



Clinical Research Management Process Improvement Initiatives

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BACKGROUND

During the summer of 2005, Mayo Clinic launched a major initiative designed to create a world class research management system designed to advance Mayo's research vision and strategic priorities. The initiative, named the Research Infrastructure Services Excellence Initiative (RISE), was preceded two years earlier by Business Process Opportunities (BPO) – a separate Mayo initiative designed to standardize systems and processes and identify and eliminate non-value added activities.

These two initiatives intersected under Mayo's research shield in the summer of 2006 with the formation of four projects that had as their goal, enhanced customer service for Mayo's researchers through the redesign and improvement of core research administrative processes.

To ensure that the projects were appropriately resourced, Mayo brought together resources made available through the institution's BPO initiative that included experts from Mayo's Quality Management Services office and experts from the Division of Systems and Procedures to work with the process owners. These resources were combined with resources for project organization, meeting facilitation and project management expertise from the RISE Office to initiate Mayo's Quality Improvement Program for the areas supporting Mayo's research program.

The four administrative processes that were chosen for the quality improvement projects were based on input received from institutional and research leadership. The processes chosen were known to have performance issues resulting in customer dissatisfaction. The four processes chosen include:

- **IRB Review Cycle Improvement Project:** Institutional Review Board protocol review and approval process
- **Protocol Development Process Improvement Project:** clinical trial protocol development for Mayo's Cancer Center researchers
- **Pre-award Process Improvement Project:** negotiating financial agreements for industry-sponsored research awards
- **Legal Contract Administration Process Improvement Project:** establishing a contractual agreement with an industry sponsor

The teams faced many of the common challenges that impact most quality improvement endeavors. The processes being improved were often not standardized and not documented, there was a lack of data to establish the baseline performance to and resistance to change was sometimes quite evident. All of these challenges were overcome largely due to the collaborative relationships that were established between the process owners and the Quality, Process and Project Management experts that supported them.

METHOD

Structured DMAIC framework was applied in solving the problem. The problem of each project was first defined by understanding the customer's expectations through the use of customer surveys and interviews, stakeholder analysis was conducted, and communication plan was put in place. Each process was mapped out in the **measure** phase. Data was collected to establish baseline performance of the process. Improvement goals were then established according to benchmarks or entitlements. Data analysis, Pareto analysis, run charts and root causes analysis were done in the **analyze** phase. In the **improve** phase, several ideas were brainstormed to move to the future state (the new improved process). Kaizen teams were formed to implement the solutions, advancing the process from the current state to the future state. In the **control** phase, a control plan, including control charts, were developed to maintain the gains.

THE QUALITY ACADEMY

Introduction

Establish in 2006 with the mission of rapid deployment of a standardized process improvement method throughout Mayo Clinic. The Quality Academy is an available resource for teams to attend and be trained by a cadre of specialized professionals in the lean and six sigma fields. The academy currently offers **Team training**, champions training, intro to lean, intro to stat, and intro to JMP. Now a part of the Mayo Clinic – College of Medicine.

Teams Training

The process improvement projects teams have attended a 10 day training at the Quality Academy. The training provided participants with the structure of the process improvement method adopted at Mayo: DMAIC – Define, Measure, Analyze, Improve and Control. It also trained participants on the use of several tools real time and exposed them to many other tools that can be used in other projects. The goal is to provide participants with the toolset necessary to pursue any process improvement project.

Team Structure

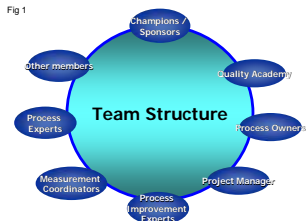


Fig 1

Training Timeline



Fig 2

IRB PROCESS IMPROVEMENT PROJECT

Process Owner: Marcia Andresen-Reid

Problem Statement, Project Goal and Scope

The IRB turnaround time for protocol review has been identified as a source of dissatisfaction by the researchers, the IRB Staff and may adversely impact patient's access to clinical trials. On average, the review of protocols took 38 days, with a high degree of variation among the 6 boards. The customers expect a more predictable and timely turnaround. Specifically, the goals of the Improvement Project were to reduce the protocol turnaround time to no more than 21 days, while maintaining the IRB responsibility to uphold the regulations. The project will focus on all submissions to the IRB and include work processes from the submission of protocols/reports to the dispatch of minute excerpts.

The Mayo IRB serves as the IRB of record for Mayo Rochester, Jacksonville, and Arizona. A coordinated approach among Mayo Rochester, Mayo Arizona, and Mayo Jacksonville providers is planned so that all will be successful in achieving this goal.

Example of tools used

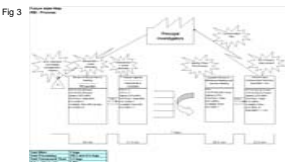


Fig 3

Results

Team was able to achieve a reduction in their cycle time of 35 percent from an average of 37 days to an average of 24 days.

Conclusions and Further Direction

This process improvement project introduced the IRB staff to tools that can be utilized for future improvement projects. Importantly, the team is prepared and energized to initiate additional projects. The IRB Performance Improvement Plan has been established with 12 subprojects, with deliverable goals that will improve service and quality.

Lessons Learned

Change is hard. Adequate resources must be available outside of the daily operations in order to succeed. Sustained and expert institutional support from IT, System's and Procedures, and Quality Management were critical to the team's success.

PROTOCOL DEVELOPMENT PROCESS IMPROVEMENT PROJECT

Process Owner: Terre McJoynt

Problem Statement, Project Goal and Scope

The protocol development process at Mayo Clinic is entirely de-centralized, with each medical specialty and each site (Rochester, Jacksonville, Arizona, and Mayo Health System) taking responsibility for and utilizing its own evolved processes for developing the protocol. Inconsistencies and errors resulting from non-standard processes, as well as, delays due to redundancies, rework, and high work load have led to diminished reputation among industry sponsors as well as dissatisfaction among investigators, and staff. The primary goal of the project is to reduce the lead time from when a research protocol/grant reaches the PDC to the time it is submitted to the IRB from an average of 38 weeks to a maximum of 10 weeks for internally-authored and a maximum of 4 weeks for externally-authored protocols. Implementation of the process improvement will be achieved without sacrificing protocol safety and compliance with regulatory requirements or increasing FTE.

Example of tools used

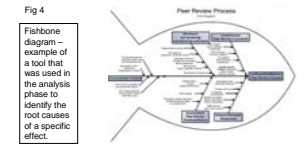


Fig 4

Results

Team was able to achieve a significant reduction in their cycle time. While it still early in the control phase of this project, the cycle time has been reduced by 77 percent, down from an average of 33 weeks to an average of 7.7 weeks.

Conclusions and Further Direction

Monitor compliance of new process. Continue monthly feedback to stakeholders. Solicit ideas to enhance tools & process. Maintain future state design. Replicate process and best practices with research community. Engage other departments in QA program

Lessons Learned

Sometimes pigs do fly—don't set goals too low. Multiply: Use multiple forms of communication multiple times to multiple groups to clearly educate the main points. Maintain the scope of the project. Celebrate milestones as they occur

PRE-AWARD PROCESS IMPROVEMENT PROJECT

Process Owner: Cheryl Nelson

Problem Statement, Project Goal and Scope

The Office of Sponsored Projects Administration (MCR) or Clinical Studies Unit/Protocol Development Office (MCA & MCJ) in Research Administrative Services exists to assist investigators and their support staff with several aspects of the grant and contract life cycle. Information suggests that the current process is too lengthy and that industry contracts have been lost in the past due to this reason alone. Targets established: Duration from receipt of complete budget request from the Principal Investigator (P.I.) to scheduling the Protocol Initiation Meeting with the PI to no more than 24 hours. Turnaround time from receipt of complete budget request from the Principal Investigator (P.I.) to Hand-off to the Legal Contract Administration in no more than 7 days. Best practices from the three sites will be incorporated in building a common future state for the process

Example of tools used

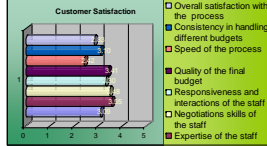


Fig 5

Results

The pre-award project resulted in a reduction in the cycle time of 72 percent, from an average of 13.6 weeks down to an average of 3.8 weeks.

Conclusions and Further Direction

Use of LEAN processes can help focus efforts on reducing waste, maintaining value added tasks and continued process improvement as more information is learned.

Lessons Learned

Process improvement is a continuing process. It is important to start somewhere, make initial improvements and then focus on areas for future improvement.

Change is difficult for staff involved in the process. It is important to educate staff on the process and have their buy-in to make the process successful.

Concentrate on tasks that YOU can control and change. Ensure that metrics allow you to capture data that does not include any effort from functions that you don't control.

LEGAL CONTRACT ADMINISTRATION PROCESS IMPROVEMENT PROJECT

Process Owner: Nickie Bruce

Problem Statement, Project Goal and Scope

With the decrease in Federal funding, industry funding for research has become more competitive. LCA has been charged with reducing the turn around time for ISMCT. Of the Clinical Trial contracts managed in LCA, 43 percent are ISMCT. Our internal and external customers have expressed concern at the length of time it takes to negotiate the agreements. LCA will need to reduce the time it takes from initial receipt of the contract to transfer of the file and/or documentation to Research Administration in order to remain competitive. The project will focus on 2 processes within ISMCT. These processes include initial receipt of the contract to completion of negotiations and the turnaround time for routing for signatures.

While ensuring compliance with Mayo policy and division guidelines, the goal of LCA is to reduce the time it takes from initial receipt of the contract to completion of negotiations from average of 105 days to no more than 30 days and to reduce the time for routing for signature from an average of 13 days to no more than 10 days by the end of 3rd quarter 2007.

Example of tools used

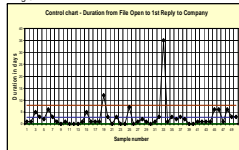


Fig 6

Results

Team was able to reduce their cycle time by 88 percent from an average of 105 days down to an average of 12 days, surpassing their goal of a 71 percent reduction in cycle time.

Conclusions and Further Direction

- Apply the lessons learned to other agreements in our unit.
- Assist in developing a framework for data gathering/management.

Conclusions and Further Direction

- Shorten contract preparation and negotiation while preserving quality of the contracts.
- Fosters understanding and integration with other work units.