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# Fast Cycle Change in Knowledge-Based Organizations: Building Fundamental Capability for Implementing Strategic Transformation

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# Fast Cycle Change in Knowledge-Based Organizations: Building Fundamental Capability for Implementing Strategic Transformation

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*ABSTRACT*

*Many organizations are engaged in some sort of transformation and change initiatives. These initiatives often start with great strategies, but fall apart as soon as implementations begin. Building the capability for implementing changes effectively must be one of the key agenda of any organization that wants to survive and thrive in a rapid changing environment. This paper discusses the experience of a knowledge-based organization in the pharmaceutical industry in building such a capability. The organization developed and implemented a methodology called Fast Cycle Change (FCC) that maximizes the "implementability" of change initiatives. That is, FCC ensures that change initiatives are initiated so that high impact can be realized rapidly, with high probability of success, and with minimal resources. Utilizing the FCC methodology on a wide range of change projects, the organization realized on average over 60 percent improvement per project in cycle time, quality or cost within 22 weeks.*

*Keywords:* Change Management, Change Capability, Change Implementation, Research and Development, Pharmaceuticals, Process Improvement, Process Management, Reengineering, Total Quality Management, Strategic Planning, Strategy Implementation

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Many organizations are engaged in some sort of transformation and change initiatives. These initiatives often start with great strategies, but fall apart as soon as implementations begin. Building the *capability for implementing changes* effectively must be one of the key agenda of any organization that wants to survive and thrive in a rapid changing environment. This paper discusses the experience of a knowledge-based organization in the pharmaceutical industry in building such a capability. The organization developed and implemented a methodology called Fast Cycle Change (FCC) that maximizes the "implementability" of change initiatives. That is, FCC ensures that change initiatives are initiated so that high *impact can be realized rapidly, with high probability of success, and with minimal resources.* Utilizing the FCC methodology on a wide range of change projects, the organization realized on average over 60 percent improvement per project in cycle time, quality or cost within 22 weeks.

## 1. INTRODUCTION

The ideas and concepts from areas such as total quality management (TQM), re-engineeering, and learning organizations have had great appeal to organizational leaders and academic researchers alike. While the gurus and practitioners have been debating fiercely about the different approaches in designing changes, all agree when it comes to implementation: it is very difficult to effect real changes for real impact. For example, according to CSC Index's 1994 "State of Re-engineering Report," over 67% of re-engineering initiatives of the companies it surveyed produced "mediocre, marginal or failed results" (See also Devenport (1995)). The failure rate would probably be much higher than 67% if these initiatives were assessed against bottom line performance measures in cycle time, quality and cost. These initiatives often start with good designs of the future that organizations aim at, but fall apart as soon as they start implementing the change. Building the *capability for implementing change* rapidly and effectively must be one of the key agenda of any organization that wants to survive and thrive in a rapid changing environment. This paper describes how to build such a capability in a knowledge-based organization.

According to how organizations design their future, there are basically two models for initiating and designing changes:

- top-down vision driven; and
- sense-and-response driven

In the top down vision driven approach, senior management, with or without wide participation, is responsible for developing the organization's vision and the high level strategy for change. Initiatives under this approach frequently start with great excitement and end with big documents in file cabinets without any real changes having been implemented. In the sense-and-response approach, it is accepted that the external environment is too complex. It changes constantly and rapidly. Constructing and betting on any long-term vision based on certain assumptions of how the environment might evolve is considered a long shot. It is more effective to design a "radar" to sense how the environment is changing and be able to respond to those changes rapidly. This is particularly relevant in, for examples, the computer, electronic and fashion industries today. The sense-and-response approach has been practiced ever since the beginning of biological evolution. However, formal conceptualization of the sense-and-response model in the organizational context is rather recent (Haeckel, Stephen H. (1995)). This concept has great appeal. However, it is still largely an academic term for "fire-fighting" when it comes to implementation. Both approaches provide useful frameworks for designing the desired future of an organization. Getting to the designed future though, eventually depends on an organization's capability to *implement* changes.

Organization-wide changes are typically achieved project by project. The top-down vision driven approach and the sense-and-response approach differ in the way projects are identified and selected. Once projects are identified, however, both approaches require the organization's capability to initiate projects with maximal "*implementability*." That is, projects are initiated so that *high impact can be realized rapidly, with high probability of success, and with minimal resources.* Fast Cycle Change (FCC) process is a vehicle to this end. The key characteristic of the FCC process is that it designs *"implementability"* into projects from their inceptions. All steps including identifying project candidates, defining outcome measures and scope, selecting team members, designing change, and developing implementation plans are geared towards maximizing the implementability. The built-in implementability in the FCC process enables organizations to simultaneously launch many diverse types of projects, and elicit wide participation and ownership. Yet, at the same time, each project team has focused objectives. These FCC teams and projects become the engine to transform an organization. The concept of implementability is analogous to *design for manufacturability* in the manufacturing environments.

The general framework of FCC was developed at the Scientific and Clinical Systems division of the Research and Development (R&D) of SmithKline Beecham (SB) Pharmaceuticals. FCC was formally introduced in May 1994. By October 1995, 20 projects had been initiated and, of the 20, 17 had been completed. (A project is considered complete in either of two situations: the project team issues a completion report demonstrating the measurable impacts; or the team declares that gaining the desired impact is no longer beneficial or feasible, and explicitly terminates the project). The results of the FCC process have been encouraging:

- **Significant impacts:** Out of the 17 completed FCC projects, 14 showed measurable impacts. As a whole, these 14 projects demonstrated an average of over 60 percent reductions in cycle time or defect rate.
- **High speed to realize impacts:** For the FCC projects initiated in 1994, the average duration from *Project Approval* to *Demonstration of Impact* was 32 weeks. The organization was very excited about this speed, considering that most of that time was invested in implementing the changes and collecting data to demonstrate impact. Yet for the FCC projects initiated in 1995, the project duration was even further reduced – to 22 weeks.

It is important to emphasize that the endpoint of the FCC process is when *impacts are demonstrated.* Speed measures the time duration of the entire project life cycle, including initiating the project, analyzing what changes are needed, designing and implementing the changes, collecting data to demonstrate impacts of the changes, and reporting the results.

Figure 1 plots the magnitude of impact against the project duration for the 14 successfully completed projects[1]. The shaded area in the upper left quadrant represents the target

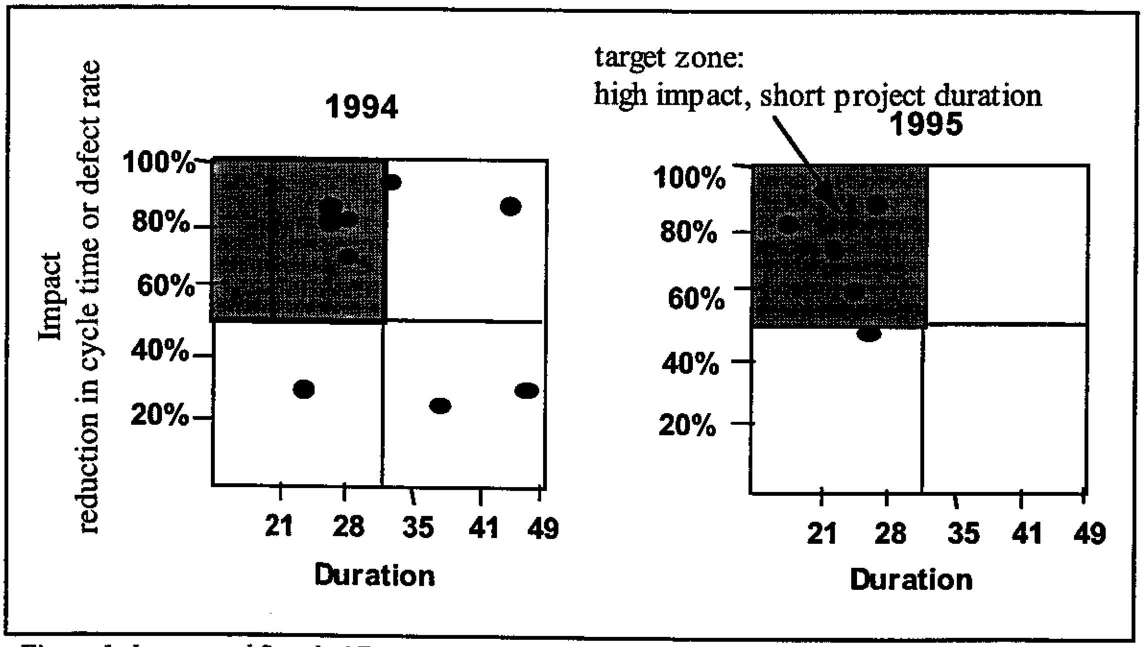



***Figure 1:** Impact and Speed of Fast Cycle Change Projects Note: each dot represents impact realized (% of improvement in cycle time, defect rate or cost) and project duration of an FCC project.*

[1] The graph captures all the projects initiated in 1994 and 1995 and completed before October 1995. We see few points for 1995 projects because several projects initiated in 1995 completed after October 1995.

**Side Bar 1: Fast Cycle Change Led to Improved Quality of Work Life**

**Time: 9:07 p.m.-November, 1994. Karen, a manager at the Clinical Data Management Department at SmithKilne Beecham Pharmaceuticals R&D, described a typical scene of their work environment:**

*"We are still at work, missing another dinner with our families. We are still processing thousands of clinical terms for a clinical study with the deadline just around the corner. We have been working evenings and weekends in the past few weeks trying to meet this deadline. Much of our work seem unproductive - correcting and re-correcting errors others should have caught long before now. This kind of rework adds a lot to our cycle time and workload. While our whole team is focusing on this deadline, work for other clinical studies is piling up. We run from deadline to deadline, never getting ahead. It is stressful and demoralizing to work around the clock and barely meet the never-ending deadlines."*

**Time: 5:24 pm.. April, 1995 - five months later. Karen described the work environment after the Fast Cycle Change effort:**

*"We go home now without feeling overwhelmed by the next deadline. We have been processing all the clinical terms as they come in so there is only a limited amount of work outstanding at any given time. Our key performance measure, cycle time for processing clinical terms, has been reduced by 81% - from an average of 77 days to 14 days. Not only we, but also our colleagues in other groups, have reduced work load through reduction of rework. For example, "unnecessary resolutions" passed to our group have been reduced significantly. We are now recognized as a high-performing group, achieving short cycle time, and we can actually have dinners with our families in the evenings. We feel like we have control over our work for the first time."*

zone where high impact was realized with short project duration. As might be expected, projects clustered closer around the target zone in 1995. This indicated that the FCC process became more reliable as the project teams and management gained more experience. It is also interesting to note that high impact does not necessarily come at the expense of long project duration. In fact the data actually showed the opposite seems to be true – short project duration and high impact tend to occur together. By reducing rework and improving predictability in their work processes, many teams also reported improved quality of work life. Karen, a FCC project owner, describes her case in Side Bar 1. Side Bar 2 summarizes the impact realized by these fourteen project teams.

It has been difficult to obtain benchmarking data to formally compare the implementability of the FCC projects with that of other organizations. Information exchanges with professionals and leaders of other organizations suggest that most projects never get to the point of demonstrating impact. For the exceptions that do, taking 12 to 24 months appears to be the norm.

Scientific and Clinical Systems at SB Pharmaceuticals has gone through an intensive learning experience in implementing FCC in a knowledge-based environment. Compared to projects undertaken before the introduction of FCC, we estimate that the 1995 change projects on average take about <u>one-third of the time</u>, but delivers <u>three times the impact</u>, and consumes only <u>a tenth of resource</u> formerly required. This represents a total *of 90-fold improvement in effectiveness in implementing* changes. It is this combination of *speed, high success rate, and resource efficiency* that makes FCC a powerful building block for transforming organizations.

## 2. KNOWLEDGE-BASED ORGANIZATION AND PROJECT IMPLEMENTABILITY

### Pharmaceutical Research and Development

SmithKline Beecham (SB) Pharmaceuticals discovers, develops, manufactures and markets novel therapeutic products. The long term survival of a pharmaceutical company is highly dependent on its ability to consistently generate therapies that meet the medical needs of people. Consequently, this industry has one of the highest research and development (R&D) investment to revenue ratios. For example, in 1995, SB Pharmaceuticals invested approximately $936 million in R&D, or 14 percent of its revenue. The R&D unit employs many highly specialized scientists with Ph.D. degrees in, for example, toxicology, pharmacology, genetics, statistics, bioinformatics, medicine and computational chemistry, biology, mathematics and computer science, as well as medical doctors and doctors of pharmacy. The R&D unit in the pharmaceutical industry is a good example of a *knowledge-based* organization.

### Side Bar 2: Magnitude of Improvements Realized by the Fast Cycle Projects

Every project below has a completion report which documents the improvement effort in detail. The project summary in Section 4 provides a brief background and a representative display of the improvement results for each project.

**Projects Related to Clinical Data Management and Biometrics:**

1) 91% reduction of the "age" of the outstanding clinical data which have not yet been entered, reviewed or verified
2) 81% reduction (from 77 days reduced to 14 days) in cycle time to code clinical terms - a critical step of processing clinical trial data
3) 82% reduction in number of loading errors when loading laboratory data from clinical trials
4) 90% reduction in cycle time to specify data validation specifications; manual checks reduced by 33% (therefore reduced resources)
5) 48% reduction in cycle time to validate Case Report Forms modules from clinical trial data

**Projects Related to Computing Environment:**

6) 83% reduction in cycle time from customer request to computer software distribution and verification
7) 30% reduction in Lotus Notes (number one source for computing help desk queries) related problems
8) 73% reduction in printer software problems
9) 30% reduction in cycle time in deploying (including delivery, setup, and training) desktop computers
10) 30% reduction in number of Help Desk queries not solved on first contact
11) 85% reduction in the cycle time to resolve queries related to laboratory computing

**Projects Related to Information Management:**

12) 60% reduction in turnaround time for journal articles and book requests
13) 70% reduction in cycle time to capture regulatory documents
14) 85% of target population access Unilert within two weeks of deployment. Unilert is an electronic information system which alerts scientists on, for example, the latest development in related sciences and competitive products.

Scientific and Clinical Systems (SCS), where the FCC was first designed and implemented, is a division in the R&D of SB Pharmaceuticals. SCS serves dozens of SB R&D facilities distributed worldwide through about 1000 associates, temporary staff, and consultants. The separation of geographical locations makes the logistics of managing projects more complex. SCS has a wide range of responsibilities, including processing and analyzing clinical data; designing, implementing and operating R&D computing network and services; building and supporting critical business applications; managing proprietary documents and information; providing strategic intelligence and scientific information; analyzing gene fragments and other genomics data; and providing consultancy in process improvement and statisitical designs and analyses. SCS's strength is derived from the core competencies at the convergence of information technology, information management, deep analytical skills and process orientation. The core competencies and operating diversity of SCS provided a good test bed for the Fast Cycle Change methodology in a wide range of knowledge-based work.

### Characteristics of Knowledge-Based Work

Improving the productivity of knowledge-based work processes has been gaining increasing interest among business leaders and academic researchers. (See Devenport, Jarvenpaa and Beer (1996)). The following characteristics of knowledge-based work may provide some insights in maximizing the implementability of change strategies in knowledge-based organizations:

- Clarity of desired outcome in knowledge work is critical yet often lacking. In manufacturing processes, the desired outcomes are usually clear. The focus is often on *how* to achieve those outcomes. In knowledge work processes, the critical questions are often *what* and *why*. It is usually more challenging in knowledge work to articulate the desired outcomes of a change effort. For example, many knowledge organizations have a clear need to better prioritize their work or projects. However, they often have difficulty in articulating what measurable outcomes an improved prioritization process would achieve. Knowledge work teams who can consistently ask and answer better the "what" and "why" questions of their work are likely to be qualitatively more effective than those who focus mainly on improving the "how" of their processes without a clear desired outcome.

- Assembly of knowledge parts is primitive. Knowledge assembly is therefore the area where major opportunities exist for improving knowledge work productivity. For example, developing a new drug requires creating a vast amount of knowledge about a compound. To produce this knowledge "end product" requires many knowledge "parts" such as knowledge in toxicology, pharmacology, medicine, pharmaceutics, statistics, computing, logistics, management and many other disciplines. Each knowledge part is in turn assembled by many knowledge sub-parts, supplied by many knowledge specialists with years of professional or Ph.D. training. In many knowledge-based organizations, the focus is on improving the production of knowledge sub-parts, rather than on strategies and methods to assemble them. We believe that there are much more opportunities in improving time, quality, cost of knowledge work processes by improving the assembly process rather than the parts themselves.

- Ownership to implement change is vital. Knowledge is ultimately created and assembled by knowledge workers. Since knowledge creation is an active process of an individual knowledge worker, it is important to build ownership and motivation by involving those who need to implement the change from the inception of the project. This is quite different from the situation in manufacturing environment, in which project initiation, design and implementation of change, and operation under the new design could be done effectively by different groups or teams.

- Time builds complexity and reduces opportunities for effective learning. Knowledge is context dependent. However, the knowledge context often changes rapidly in the mind of each knowledge worker, sometimes even without their own conscious awareness. As a consequence, the knowledge parts produced by knowledge workers cannot be easily assembled together as they are created and designed for different ends. Complexities and problems with alignment tend to increase exponentially as the project duration extends. Long feedback cycles also lead to more opportunities for issues to be confounded and therefore greatly reduces learning opportunities.

### Change Capability of An Organization

**An organization's change capability** is a function of three parameters calculated from a portfolio of completed change projects: the average impact (I), average project duration (D) and average resource required (R). That is:

**Change Capability = I /(D x R)**

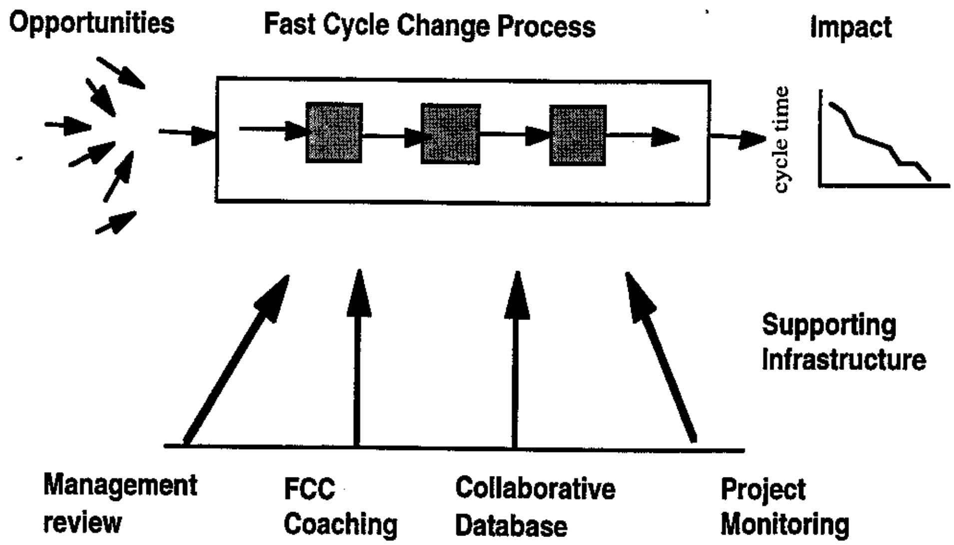
The impact of a change project is usually measured by % reduction in cycle time, defect rate or cost. Project duration is measured by the time between project approval to demonstration of impact. Resource required is measured by the total investment to initiate and design the change so that change is ready to be made in operations. When we can establish the measure of an organization's capability in implementing changes, we can seek to improve the capability over time.

The following principles about initiating and conducting change projects can greatly improve and enhance the Change Capability of an organization:

- **Articulate the outcomes.** It is essential to represent the desired outcome in a simple graph during the project inception stage. The outcome should be graphed as the measurable gap between "what it is" and "what is desired." Developing this graph helps knowledge workers focus on "what the change will accomplish" before they jump into "what the change should be."

- **Focus on transition when assembling the team and designing change.** Changes are often designed as if an old design can be abandoned abruptly on one day and a new design can be installed the next day. In reality, this rarely happens. During the transition period, it is only practical for work to be carried out according to a mixture of the old and new designs depending on the stage the work is in. These transition periods can last for months to even years, during which time a great deal of learning is likely to be gained and the original change will need to be re-designed. Therefore, in many situations, the transition period is what really counts during implementation. To maximize ownership for implementation the core design team members should be se-

**Figure 2: Fast Cycle Change Methodology**




lected from those who will be driving the implementation of the change during the transition period. When the change is designed with specific work and specific people in mind, the scope of the design is likely to be much more focused and relevant.

- **Keep change design simple.** The number of key features in the change design should be kept between three to six. Take a process re-design effort as an example: We often see a huge new process map that extends across an entire wall with 100 or more steps. A lot of resources are consumed in constructing these complicated process maps but they are rarely relevant during implementation in knowledge work environments. This distracts the team from the few key changes that provide most leverage, and takes away ownership of the knowledge workers who need to implement the new process. It is also impossible to communicate that level of complexity to a wide audience. In addition, steps at that level usually become obsolete during implementation when they are examined closely. It is usually much more effective to identify the three to six key changes that can be represented in a simple process map with less than 10 steps.

- **Focus on the assembly.** When designing the changes, focus on the assembly of parts instead of the production of the parts. For example, when redesigning a process, emphasis should be on the specifications of the knowledge end product, knowledge parts and their interdependencies, the roles in relation to the end product, and the sequences of when each part should be produced.

One way to greatly facilitate the execution of the above principles is *"fast prototyping."* To do that, the project sponsor and leader mock up the project completion report as if the project were completed, as a way to formulate the project. The mock up report should include the graph that displays desirable impact (with fake data) in a measurable way. The main purpose of this graph is to visualize what the team aims to accomplish. Then the gap between the current situation and the ideal needs to be drafted. The purpose is to clarify the goal and the scope of the project. The gap will be developed much further by the project team. Then, what and how to transition from the current to desired state needs to be sketched. The objective is to help identify the key people who will implement the changes during the transition. They should be the core team members to design the change. This prototyping during project initiation is critical to maximize the implementability of change projects.

## 3. FAST CYCLE CHANGE METHODOLOGY

Figure 2 shows the key components of the FCC methodology. The methodology is a system that transforms potential opportunities into realized impact. The potential opportunities and the realized impact are linked by the FCC process. The success of the FCC process builds on the supporting infrastructure with four key components: management review, FCC coaching, an FCC project collaborative database, and project monitoring. In the following we describe these components in detail.

### 3.1 The Fast Cycle Change Process

The FCC process formally starts when a project is approved and ends when impact has been demonstrated as shown in Figure 3. The target duration from project approval to demonstration of impact is 22 weeks. The 22-week target allows: the owner and facilitator about three weeks to schedule, plan and prepare for *all* team meetings; then the project team meets and completes the **change design and plan for implementation in about three weeks**, then, upon approval of the implementation plan, spends **four to six weeks to execute the implementation plan**, with the remaining **six to eight weeks to demonstrate impact** by running and evaluating the new design with on-going work.

Most teams were surprised when they realized that the 22-week FCC process translates to only three weeks to analyze, design, plan for implementing the change. The purpose of the tight timeline, particularly during the change design stage, is to drive better initiation of projects, more efficient use of resources, more rapid implementation and testing of the change, and a strong focus to realize the desired impact.

The FCC process can be conveniently split into four stages: Initiation, Change Design, Implementation, and Demonstration of Impact.

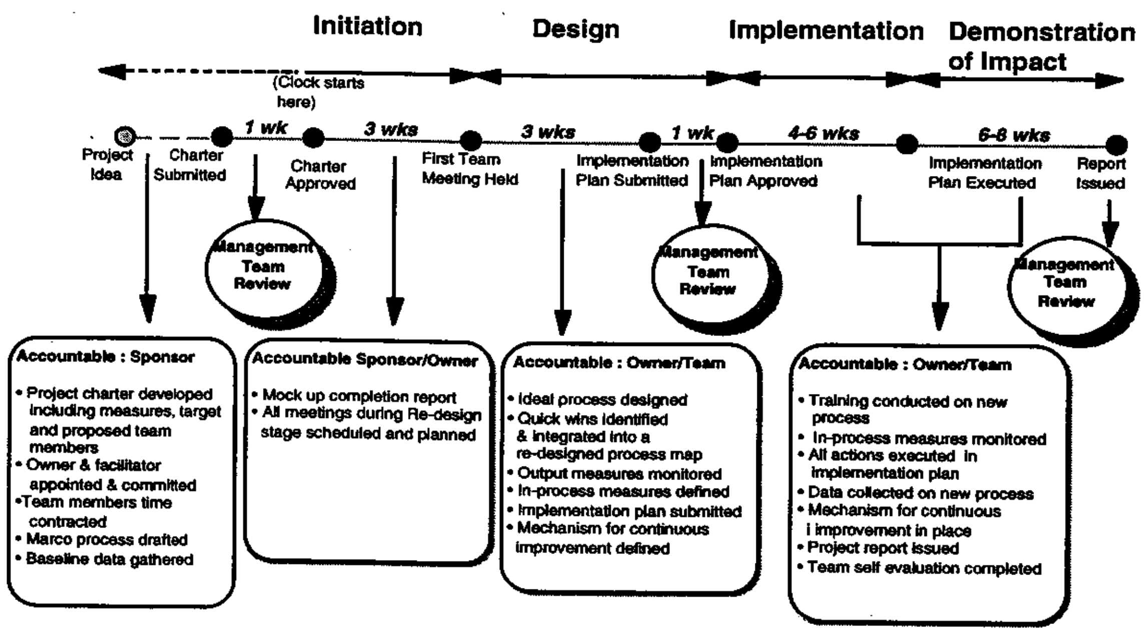
- **Initiation (3-week)**

Proper project initiation is the most important, yet often neglected aspect of a change project. This stage includes all the work up to the kick off of the first team meeting. The project owner and the facilitator mock up the project completion report as if the team has successfully completed the project. The mock up report includes the baseline data documenting the current performance, a graph that helps one visualize the desired impact represented by the difference between the current and the anticipated performance when project is completed, and work that will go through the change design and achieve the anticipated performance. With the mock up completion report, the owner and facilitator can then define and recruit appropriate team members with contracted time commitment, draft current "macro" process flow describing the major 5 to 10 steps of the process, schedule and plan all the team meetings during the change design stage.

- **Change Design (3-week)**

We can use a cycle time reduction project as an example to illustrate the typical activities that occur during the change design stage. The first team meeting kicks off this stage. There are usually two one-day team meetings in this stage. In the first meeting, the owner first provides a 30-minute briefing on the key concepts in cycle time reduction. Then the project owner or facilitator goes through the mock up completion report to help clarify the end point of what the project team aims to achieve. After that the team confirms the project plan which incorporates the FCC

**Figure 3: Fast Cycle Change Process**



process timeline. Then the team finalizes the current "macro" process highlighting the issues . For a cycle time reduction project, the issues can be categorized into three areas: *rework, idle time* and "*backlog.*" Rework is everything done more than once. All reviews and approvals are by definition rework. Idle time occurs whenever no activities are being performed toward end products or services the customer will receive. There is often confusion between idle time in process and idle time in people. Eliminating idle time of a *process* is usually opposite to the goal of keeping *people* busy at all times. When people are trying to keep up with the work and are busy at all time, the process is usually idle somewhere waiting to be worked on. Backlog includes all the activities that could be done before the start point of the process. In knowledge-based work this is usually a big component of cycle time and a notorious area for hidden inefficiency.

After the team members have built a common understanding of the current process, they then paint a vision of the ideal process. When the goal is to reduce cycle time, an ideal process is one that has no rework, no idle time and no backlog, i.e., every minute consumed by the process is adding value to the customer. Typically, however, the *actual* and *ideal* cycle times *ratio* is in the order of *hundreds-to-one*. The goal is to reduce this ratio to as close to *one-to-one* as possible. A huge gap between the actual and ideal cycle times indicates great opportunities for improvement. For example, it is quite common for a process to have actual and ideal times in a ratio of 200 to 1. A reduction to 40 to 1, which teams usually find a reasonable goal, represents an 80 percent reduction in cycle time.

Usually, teams can brainstorm 20 to 30 ideas to reduce backlog, rework and idle time to reduce the gap between actual and ideal processes. The next challenge for the team is to organize these 20 to 30 ideas into three to five recommendations. A fully developed recommendation has three components: Situation, Target and Proposal. For a cycle time reduction project, *Situation* describes the parts of the process a recommendation addresses; what the specific backlog, rework and idle time are in those parts of the process; and how much time these three kinds of non-value added time are consumed in the process. *Target* describes the expected *outcome* and how much cycle time will be reduced when this recommendation is fully implemented. The *Proposal* is the sequence of steps to close the gap between the Situation and Target. FCC teams usually complete all of what has been described so far – except for the Proposals – in the first day-long meeting. Team members leave the first meeting with actions to develop the Proposal part of the recommendations.

In the second day-long meeting, the team discusses and finalizes the recommendations. Then the recommendations are consolidated into an integrated process map. All the interfaces among the recommendations are worked out at this point. This is followed by the design of the *process monitoring forum.* This design includes the definition and display format of the output and in-process measures. The display of output measures indicate what are important to the process customers, what performance the customers expect, and what the actual performance is relative to the expectation. What must happen upstream in the process to deliver the desired performance is also identified. In-process measures highlight the issues in the upstream process so that corrective actions can be taken to positively impact the output measures. Owners accountable for the these measures are also agreed upon. Who monitors the measures, who receives the feedback, in what forum the feedback is given, and what triggers corrective actions are also explicitly defined and agreed upon. The team concludes the second meeting with schedules and agenda of the regular meetings during the implementation stage. The implementation plan, which is essentially the minutes from these two meetings, is then submitted to the management team for review. The approval of the implementation plan ends the Change Design phase.

- **Implementation (4 - 6 weeks)**

Upon approval by the management, the project team is ready to execute the implementation plan. Typically the team spends about four to six weeks executing the plan before actual work can run through the new design.

- **Demonstration of Impact (6 to 8 weeks)**

The next step is to run the change design in actual operation for a number of cycles to check if the desired impact can be achieved. Once the design has been run through for a sufficient number of cycles, the team can compare the performance of the new design with the baseline performance. When the impact is demonstrated, and a mechanism is in place to ensure the performance can be sustained or further improved, the team presents the completion report to the management team. Upon approval, the project is formally closed. Every FCC team is then recognized, with a summary of the team's accomplishment distributed to the chairman and all associates of the Research and Development division. The FCC teams also present their projects in poster form at the annual "all-hands" meeting to share their experiences with other associates.

It is worth emphasizing that when an FCC project is complete and the FCC team is disbanded, the change effort does not stop. On the contrary, this is when continuous improvement starts. Improvement takes place through monitoring performance measures and taking appropriate corrective actions. Continuously improving the performance becomes part of the job of the process owner.

**Table 1: Check Lists of the Management Reviews of the FCC Projects**

| | |
|---|---|
| Project Charter Review | • the desired outcome of the change is important to the organization<br>• the measures of the desired outcome are operationally defined<br>• work on which change will be implemented in the next few months is identified<br>• the team members are those who are key to implement the change on the work identified above<br>• the required resources are committed from participating departments and groups<br>• date for next review (Implementation Plan) is scheduled |
| Implementation Plan Review | • the change design from the team is likely to achieve the desired outcome<br>• the implementation plan clearly defines who will do what by when<br>• resources to implement the change have been secured<br>• the anticipated impact of the project still justifies further investment given what the team has learned. If not, encourage the team to terminate the project.<br>• date for next review (Completion Report) is scheduled |
| Completion Report Review | • desired outcome has been achieved<br>• long-term accountability for maintenance and continual improvement have been established<br>• recognition for the teams have been provided |

### 3.2 Project Team Structure Management Review

**Project Team Structure**

An FCC project team has a sponsor, an owner, a facilitator, and team members. We recommend a team size of about six members excluding sponsor but including owner and facilitator. Teams larger than eight members are discouraged. The accountabilities of sponsor, owner, facilitator and team members are highlighted in Figure 3.

**Management Review**

The management team of Scientific and Clinical Systems reviews every FCC project at three key check points during the life cycle of a project. The management team consists of the Senior Vice President and eight department heads of SCS. Typically, the management team invests about 5 to 15 minutes per project of their bi-weekly half-day meeting to review FCC projects. The numbers of reviews for each project are kept to a minimum. The three reviews identified as the main leverage points for management inputs are: project charter, implementation plan, and completion report. The turnaround time from submission of these documents to completion of review is less than a week. The checklists of what the management team aims to ensure at these three reviews are summarized in Table 1.

**Coaching Support**

The team receives training about the Fast Cycle Change process by conducting the change project. There is no formal classroom training for the team, except that the facilitators are given a half-day briefing on the key features of the FCC process. The FCC coaches provide project-specific coaching for team owners and facilitators at four key points of the FCC process:

- compilation of project charter
- planning of all meetings necessary to produce an implementation plan. This is done as soon as the project is approved. The coaches help the owner and facilitator fill out the meeting agenda templates in the FCC project database. This way, the owner and facilitator receive coaching on the Fast Cycle Change Process in the specific context of their own project.
- compilation of implementation plan
- compilation of the completion report

In addition to the coaching responsibility, these FCC coaches also provide guidelines for running FCC projects, design and maintain the FCC project database, and monitor the projects. One PI expert is part of the senior management team and is an active contributor to the reviews of the project charter, implementation plan and completion report. It took about 1.5 full time equivalents of FCC coaches to support the 20 FCC projects.

**Project Monitoring**

The status of all FCC projects is monitored and reported to all SCS associates in the mangement report, which is published monthly. The status is also monitored as a standing agenda item of the bi-weekly senior management team meeting. The status of all projects are summarized in a table with 5 columns: project name, project sponsor/owner/facilitator, measures and target of the projects, time since last project milestone, cumulative time since charter approval, and the evaluation of the project upon completion.

**FCC Project Database**

Most FCC teams in SCS have transnational membership. A collaboration database based on Lotus Notes™ (see for example, Lotus Development Corporation (1991-1993)) platform greatly facilitated the communication among the team members from different physical locations. Team members posted all documents including team charter, meeting agenda, meeting minutes, between-meeting discussions, implementation plan, and completion report during the entire life cycle of a project. The FCC process is largely imbedded in the templates of the key documents in this database.

## 4. RESULTS

In the introduction, we discuss the Fast Cycle Change results from a process viewpoint, i.e., we summarize the results of the projects as a whole portfolio. For speed, the time from approval of project to demonstration of improvements averaged 32 weeks in 1994 and 22 weeks in 1995. A large portion of these times was spent on running the new processes and collecting data to demonstrate improvements. The improvement in speed from 1994 to 1995 was a result of both improved *design* and *execution* of the Fast Cycle Change process. At the end of 1994, the FCC coaches, based on the observation of and direct feedback from the 12 project teams, fine-tuned the design of the FCC process and supporting infrastructure. Moreover, the organization, particularly the sponsors, had gained experience to better articulate improvement opportunities and therefore better initiate change projects. These improvements in the design and execution resulted in an even faster FCC process in 1995. For impact, we indicate that the projects averaged over 60 percent improvements, measured by either cycle time reduced or defect rate reduced.

Compared with the change projects before the introduction of FCC, we estimate that we have improved the organization's Change Capability by 90 fold: the change projects in 1995 on average take about one-third of the time to complete, but deliver three times of the impact, and consume only a tenth of resources. That is:

Change Capability after FCC = $3 \times 3 \times 10 \times I / (D \times R)$ = 90 x Change Capability before FCC

where I, D, R are the average impact, project duration and resources required of the change projects before FCC.

In the Appendix, we provide a brief background and a representative graph displaying the impact of each FCC project completed before October 1995.

## 5. KEY LESSONS LEARNED

The Fast Cycle Change projects have provided a huge experience base for making the change process faster, more likely to realize high impact and more resource efficient. The many specific lessons can be summarized into the following principle:

*Focus on realizing impacts within 4-6 months and then iterating the improvement cycle frequently and rapidly.*

Most teams tend to spend too long in the project, particularly in analyzing and designing the change. Six to twelve months investment in analysis and design without implementing any change is quite common. There are serious pitfalls with this approach:

- Environment often changes. In today's rapidly changing world, most opportunity windows are much shorter than, say, 12 months. Merger, restructuring, key team members changing jobs, etc. are often the reasons why many change initiatives never get to implementation after a large investment in analysis and design. Moreover, the ideas for change which once made sense often become obsolete within that time frame.

- When team members invest a lot of time and see no real change, commitment tends to degenerate when they get to the implementation stage.
- With a long period of analyses, teams tend to over-design the change. When design include great details, it tends to introduce complexities. As a result, it is not only difficult to communicate and train on the change design, but it also takes away the ownership of those who need to implement the change. In both situations, the chance of success is greatly reduced.
- Features of detailed change designs on paper without rapid implementation and testing often become irrelevant during implementation. Teams tend to *learn much faster* about what works and what does not when they are actually *implementing changes* and can get objective and rapid feedback through measures.
- When the project timeline is extended, there are more opportunities to hide project issues such as inappropriate team membership, lack of commitment, etc. When problems go undetected for an extended period of time, issues become too tangled to resolve. In addition, learning opportunities for preventive measures are likely to be missed.

The principle above translates to many specific actions we have taken in the last two years:

- The project owner should be the one who is accountable for maintaining and continuously improving the performance at the "conclusion" of the change effort.
- Before the team meets, the owner and facilitator should get the inventory of work that will go through the change (to be designed) within the next few months. Then design the change specifically for this inventory of work. This consideration usually leads to discussion about team membership. Focusing on this inventory of work often helps direct team effort to important issues and greatly reduces the scope and complexity of the change effort.
- Minimize the generic classroom training and training manual. On-the-job, project specific coaching is usually more effective.
- Minimize intermediate documentation. They distract the team from their main goals. To do that, the team owner and facilitator should *mock up the project completion report* at the beginning as part of initiating the project. At this point it is very important to have clarity on how the improvement results will be displayed and what specific work will go through the change initially to produce desired results. Then organize meetings to produce and implement decisions and actions needed to fill in missing information in the mock up completion report. All other documentation should be kept to a bare minimum. This greatly increases the focus of the team and minimizes unnecessary overheads of the project.

## 6. CONCLUDING REMARKS

Information technology has exploded in the past decade and has become an integral part of daily business operations. While it was a breakthrough when the computer was invented five decades ago, the deep penetration of information technology into everyday life arrived only in the past decade, when there has been a dramatic improvement in cost, user friendliness and selections of software. We believe parallel advances are needed to improve the productivity of knowledge-based work to take full advantage of the best of ideas found in, for examples, TQM, JIT, Re-engineering, and Learning Organizations. Not only do we need to improve productivity of knowledge-based work, we must also improve the way we improve. Organizations must improve the capability for implementing change so that high impact can be realized *rapidly, with high probability and minimal resource.* Certain thresholds in the Change Capability must be passed before an organization can thrive or survive in the rapid changing environment.

This paper describes how the FCC methodology has improved an organization's capability for implementing change by 90 fold. Improving the change capability is fundamental to the success of most organizations, and is particularly critical for those which seek to achieve strategic transformation.

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*Lotus Notes Users Guide (1991-1993)*, Lotus Development Corporation.

# Fast Cycle Change: Project Summary

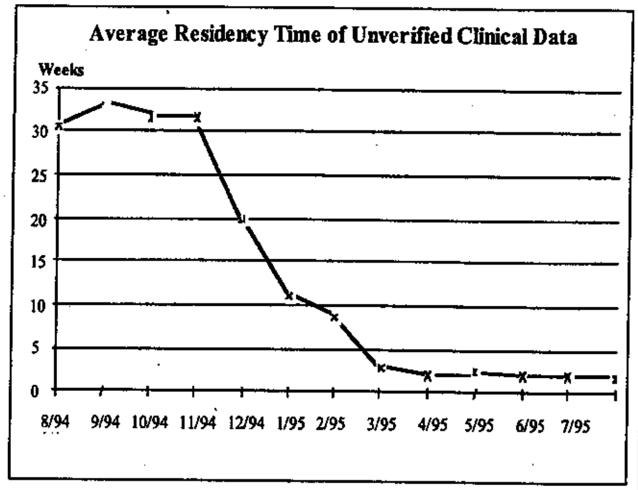
**PROJECT 1: CLINICAL DATA REAL-TIME HANDLING**

All data from a clinical trial must be reviewed, entered into the clinical database, verified, and validated before the database can be "frozen" for final statistical analyses. This clinical data handling process lies on the critical path for drug development and can impact the timing on regulatory submission.

The industry has a long tradition to process large batches of clinical data at the end of clinical studies. This practice leads to many chronic problems; e.g. repeated errors propagated, long cycle time to "freeze" database and data problems leading to rework during study reporting stage.

The objective of this project was to move the entry, review and verification of clinical data from batch processing to real-time processing. The primary measure was the residency time - how long the unverified data had been outstanding since receipt.

**FIGURE 1: CLINICAL DATA REAL-TIME HANDLING**
**91% Reduction in Residency Time**

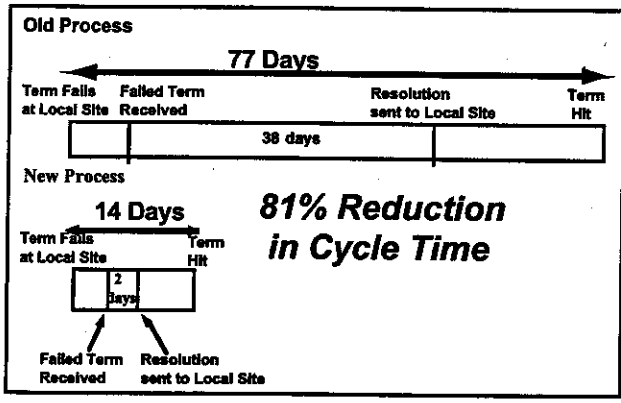



**PROJECT 2: CLINICAL TERMS AUTOENCODING**

After clinical trial data are reviewed and entered into a database, they are then processed by the *autoencoder* which matches clinical terms with existing terms in the clinical dictionaries. If the term matches, it is automatically coded. Otherwise, a code failure is registered with the autoencoder, thereby flagging the failed term and sending a report to the reviewer responsible for the study. Significant effort is required to resolve these failed terms. Given the large number of terms entered, even a very low failure rate creates thousands of terms requiring resolution (over 10,000 in 1994). In the past, there were cases where resolution of terms placed this process on the critical path and delayed drug projects.

The primary objective of this team was to reduce the cycle time from when a term failure is registered to when a term failure is resolved (including updating the dictionary, rerunning the terms against the updated dictionary, and achieving term "hits").

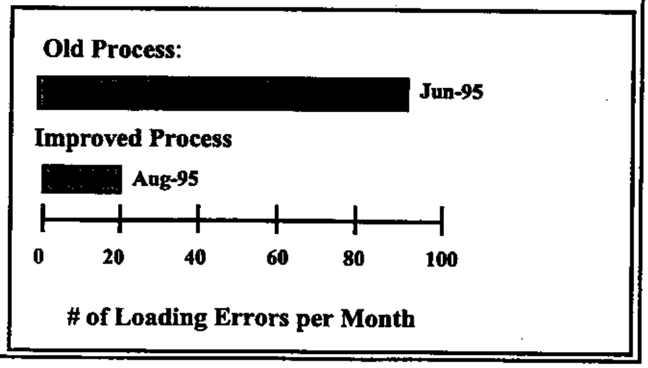
**FIGURE 2: CLINCIAL TERMS AUTOENCODING**
**81% Reduction in Cycle Time**




**PROJECT 3: ELECTRONIC DATA TRANSFER**

Successfully loading and processing laboratory test data from a clinical trial is a necessary step for getting a clean clinical trial database for statistical analysis and clinical reporting. Traditionally, laboratory data are processed in batch, often at the end of a clinical study. Processing a large volume of laboratory data at the end of a study drains resources at the time when they are needed most. In addition, systematic problems are left unidentified and propagated until the late stage. The objective of this project was to reduce the number of errors and cycle time for loading and processing laboratory testing data.

**FIGURE 3: ELECTRONIC DATA TRANSFER**
**82% Reduction in Laboratory Data Loading Errors**



# Fast Cycle Change: Project Summary

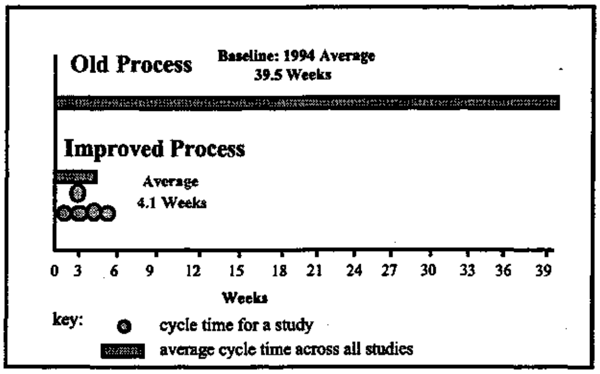
**PROJECT 4: DATA VALIDATION SPECIFICATIONS**

The Data Validation Specification (DVS) process defines the set of data checks and procedures that are used for validating clinical trial data entered into the project database from the Case Report Forms (CRF). Data validations are performed by manual review of CRFs or by the use of computer tools to identify data errors, which are then corrected and entered into the database.

Traditionally, the DVS process has suffered from several problems. For example, checks not specified and performed until close to or even after clinical trial study ends, duplication of manual and computer checks, lack of adequate or relevant checks leading to delays and rework even after database was frozen.

The objective of this project was to define a process by which the right set of data checks are specified before the start of a clinical study, and also to reduce manual checks (replaced by automated computer checks) resulting in improved database quality and more resource efficient.

**FIGURE 4: DATA VALIDATION SPECIFICATIONS**
**90% Reduction in Cycle Time (below)**
**86% Reduction in Manual Checks (not shown)**

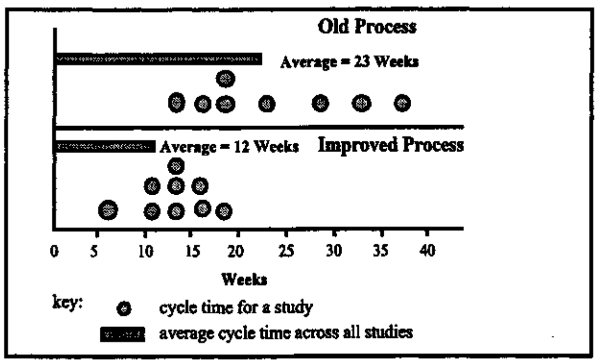



**PROJECT 5: REAL TIME CLINICAL DATA VALIDATION**

Validation of clinical data is a critical step in the Clinical Data Handling process, which directly impacts the clinical study cycle time. All data from a clinical trial must be reviewed, entered, verified, autoencoded, and validated before the database can be frozen so that statistical analyses can be performed.

Other improvement projects have dealt with transitioning to real time processing for data entry, review, verification and autoencoding. Validation is the last piece of the Clinical Data Handling process to complete our transformation from batch processing to real time processing. The primary objective of this project was to reduce the time from Data Received to Data Validated.

**FIGURE 5: REAL TIME CLINICAL DATA VALIDATION**
**48% Reduction in Cycle Time**

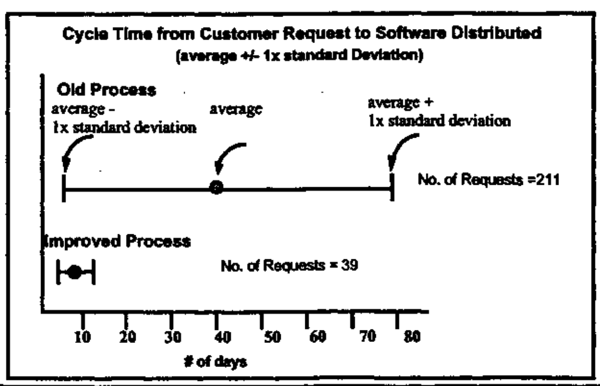



**PROJECT 6: COMMON PLATFORM SOFTWARE DISTRIBUTION**

This project was to improve the delivery of requested software to selected timesharing and server systems on the R&D network. This included new releases and updates to timesharing software. The software must be available on multiple systems on the company's network. Inappropriate distribution can result in computing resource usage problems in the overall network reliability. Historically, cycle time for distributing software has been long resulting in dissatisfied requesters.

The goal of this project was to reduce the cycle time from customer request to software delivery while maintaining the quality of the deliverables.

**FIGURE 6: COMMON PLATFORM SOFTWARE DISTRIBUTION**
**83% Reduction in Average AND Variation of Cycle Time**



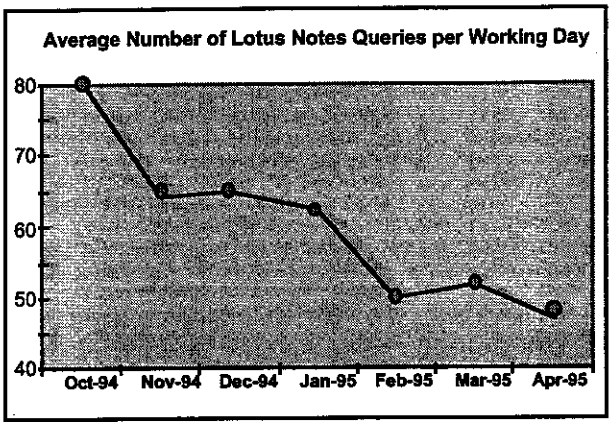
# Fast Cycle Change: Project Summary

**PROJECT 7: PREVENTION OF LOTUS NOTES RELATED PROBLEMS**

R&D Help Desk is the front-line support of all R&D computing clients responsible for prevention and resolution of computing problems. SB R&D is one of the early companies that use Lotus Notes as its collaborative computing system. Over the first ten months of 1994, the Help Desk logged an average of 520 Lotus Notes calls per month with a peak of over 2000 in August.

This project was aimed at identifying and eliminating the root causes for the most prevalent Lotus Notes related queries and establishing a process for continued review, analysis and elimination of the root causes of user queries.

**FIGURE 7: PREVENTION OF LOTUS NOTES RELATED PROBLEMS**
**Over 30% Reduction in # of Problems**

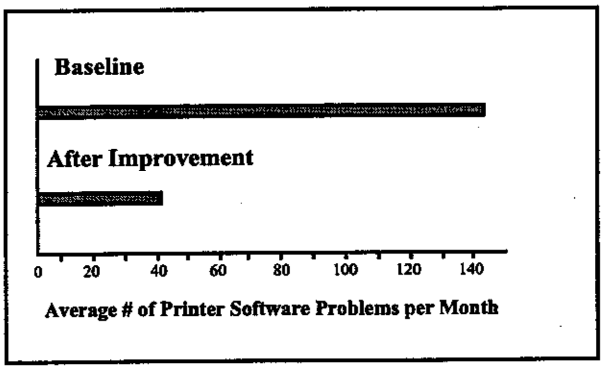



**PROJECT 8: PREVENTION OF PRINTER RELATED PROBLEMS**

R&D Help Desk is the front-line support of all R&D computing clients responsible for prevention and resolution of computing problems. Queries to the Help Desk are logged into an automatic tracking system and given a defined category according to the nature of the call.

The objective of this project is to establish a process for continuously identifying and eliminating the number of problems in the leading category. Printing was first identified as the leading problem for immediate attention.

**FIGURE 8: PREVENTION OF PRINTER RELATED PROBLEMS**
**73% Reduction in # of Printer Related Problems**

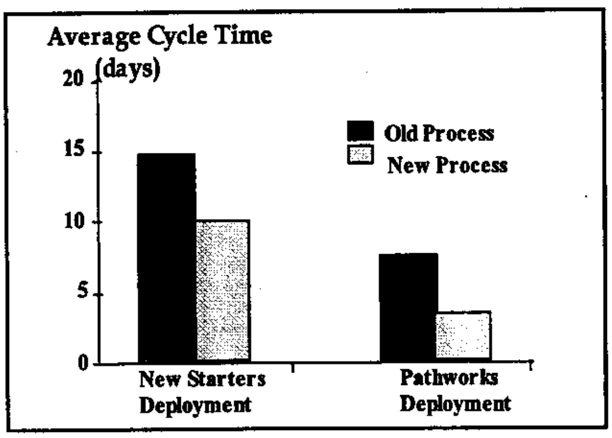



**PROJECT 9: DESKTOP DEPLOYMENT**

Desktop computer deployment provides Hardware and Software deployment for all R&D clients. This includes new starter training, new desktop deployment, "Pathworks" (network system) deployment, physical moves, and software deployments in support of all R&D computing.

The objective of this project was to reduce the cycle time for all desktop deployments and at the same time reduce the resources to support these deployments.

**FIGURE 9: DESKTOP DEPLOYMENT**
**Over 30% Reduction in Deployment Time (Shown below)**
**(Resource to deploy "Pathworks" reduced from 4 FTE to 1 FTE-Not Shown below)**



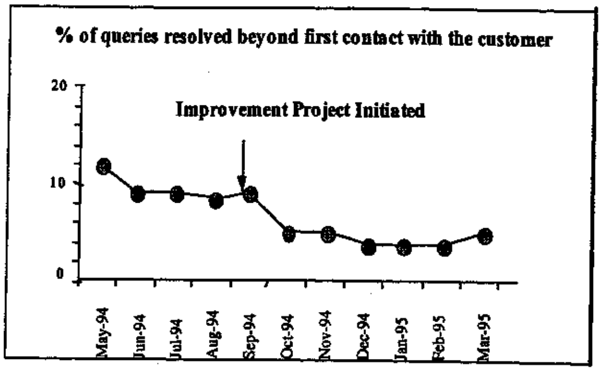
# Fast Cycle Change: Project Summary

**PROJECT 10: TECHNICAL INFORMATION EXCHANGE**

Timely technical information about R&D's complex Information Technology environment of over 500 computing software packages and layers of hardware infrastructure is critical.

The goal of this project is to improve the Help Desk (the frontline support group) access to needed technical information — information normally available only to the various system-specific experts. Better informed, the Help Desk could answer more questions on first contact when customers (end users) call and therefore get R&D associates back to work much quicker. The measure of success of this technical information exchange was reduction in the percentage of queries resolved beyond the first contact with customers.

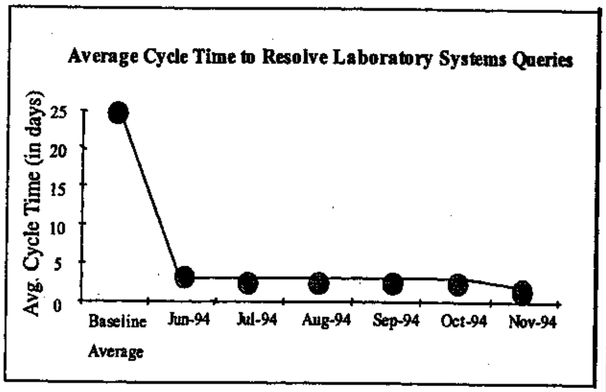
**FIGURE 10: TECHNICAL INFORMATION EXCHANGE**
**Over 30% Reduction of Calls Resolved Beyond First Contact**




**PROJECT 11: LABORATORY SYSTEMS QUERY RESOLUTION**

Computer system support and related query resolution is an important service in R&D. Historically, laboratory computing systems queries were handled independently of other systems support and differently in the US and UK with great costs in both resources, cycle time, and customer satisfaction. The primary objective of this project was to reduce cycle time to resolve laboratory systems related queries.

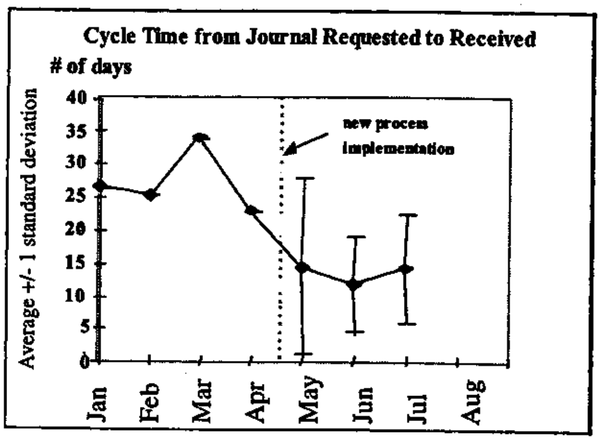
**FIGURE 11: LABORATORY SYSTEMS QUERY RESOLUTION**
**85% Reduction in Cycle Time**




**PROJECT 12: LIBRARY MANAGEMENT**

Timely access to external scientific research documents is critical to pharmaceutical R&D. The scientific documents can come from an internal or external collection of journals or books. The objective of this project was to reduce the cycle time from customer Request to Receipt for journal articles and books.

**FIGURE 12: LIBRARY MANAGEMENT**
**Over 60% Reduction in Cycle Time**

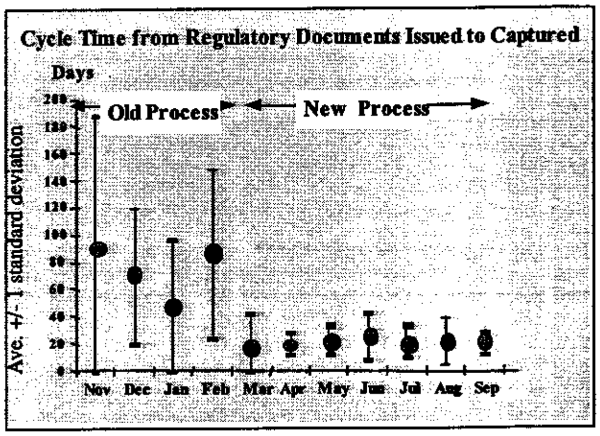


# Fast Cycle Change: Project Summary

**PROJECT 13: PROPRIETARY INFORMATION CAPTURE**

Document Management group is responsible for developing, maintaining, and supporting repositories of R&D's regulated and scientific business information. Unavailability of regulatory documents or lack of file integrity can have dire consequences. In the simplest cases, a submission is delayed while documents are found. In more extreme cases, regulatory agencies could refuse the submissions from companies for extended periods of time. The primary objective of this project was to reduce cycle time for capturing regulatory documents.

**FIGURE 13: PROPREITARY INFORMATION CAPTURE**
**70% Reduction in Cycle Time**




**PROJECT 14: CURRENT SCIENCES AND INDUSTRY AWARENESS**

Timely information about current sciences, clinical events, technology, competitors and industrial trend is essential for effective decision making in pharmaceutical R&D. This information had been provided by four separate paper products. This resulted in duplication of notifications, inconsistency across therapeutic areas, and labor intensive to produce. The objective of this team is to design and implement a process to provide the information electronically that was easier to access but required less resources to produce. The primary measure was the utilization rate: % of population who had accessed the information within two weeks of availability. The secondary measure is the resource required for this process (not shown here).

**FIGURE 14: CURRENT SCIENCES AND INDUSTRY AWARENESS**
**85% Utilization Rate within Two Weeks of Availability**