MHALEAN SIX SIGMA ANALYZE TOLLGATE

Moving Clinical Trials Upstream

University of Missouri

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Green Belt Certification Six Sigma Initiative Charter

INITIATIVE TITLE: Moving Clinical Trials Upstream

ORGANIZATION NAME: University of Missouri

Project Roles and Team Members

Executive Sponsor: Parvesh Kumar, MD
Process Manager(s): Taylor Mathews, RN
Physician Champion: Hasan Naqvi, MD
Green Belts: Britlyn Brown, BSN, RN
Tami Day, DNP, RN
Team Members:
Mihiri DeSilva, RN (Clinical Research)
Morgan Stubblefield (Clinical Trial Support Office)
Jamie Caldwell (Clinical Trial Support Office)
Andy Stelling (OSPA)
Stacy Baker (MOI)
Natalie Taylor, RN (Neurology)
Elizabeth Porting-Jackson
Austin Rolfes

Problem Statement

The clinical trial start-up time from site selection to open to enrollment is greater than the acceptable timeframe of 120 days.

Business Case

Delays in clinical trial start-up process result in lost revenue ($92,176;CoVPN study); unpredictable/unbalanced workload for study coordinators; customer dissatisfaction (internal and external); decreased workforce efficiency resulting in higher operating costs; staff dissatisfaction from inefficient processes; breakdowns in communication across system; lack of universal understanding of roles & responsibilities.

Initiative Scope

All industry-sponsored clinical trials coordinated by the Clinical Research Center, Missouri Orthopedic Institute and the Department of Neurology.

Goal Statement

Improve the clinical trial start-up process that achieves six sigma performance to decrease defects to 76,666 of every 1 million opportunities which increases sigma score from 0.7 to 2.9 and increase yield from 22% to 91.92% by April 2023.

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ANALYZE - Critical Xs / Root Causes Identified

- High correlations between total times to complete study start-up & individual steps in the process.
- No statistical significance between department is completing start up process, study coordination, principal investigator, or Central vs. Local IRB.
- Multiple steps in the study start-up process need improvement in order to reduce the amount of time from site selection to open to enrollment.
- Our focus was actual process v. a specific department involved in the process.

IMPROVE - What was Implemented

- Utilize the clinical trial data management program, Oncore, to track and monitor study start-up process. This is being beta tested in our organization with several departments, not our unit at this time.
- The task list in Oncore had to be built by the Business Analytics team in the School of Medicine's Office of Medical Research.
- A small improvement team was organized and input received prior to the Oncore build.
- Once built, a small, select group began beta testing the new format

IMPROVE – What was Implemented

Utilize OnCore clinical to track study start-up.
Goal: Start-up ≥ 103 days

Use OnCore task list to track the following dates:

Protocol received
Contract received
Budget received
Budget negotiated
Budget finalized
Contract finalized and fully executed
Final study packet approved
Date study open to enrollment

IMPROVE – Results to Date

Utilization of OnCore to track study start-up process is in beta testing with a few select departments. Results are pending but anticipated to be available in November, 2022.

CONTROL – Next Steps

- After beta tests utilizing the OnCore data management system conclude, we plan to potentially spread that to other departments throughout the University system.
- For studies to be coordinated within our unit, our team will consider continuation of ownership of the study start-up process.
- We plan to report results to research leadership within the organization and provide input for ongoing improvement.
- Our "ah-ha" moment was at the time of analysis when we realized there was no one area causing delays.

OVERALL LESSONS LEARNED

We learned that 1) our team can learn and process the clinical trial study start-up; 2) how much underlying resistance there was from leadership who either pushed back on efforts or simply did not support

We were surprised to learn that the start-up timeline did not vary between departments across the system.

For our next improvement project, we will take on a project in which our team has more control. Having to rely on many departments outside our own was far too challenging at the local level.

NEXT PROJECT(S)

Learning the Lean Six Sigma methodology

REWARD AND RECOGNITION

Our team would like to thank the following for their support, encouragement, and expertise:
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