Project Management at the Research Site

Laura R. Holtz, MS, PMP, CCRP
Clinical Research Associate
Yale Center for Clinical Investigations (YCCI)
Yale University
Society of Clinical Research Associates (SOCRA)
Board Director and Board Treasurer
I have no financial disclosures or conflicts of interest (COI) with the presented material in this presentation. (2022)
Talk

Objectives

Describe
Describe the Project Management Institute (PMI) process phases model.

Analyze
Analyze clinical trial site tasks and responsibilities as it relates to the Project Management.

Evaluate
Critically evaluate the impact of a structured project management on site performance.
Common Hazards

- Over budget
- Over schedule
- Low recruitment
- Amendments
- Deviations
- Understaffed
- Audits/Inspections
Clinical Trial as a Project

1. What is your role in the Clinical Research enterprise?

2. What is your project? (i.e., regulatory management, recruitment, budget management, staffing, etc.)

3. What project “tasks” are you delegated or assigned?
Project

Project:
- Temporary; with a beginning and end
- Unique; not routine operations

Using a real-world example will help illustrate concepts in this presentation.

https://www.pmi.org/about/learn-about-pmi/what-is-project-management
Project Management

**Project:**
- Temporary; with a beginning and end
- Unique; not routine operations

Project Management is the application of knowledge, skills, tools, and techniques to **project activities** to meet the **project requirements**.

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Project Management Institute™ Framework

Project:
- Temporary; with a beginning and end
- Unique; not routine operations

Project Management is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements.

Project Management Institute (PMI) framework
5 Process groups
10 Knowledge areas

https://www.pmi.org/about/learn-about-pmi/what-is-project-management
PMI Process Groups

Initiating
- Project Objectives
- PM Identified
- Constraints
- Authorization

Planning
- Statement of work
- Project plan
- Project glossary
- Assumptions, constraints, critical success factors
- Project plan updates

Executing
- Project deliverable
- Deliverable acceptances
- Actual effort & completion data
- Change requests
- Issues

Controlling
- Performance/status reports
- Plan change requests
- Change management results
- Issues management results

Closing
- Product and vendor evaluations
- Acceptance documentation
- Legal, contract, budget closure
- Project archives
- Re-deploy resources
- Outstanding issues and changes

Ongoing Cross Project Improvement
Apply past project content and lessons-learned on future projects

https://www.e-education.psu.edu/geog871/sites/www.eeducation.psu.edu.geog871/files/image/process_elements.png
**Process Groups: Example**

<table>
<thead>
<tr>
<th>Process</th>
<th>Project: Submitting study protocol to the IRB for initial approval</th>
</tr>
</thead>
</table>
| **Initiating** | - Identify who will be drafting IRB application- Responsible party  
- Identify who needs to approve before submission- Authorizing stakeholder  
- Identify the outcomes of IRB submission- Obtain IRB approval |
| **Planning** (10 Knowledge Areas) | - **Scope** of work (what is included in submitting to IRB, and not!)  
- **Time** needed to complete IRB submission  
- Resources needed to draft, **cost** of supplies/ materials, etc. |
| **Executing** | - Drafting IRB submission package, Informed Consent forms (ICF), recruitment materials; answering questions from team.  
- Obtaining approval on drafts from stakeholder, as needed  
- Submitting IRB application (protocol, ICF, Investigator brochure, etc.) to IRB for review |
| **Controlling and Monitoring** (may result in additional planning and execution) | - Identifying errors or gaps and making revisions.  
- Responding to pre-review questions from the Human Research Protection  
- Address unforeseen delays in executing, and revising plans |
| **Closing** | IRB approval received |
PMI Knowledge Areas

• 10 domains for Project Planning

• Planning define BASELINE

• Baseline establishes expected results

• Scope + Cost + Schedule = Performance Measurement Baseline
Clinical Site Operation: Participant Enrollment
Knowledge Areas for Project Planning

Success!

Baselines are established in planning phase.

Start with the END in mind, and back into the Baseline.
Application of Performance Measurement Equation

Will the research site complete participant enrollment (scope) on time (schedule) with the staff/resources budgeted (cost)?
Scope Baseline

Scope: Combined objectives and requirements needed to complete the project.

Work packages - Groups of tasks to complete project

• Determine relationships and dependencies between groups.

• Consider order of groups - before/after/concurrent
## Participant Enrollment Work Package

<table>
<thead>
<tr>
<th>Task Breakdown</th>
<th>Task Before</th>
<th>Task After</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Distribute study recruitment materials</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>30 days (ongoing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Screen potential participant</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>2 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Obtain informed consent for participant</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>2 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Confirm eligibility for participant</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>5 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Enroll participant</td>
<td>4</td>
<td>X</td>
</tr>
<tr>
<td>1 day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL Time</td>
<td>10 days per participant</td>
<td></td>
</tr>
</tbody>
</table>

**TIP:** Record in the Delegation of Authority log staff assigned to tasks.
Figure 1: IN-PEACE study work breakdown structure (WBS)
Schedule Baseline

Project Schedule

<table>
<thead>
<tr>
<th>No</th>
<th>Activity</th>
<th>Duration (days)</th>
<th>Dependencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>technical design of module A</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>technical design of module B</td>
<td>5</td>
<td>FF on (1)</td>
</tr>
<tr>
<td>3</td>
<td>development of module A</td>
<td>15</td>
<td>FS on (1)</td>
</tr>
<tr>
<td>4</td>
<td>development of module B</td>
<td>20</td>
<td>SS on (3), FS on (2)</td>
</tr>
<tr>
<td>5</td>
<td>development of feature in module B</td>
<td>1</td>
<td>SF on (4)</td>
</tr>
<tr>
<td>6</td>
<td>implementation of module A</td>
<td>5</td>
<td>FS on (3)</td>
</tr>
<tr>
<td>7</td>
<td>implementation of module B</td>
<td>7</td>
<td>FS on (3), (4)</td>
</tr>
<tr>
<td>8</td>
<td>testing of module A</td>
<td>6</td>
<td>SS+4 on (6)</td>
</tr>
<tr>
<td>9</td>
<td>testing of module B</td>
<td>10</td>
<td>FS on (7)</td>
</tr>
<tr>
<td>10</td>
<td>integration testing</td>
<td>5</td>
<td>FS on (8), FS-2 on (9)</td>
</tr>
<tr>
<td>11</td>
<td>Deployment</td>
<td>1</td>
<td>FS on (10)</td>
</tr>
</tbody>
</table>

Months

1

2

3
Enrollment Schedule Baseline

Enrollment begins: March 2019  
Proposed enrollment: 200 participants

Final project date: December 2023  
Intervention period: 24 months

**Baseline:** Enrolled participants PER MONTH to meet enrollment schedule.
Estimating Costs for study

Estimating Costs based on work packages (most accurate estimating)

**Fixed costs**: equipment, contracts, supplies, space, etc.

**Estimation**: Staff time to complete task

Assumption: Work hours available
1760 hours (220 days) / year = 147 hours per month = 36.75 hours per week

TIP: Factor in holidays, vacation, when establishing available work time
# Exercise: Task time for 1 Participant Recruitment

<table>
<thead>
<tr>
<th>Participant Recruitment Task</th>
<th>Staff Time to complete task</th>
<th>Time</th>
</tr>
</thead>
</table>
| Screen potential Participant           | • Review Participant medical record  
• 10 question screening at appointment  
• Confirm inclusion with physician  
• Escort Participant for lab work for eligibility                                                                 | • 25 min  
• 60 min  
• 20 min  
• 30 min |
| Obtain informed consent (IC)           | • Schedule informed consent visit  
• Conduct informed consent discussion  
• Complete documentation of IC in research chart/ clinical electronic medical record (EMR)  
• Create Source File and document in electronic data capture (EDC)                                                                 | • 25 min  
• 90 min  
• 15 min  
• 10 min |
| Confirm eligibility                    | • Obtain lab work report  
• Confirm eligibility with physician  
• Complete documentation in source file                                                                                                                      | • 10 min  
• 20 min  
• 10 min |
| Enroll Participant                     | • Enter Participant information into research database  
• Schedule appointments  
• Mail study materials to participant                                                                                                                       | • 45 min  
• 10 min  
• 10 min |
| **Total Time:**                        | 390 minutes / 6.5 hours to complete 1 Participant recruitment                                                                                               |          |
Estimating Total Cost for Participant Enrollment

1. Calculate total number hours for work package per Participant enrollment
   390 minutes / 6.5 hours

2. Enrollment target: 50 Participant total for this study

3. Establish hourly rate (staff salary)
   - Salary + fringe/ Annual hours = hourly rate
     Ex. $100,640 / 1760 hrs. = $57.18/ hr.

Equation to calculate cost per work package for project

# of hours x # participants x hourly rate = estimated cost

6.5 x 50 x $57.18 = $18,583
Estimating Staff Effort for Participant Enrollment

Goal: 50 Participant in 12 months
Target: 5 per month \( \frac{50}{12} = 4.1, \text{ round up} \)

Time per Participant enrollment = 6.5 hours

6.5 hrs. * 5 Participant = 32.5 hours per month

5% of Research Assistant time will be spent on Participant Enrollment work package per month

\( \frac{146 \text{ total hrs. month}}{32.5 \text{ task hrs. month}} = 4.46\% \text{ full time effort (FTE)} \)
Project Management and Site Performance
### Planning for TOTAL Participant interventions

<table>
<thead>
<tr>
<th>Month #</th>
<th>Month</th>
<th>Participant Enrollments</th>
<th>Outcome Assessments-Quarterly</th>
<th>Total Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3/19</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>4/19</td>
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<td>10</td>
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<tr>
<td>3</td>
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<td>0</td>
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<td>4</td>
<td>6/19</td>
<td>10</td>
<td>5</td>
<td>15</td>
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<tr>
<td>5</td>
<td>7/19</td>
<td>10</td>
<td>10</td>
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<tr>
<td>6</td>
<td>8/19</td>
<td>10</td>
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<td>20</td>
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<td>7</td>
<td>9/19</td>
<td>10</td>
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<td>25</td>
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<tr>
<td>8</td>
<td>10/19</td>
<td>10</td>
<td>20</td>
<td>30</td>
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<tr>
<td>9</td>
<td>11/19</td>
<td>10</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td>10</td>
<td>12/19</td>
<td>10</td>
<td>25</td>
<td>35</td>
</tr>
<tr>
<td>11</td>
<td>1/20</td>
<td>10</td>
<td>30</td>
<td>40</td>
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<tr>
<td>12</td>
<td>2/20</td>
<td>10</td>
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<td>13</td>
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<td>14</td>
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<td>6/20</td>
<td>10</td>
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<td>9/20</td>
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</tr>
<tr>
<td>20</td>
<td>10/20</td>
<td>10</td>
<td>60</td>
<td>70</td>
</tr>
<tr>
<td>21</td>
<td>11/20</td>
<td>5</td>
<td>60</td>
<td>65</td>
</tr>
</tbody>
</table>

**TIP**: Look for month with maximum workload to calculate needed resources.
Minimize Protocol Deviations

Standard Operating Procedures (SOP) help to avoid scope creep

Detailed, written instructions to achieve uniformity of the performance of a specific function (ICH/GCP 1.55)

Describe the process- a sequence of operations designed to achieve a predictable and consistent result
Quality Management: Source Documentation

Apply ALCOA-C to achieve standard data quality

A – Attributable
L – Legible
C – Contemporaneous
O – Original
A – Accurate
C - Complete
Quality Management: Monitoring Baseline with Actuals
Risk Management: Contingency planning

• Determine items that cannot be recreated or replaced and evaluate risk of loss. For greatest risk, prepare backup plan.
  
  Electronic Data Capture becomes corrupted
  Paper Source files are destroyed

• Identify minimum resources and personnel needed for business continuity to meet baselines
  
  Protocols, supplies, materials, SOP, personnel, space, connectivity

• Prioritize highest risk activities and stakeholders for communication
  
  FDA, IRB, study participants, etc.
## Integrated Change Management
### Building efficiencies

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessing</td>
<td>Assessing breakdowns and failures (Root Cause Analysis) and implementing fixes (Corrective and Preventive Action plan)</td>
</tr>
<tr>
<td>Evaluating</td>
<td>Evaluating alternative processes or plans (process improvement pilots)</td>
</tr>
<tr>
<td>Using</td>
<td>Using the PMI process to plan, initiate, evaluate the change</td>
</tr>
<tr>
<td>Documenting</td>
<td>Documenting the change to ensure replication and consistency</td>
</tr>
</tbody>
</table>
Thank you!

Laura R. Holtz, MS, PMP, CCRP
Clinical Research Associate
Yale Center for Clinical Investigations (YCCI)
Laura.Holtz@yale.edu