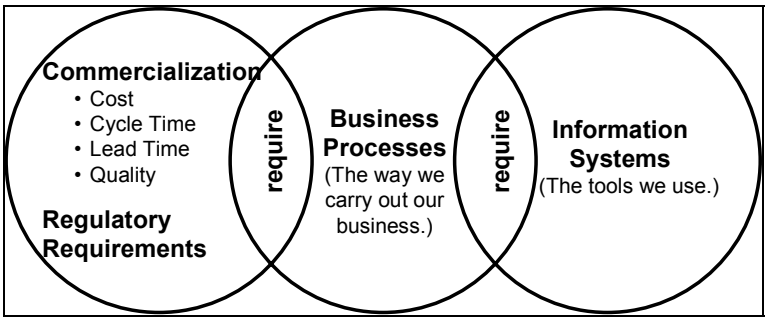


Most modern Systems Development Life Cycles include this set of business requirements by conducting interviews not only with users, but also with managers from the client organization. However, when you look closely at the outputs of these Systems Development Life Cycles, you find that the business requirements are merely documented and, eventually, filed. Seldom do they have a significant impact on the actual development of the system. Never are they used within the system validation and acceptance procedures .

The reason for this is a general lack of understanding of how the system contributes to meeting business requirements; How does the system improve the company's profitability? How does the system impact the quality of the company's products? How does the system impact the development lead time for these products? What value can be assigned to a 10% reduction in this development lead time?

Systems developers often miss the point when proffering technological solutions., because their training stops them short. They must learn the logic behind four fundamental statements. This logic will lead to the delivery of business value:

1. **User Requirements can be met through the design and implementation of the I.T. system alone.** (It is only a matter of programming and technical know-how.)
1. **Technical Requirements can be met through the design and implementation of the I.T. system alone.** (It is only a matter of programming, technical know-how and technology choice.)
2. **Business Requirements can <u>not</u> be met through the design and implementation of I.T. systems alone.** (There is no systems programming for profits or quality improvement)
3. **4. But there <u>is</u> a link between Business Requirements and I.T. Systems**. (The link between I.T. Solutions and Business Requirements is the *Business Process*.)



The picture on the left **illustrates that the business in first place meets the Commercialization and Regulatory Requirements by the way business is conducted. The way business is conducted is determined to some degree by the tools used to support the business, namely the information systems.**

More importantly, these four statements have an impact not only on the individual systems enhancement or replacement project, but also on the way these projects are launched and organized, and on how responsibilities for the delivery of business value are distributed within the organization.

An Example

We were asked to provide guidance in a project where the following example actually occurred. It is a common situation.

The research unit of a pharmaceutical company has both an Adverse Reaction and a Patient Data Management System. They were designed independently and of course/consequently do not use the same core database. Each system in itself meets the respective requirements of the safety and clinical units to a satisfactory degree.

Even though a sophisticated and well-resourced data reconciliation process has been implemented with numerous quality checks along the way, a few mistakes were discovered and made management nervous about two things: the reliability of the process, and potential repercussions from the regulatory authorities.

To resolve the problem, a corporate initiative is formed to review new tools available on the market and to replace the corporate clinical and regulatory systems with systems of a new generation.

A first, high level review of the market reveals the following situation:
There are essentially only three vendors that can be seriously considered. Only one of them offers what was originally requested: both Patient Data Management and Safety Monitoring in one database, ensuring automated data reconciliation and discrepancy management. Unfortunately the system is based on a platform with a questionable future and offers far less functionality than the other two vendors in their individual systems.

Observation: This “systems” project originated from a Business need, not a User or Technical need. This Business need is for consistent information that drives regulatory and clinical reports. If we were to examine performance issues, another Business need might be to reduce the number of resources required to ensure this consistency.

This situation calls for a serious assessment of the actual business value brought by each of the solutions offered.

- What is the business value of the better functionality the two non-integrated systems are offering?
- How will the organization take advantage of the individual functionality of the two systems?
- What risk is the company exposing its drug portfolio and development pipeline to by maintaining a “manual” data reconciliation procedure?
- How can the quality of the reconciliation process be improved without offering the common database?
- How long will it take and how much will it cost to add the required functionalities to each of the two individual systems?

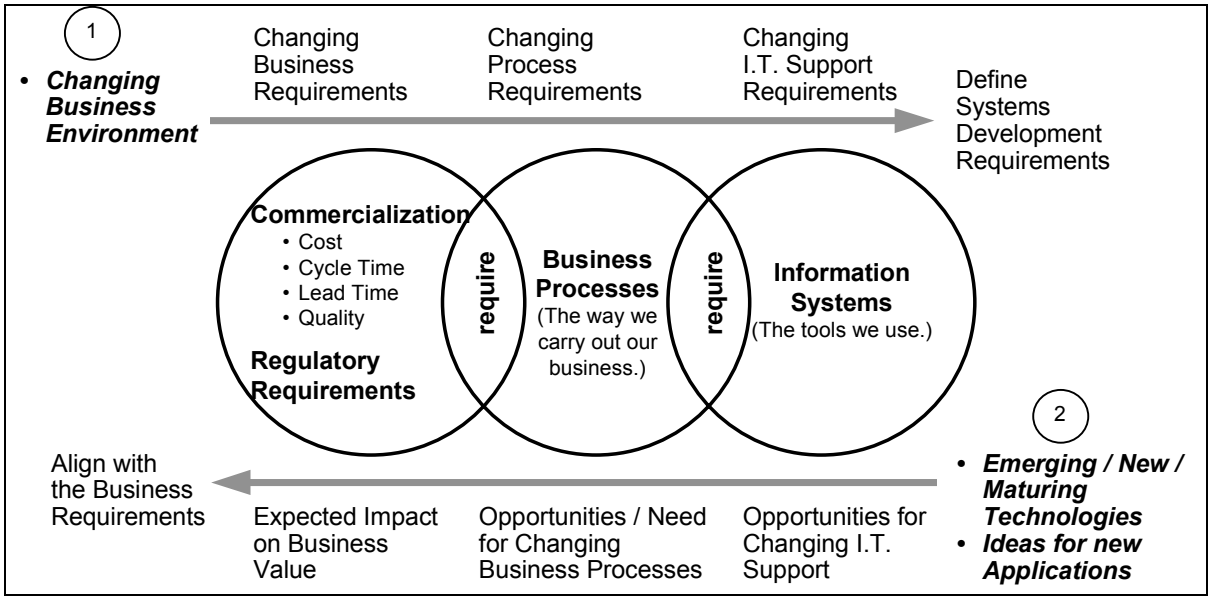
Traditionally, these questions lead to difficult, and often emotional, discussions. The flames of discord are generally fueled by differing levels of confidence in the promises made by the systems vendors.

The PROsys Business Process methodology is designed to base these systems discussions and decisions on clear visualizations and evaluations of the link between systems functionalities, the business process and the business objectives of the organization.

THE STRATEGIC LINK

As stated earlier, the real link between business objectives and systems solutions is the "Business Process", or "The way we do our business". And this link is strategic for every company. For, though supported by technology, it is through its operational Business Processes that the company meets the requirements set by its environment, its business strategy and the regulatory authorities.

The PROsys Business Process Framework allows this Strategic Link to be pursued from two starting points, or from any point in-between:



The first starting point is a Changing Business Environment. Stricter Regulatory Requirements or the need to bring products to the market faster would be two examples of a Changing Business Environment.

At the opposite end of the spectrum, the second starting point allows New and/or Emerging Technologies to be evaluated in such a way that they can really enable the organization to achieve its business objectives, or to set more aggressive business objectives.

Starting from either point calls for understanding the same basic issues:

1. What are the Upper Level Objectives set for the Business?
2. How do these Business Objectives translate into Business Process Performance Metrics for:
    - Lead Time?
    - Cycle Times?
    - Quality?
    - Resource Consumption?
    - Cost?
3. How (well) do the processes meet performance requirements?
4. What are the interrelationships between these performance metrics? (For example, what is the trade-off between reduced resource availability and quality?)
5. Where and how is the process supported by systems functionality?
6. How does systems functionality impact the business process and its performance with respect to the performance requirements?

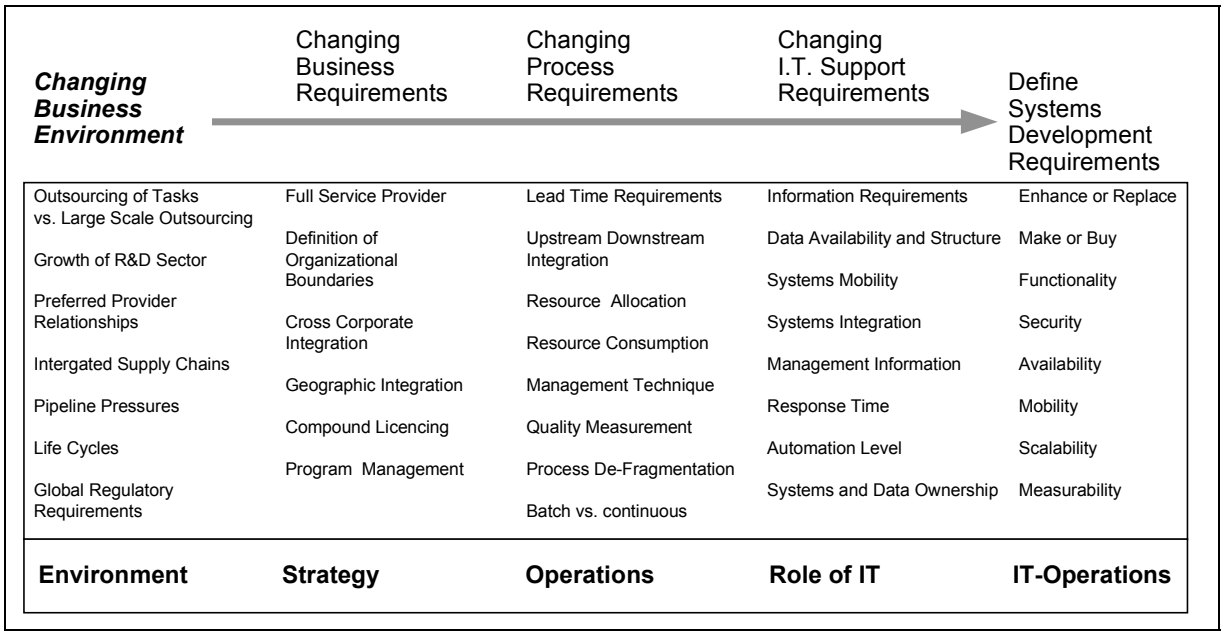
PHARMACEUTICAL R&D

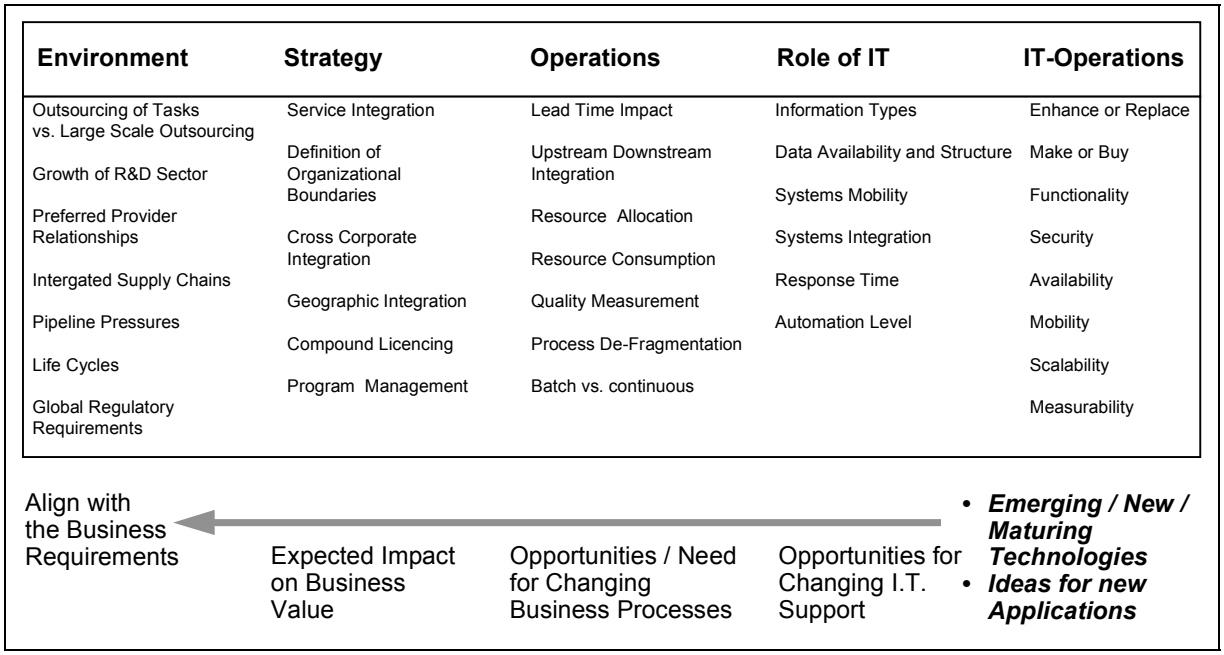
While some of these questions can be answered for the entire industry, others are company-specific.

One system may be ideal for a company that has a full pipeline in Phase III trials, but another company's focus may be on Phase I trials to refill the pipeline after cuts in research spending in the 80's.

Another system may deliver great business value in a US or European trial, but the telecommunications infrastructure in developing countries (South America or Africa) might negate its value in the international arena.

The table below collates some of the issues to be addressed in the System Value discussion. It re-phrases the issue based on which starting point is used.





PROsys has built detailed models of most aspects of the pharmaceutical development process, Having also evaluated countless process and systems scenarios, it appears that the following generic commonalities apply to the entire industry:

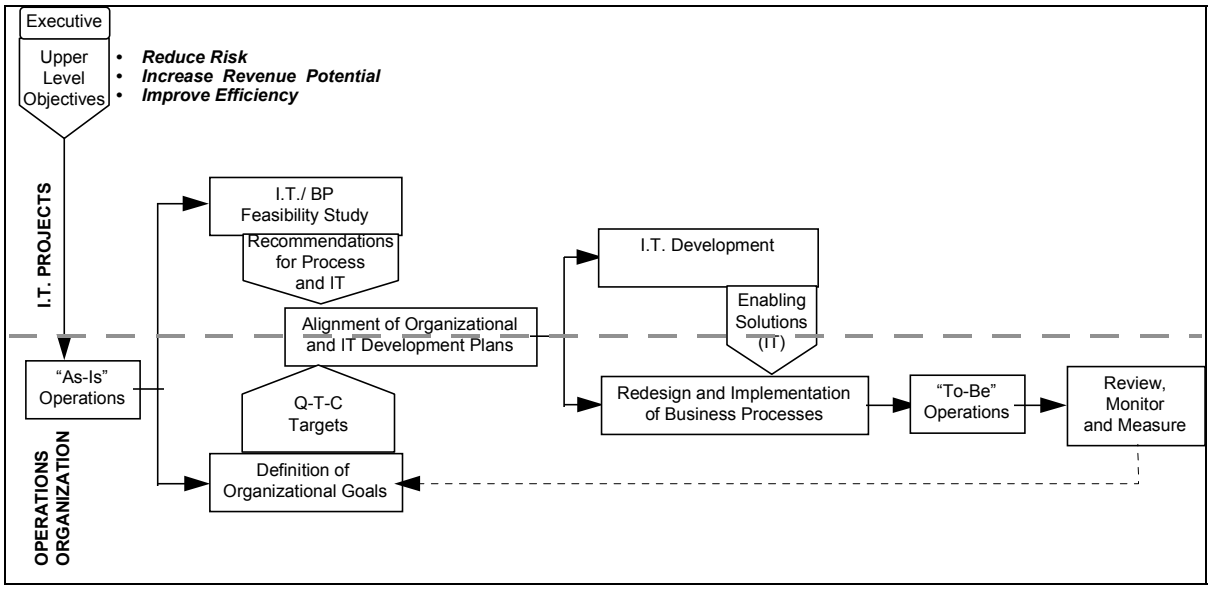
- Regulatory Requirements expressed by the FDA and other regulatory bodies will impact the way pharmaceutical companies work. Increased levels of standardization and globalization will require the permanent adaptation of corporate standards in safety monitoring and reporting processes, as well as in the clinical trials process itself. If the need for rapid adaptation is to be met, it will become crucial to manage such processes directly against the requirements defined for their products and outputs.
- The continued trend toward globalization will impose more stringent quality requirements on markets that were formerly more lenient or less supervised than the US or European markets. This will require new organizations, processes and systems that provide increased study design and conduct capabilities to smaller local and regional organizations.
- As serious violations of data quality requirements can lead to temporary or complete revenue loss, Data Quality can never be compromised. Data Quality and Integrity are as good as a life insurance policy for the pharmaceutical company.
- The value of Time to Market generally far outweighs efficiency gains in the development process. Hence, Systems Integration Issues should have a higher priority than Automation Issues.
- Lead Time gains only generate business value if they appear in processes on the critical path to submission. The critical path for a compound that will eventually be submitted for approval begins with its discovery, not in the 'end game' just before submission.
- A move towards electronic submissions has an impact on the Clinical Trials process long before the actual preparation of the submission begins. The process needs to aim at this form of submission starting at Protocol Design.
- The development of Managed Care requires an earlier focus on Outcomes Research as an integrated element of Portfolio Management and Study Design. This implies a closer integration of Clinical and Marketing processes, and the appropriate data connection between Phase III and Phase IV Clinical Trials.

In addition to these generic industry requirements, an approach driven by business value must respect the company-specific definition of business value, and the company's unique way of generating this value.
Systems development requires a well-integrated process. To identify, define, select and develop a systems solution that will contribute to the business value of a specific organization, the following factors have to be considered:

- The status of the Drug Pipeline
- Risk factors within the Drug Portfolio
- Geographic markets and research locations
- The global organization of R&D-activities
- The Clinical Trials Process
- Mid and long term Business Objectives
- the existing IT-Environment (Legacy and Infrastructure)
- The relationship between the operational units of the business, and its IT Organization
- ...

EMBEDDING I.T. DEVELOPMENT INTO A BROADER BUSINESS CONTEXT

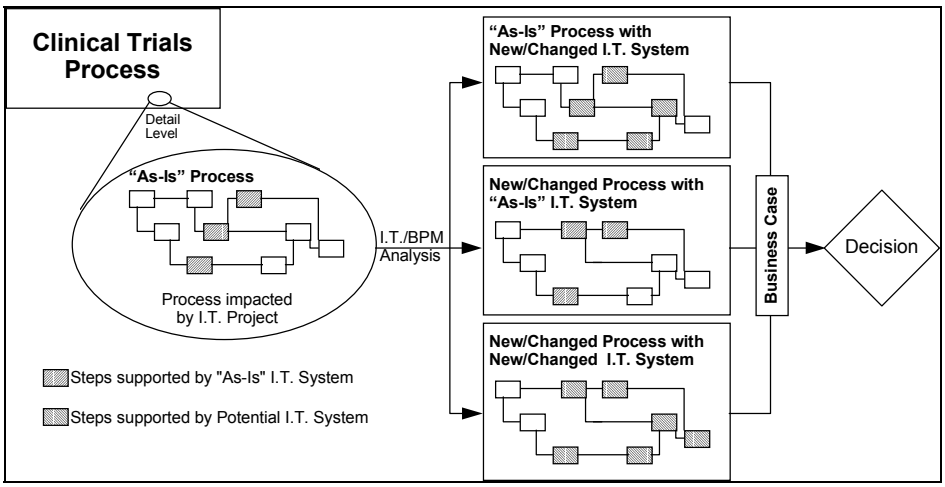
The PROsys Business Process Framework addresses the factors listed above by making every "IT-Project" a "Business Project".



It focuses the systems development process entirely on achieving a targeted process performance level, by developing or implementing information systems that are well aligned with, and integrated into, the underlying business processes.

The integrated IT-BP Feasibility Study generates a model that shows the interaction of information systems with the business process. It identifies the measureable contribution of individual systems functionalities to objectives related to particular performance criteria.

The options identified in the feasibility study are aligned with Quality Time and Cost Targets set by operations management before design of the actual system and implementation of the target process are kicked off.

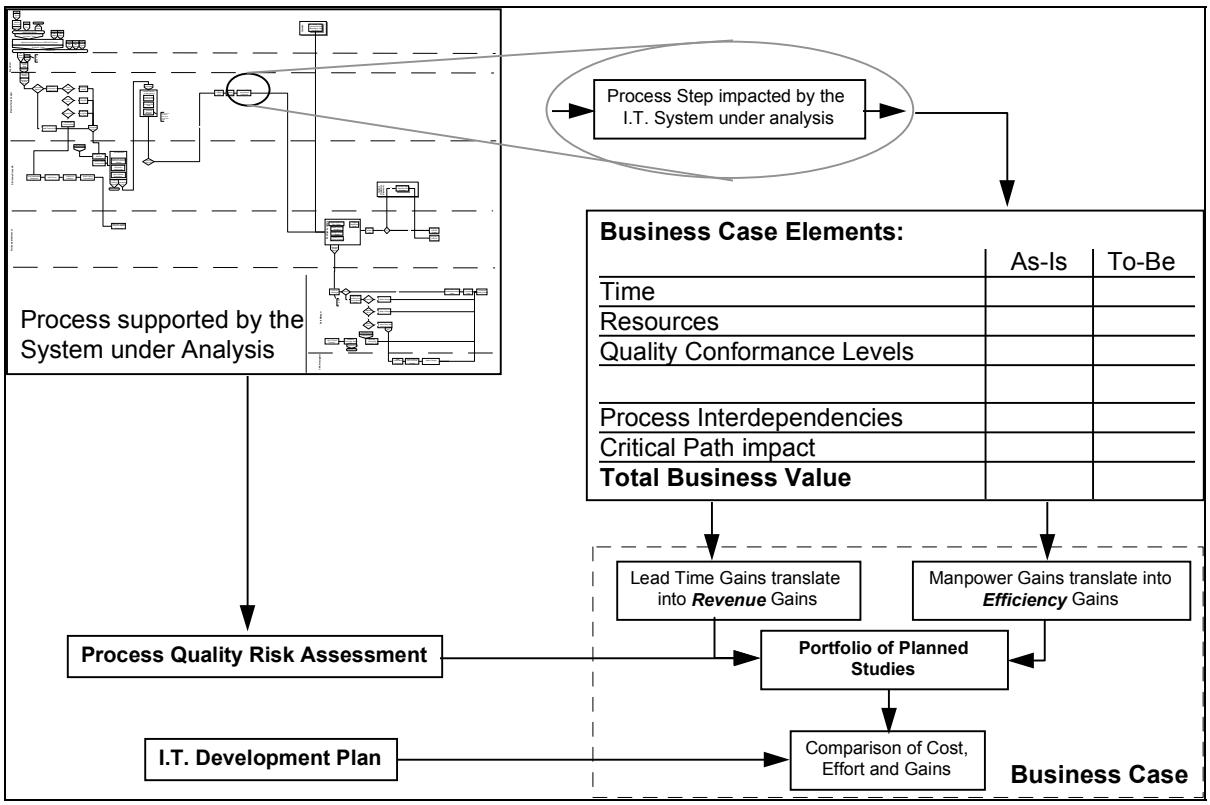


The IT-BP feasibility study leads to decisions for different process and systems scenarios for the area targeted by the project. The decisions are made against criteria that generate business value.
Which scenarios are evaluated depends to some degree on whether the project aims at systems enhancement, systems replacement, off-the-shelf solutions or complete development.

Regardless of the nature or magnitude of the project, the Business Case allows for a performance-based business decision about systems functionalities, rather than a technical systems decision.

THE ELEMENTS OF THE BUSINESS CASE

The business case generated by the IT-BP Feasibility Study reflects the nature of the business in the elements it considers.



Lead Time, Cycle Time, Quality and Resource Consumption are equally considered. No project should ignore the interrelationship between these three performance requirements. There are always trade-offs amongst the three, and ignoring any of them can have such great consequences that an additional initiative or separate project may well be needed further down the road.

CONCLUSION

Though it may appear at first that adding the step of an IT-BP Feasibility Study to a project might increase resource consumption and add to the time needed to complete a project, the value of the approach is in its tight focus on how the project actually delivers business value.

Discussions of nice-to-haves vs. have-to-haves are eliminated, as all systems-related decisions receive a solid business foundation.

The roles (and contributions) of IT and Operations are respected, each within their domain/remit. The improvements which can be achieved through process changes and systems changes are considered together, and the success of the overall project is measured against the achievement of the original/upper level business objectives.

This approach is not immune to changing business priorities. However, because they are derived from the direction defined at the highest level of the company, the business objectives supported by the project will not change overnight, and the basic foundations of the project remain more or less stable. Thus, when driven by clearly stated mid to long term corporate objectives, the project itself is less likely to be impacted by such short-term “emergencies” as an FDA query or an urgent submission.

AREAS OF APPLICATION

By applying the approach described in this paper, PROsys has developed models of most aspects of pharmaceutical development. The areas are listed below, and can be easily adapted and customized to a particular company's needs..

- **Integrated Business Process and Systems Modeling** for all Clinical Trials Processes:
  - Phase I
  - Phase II
  - Phase III
  - Phase IV
- **Integrated Business Process and Systems Modeling** for Adverse Reaction Processes:
  - Monitoring
  - Management
  - Reporting
- **Clinical Trials Monitoring and Management** on three levels:
  - Executive
  - Managerial/Functional
  - Operational
- **Laboratory Data Management and Evaluation**
- **Medical Terms Review**
- **Global Medical Dictionary Management**
- **Global Meta Data Management**
- **Patient Data Management**
- **Patient Data Flow**
  - Paper Based
  - Remote Data Entry
  - Remote Site Monitoring
  - Imaging
- **Central Drug Repository**
- **CRO Interaction and Management**
- **Data Quality Management**
- **Information Strategy Definition and Implementation**