

Minimizing Clinical Trial Deviations Through Lean Six Sigma and a CRO Compliance Committee

A. Barkman, T. Cummings, J. Kessler

University of Maryland Marlene and Stewart Greenebaum Comprehensive

1. Background

The University of Maryland Greenebaum Comprehensive Cancer Center Clinical Research Office (UMGCCC CRO) Compliance Committee reported an abundance of re-occurrences and similar occurrences of clinical trial deviations deriving from research specimen collections and sample management. The purpose of this project was to analyze and determine the root causes of lab and sample deviations, to improve sample collection, and minimize research lab errors and deviations. In a root cause analysis conducted at UMGCCC by a Lean Six Sigma Green Belt, we determined the following were the most significant and impactful contributors to sample management deviations: inconsistent performance of procedures, lack of quality control processes, inconsistent usage of the calendar of events, and staffing of the lab and medical assistant teams.

2. Goals

- Improve lab collection and minimize research lab errors and deviations
- The immediate goal was to determine the root causes of sample collection RNIs and deviations.
- The long-term goal is to reduce the sample management error rate by at least 50% 6 months after implementing solutions.

3. Solutions and Methods

- **Define:** Using Lean Six Sigma (LSS), we defined the problem statement that the amount of lab deviations in 12 months (n=82) was too high and set a goal to minimize deviations.
- **Measure:** Created a “current state” process map of the sample management process. The process map identified the path of sample collection and defined value-added activities.
- **Analyze:** By creating a fishbone diagram, we identified the effect (Y): research lab deviations and identified the Critical (X)s: root causes. We then prioritized the root causes and proposed quick wins and rapid improvements.
- **Improve:** Through identifying the root causes, we then prioritized a list of solutions. A “future state” process map was created and a pilot plan was formed.
- **Control:** We revised process documentation, updated SOPs and training plans, and planned to transition sample management to the process owner.

4. Outcomes

- Updated the Research Specimen & Procedure Management SOP and implemented quality control training
- Updated the processes for calendar entry of research specimen collection requirements
- Provided supporting evidence and documentation that a Clinical Lab Coordinator management position was necessary for the CRO. This position was filled and the coordinator took over as the “process owner”

Category: Training and Quality Assurance – Work In Progress

- As this is currently an active project, a full 12 months of data is not yet available. However, in the past four months post implementation, we have seen a mean of 4.5 lab deviations per month. Which would extrapolate to 54 deviations over 12 months post implementation. This represents a 34% reduction in errors.

5. Lessons Learned

This work demonstrates that LSS methodology can be applied to operational issues in clinical research, including clinical trial deviations. By identifying root causes and prioritizing solutions, the UMGCCC CRO Compliance Committee was able to review and discuss the deviation report descriptions, brainstorm causes for deviations, discuss possible solutions, and mitigate strategies to be relayed by the CRMO leader representative. Future directions for GCCC include creating a monthly compliance report and quarterly reviews of research specimen and management deviations by the Compliance Committee.