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Lean Leadership in Research

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LEAN LEADERSHIP IN RESEARCH

A Project Capstone

Submitted to the Faculty

of the Department of Leadership Education

College of Education

of Winona State University

by

Dania Helgeson

In Partial Fulfillment of the Requirements

for the Degree of

Master of Science

July 30, 2020



Comprehensive Exam Project Presentation

Lean Leadership in Research

Dania Helgeson

Master's Program Leadership Education

7/30/2020



Introduction

- As a Clinical Research Coordinator (CRC) there is a lot of challenges for the clinical trial start-up process.
 - Multiple stakeholders
 - Wasted time
 - Inefficient work process



Purpose of the Study

- The purpose of this study is to improve the start-up process for Clinical Trials in the Cancer Center.

Research Questions

The following questions guided this study:

RQ1: What are the challenges in the clinical trial start-up process?

RQ2: What are some recommendations to improve the clinical trial start-up process?



Project Stakeholders

Front – Line Stakeholders

- Clinical Research Coordinators
- Research Protocol Specialists
- Principal Investigators

Second – Line Stakeholders

- Research Associates
- Pharmacists
- Inpatient team
- Chemotherapy Units
- eCTX group
- Gonda 10
- CRTU (if used)
- Shipping department



Research Methodology & Rationale

- Action research
- Interviews
 - 4 Clinical Research Coordinators
 - 2 Principal Investigators
 - 1 Research Protocol Specialist
 - 1 Supervisor
- Surveys
 - 18 responses (43% response rate)

Research Question 1 Findings

RQ1: What are the challenges in the clinical trial start-up process?

Theme: Non-Value Added

Data Collection Method:

Interviews and Surveys

Data Analysis Method:

Thematic Coding

Many areas of non-value in the study start-up process were recognized.

- Logistics meeting incomplete
- Lack of communication
- No standardized process
- Duplicated work

Research Question 2 Findings

RQ2: What are some recommendations to improve the clinical trial start-up process?

Theme: Standardized Process

Data Collection Method:

Interviews and Surveys

Data Analysis Method:

Thematic Coding

The responses from the interviews to develop a checklist or algorithm:

- Checklist: 7
- Algorithm: 4
- Checklist & Algorithm: 5

Based off the responses it was recommended to create a checklist and algorithms.

Project Description

- Checklist and algorithms were developed from the data collected in the interviews and survey.
- Checklist and algorithms piloted by the CRCs for feedback.
- The final document is a standardized checklist and algorithm for a clinical trial study start-up.

Project Outcomes Linked to Research

| Project Outcomes | Research |
|------------------------|---|
| Checklist & Algorithms | <ul style="list-style-type: none"><li data-bbox="1065 422 2346 515">• Engaging with those employees on the front-line. (Dombrowski & Mielke, 2013)<li data-bbox="1065 594 2346 743">• Making sure to have all key stakeholders and even someone who doesn't work directly with the project be involved. (Simon & Canacari, 2012)<li data-bbox="1065 822 2346 915">• Asking the question “why” five times after each answer. (Dombrowski & Mielke, 2013)<li data-bbox="1065 993 2346 1086">• Identifying waste, as that has shown to be the most effective way to improve the process. (Fillingham, 2007)<li data-bbox="1065 1165 2346 1315">• The lean methods focus is to have better quality throughout the organization while reducing costs. This leads to the end of goal of elimination of waste. (Kanbanize, 2020) |

Leadership Implications

Core Course

Leadership Implications

Systems Thinking

Dynamic System – collective and collaboration
Mental Models – beliefs and assumptions

Change Leadership

4 frames of leadership – structural, human resource,
political and symbolic

Communications

Clear and concise – everyone interprets different
Listening to feedback

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