PROJECT MANAGEMENT

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Project Manager
AGENDA

• What is Project Management?
• PM Knowledge.
• Trial Feasibility.
• Our difference.
• Is Project Manager needed?
Project Management

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

(PMBOK Guide, Fifth edition)
Stakeholder Management

Tuckman ladder

- **Forming**
  - Unclear purpose
  - A lot of guidance

- **Storming**
  - Conflict
  - Clarify of purpose

- **Norming**
  - Agreement and consensus
  - Clear role

- **Performing**
  - Clear vision and purpose
  - Delegation

- **Adjourning**
  - Learning from mistake
  - Recognition

Identify stakeholder
Plan Stakeholder management
Manage Stakeholder engagement
Control stakeholder engagement
PM Knowledge Area

10 Knowledge Areas.
47 Processes.
# PM Knowledge Area

## Project Management Process Groups

<table>
<thead>
<tr>
<th>Knowledge Areas</th>
<th>Initiating</th>
<th>Planning</th>
<th>Executing</th>
<th>Monitoring &amp; Controlling</th>
<th>Closing</th>
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### The Five Process Groups

A **Process** is a “set of interrelated actions and activities performed to achieve a pre-specified product, result or service”

- **Initiating**
- **Planning**
- **Executing**
- **Monitoring & Controlling**
- **Closing**

Mapping Project Management Process Groups to Knowledge Areas

PM Knowledge Area

- **Scope Management.**
- **Time Management.**
- **Cost Management.**
- **Quality Management.**
- **Risk Management.**
- **Human Resource Management.**
- **Communication Management.**
- **Procurement Management.**
- **Stakeholder Management.**
- **Integration Management.**
Ridiculous timeline?..

How to achieve the timeline....
Time Management

• Sequence activities
• Identify Activity Resource.
• Identify Activity Duration.
• Develop Schedule
  – Critical path, float, buffers.
• Optimise Resources
  – Leveling, smoothing, crashing, fast tracking.

DEVELOP PROJECT SCHEDULE
Time Management

- **Study Setup Phase**: Jan 1 '15 - Aug 14 '15
  - Duration: 162 days
  - Start: Jan 1 '15
  - Finish: Aug 14 '15

- **CTA and Budget**: 91 days
  - Start: Jan 1 '15
  - Finish: May 7 '15

- **Protocol**: 31 days
  - Start: Jan 1 '15
  - Finish: Feb 12 '15

- **CRF**: 25 days
  - Start: May 8 '15
  - Finish: Jun 11 '15

- **eCRF**: 46 days
  - Start: Jun 12 '15
  - Finish: Aug 14 '15

- **Randomization**: 26 days
  - Start: May 8 '15
  - Finish: Jun 12 '15

- **Informed Consent Form**: 15 days
  - Start: May 8 '15
  - Finish: May 28 '15

- **IRB**: 51 days
  - Start: May 29 '15
  - Finish: Aug 7 '15

- **Regulatory Authority**: 51 days
  - Start: May 29 '15
  - Finish: Aug 7 '15

- **Study Operations Manual**: 26 days
  - Start: Jun 12 '15
  - Finish: Jul 17 '15

- **Monitoring Plan**: 26 days
  - Start: Jun 12 '15
  - Finish: Jul 17 '15

- **Investigational Product Manual**: 41 days
  - Start: Jun 5 '15
  - Finish: Jul 31 '15

- **Study recruitment**: 174 days
  - Start: Aug 10 '15
  - Finish: Apr 7 '16

- **Database Lock**: 101 days
  - Start: Apr 8 '16
  - Finish: Aug 26 '16

- **Study Close-Out**: 15 days
  - Start: Jul 28 '16
  - Finish: Aug 17 '16

- **Final Statistical Analysis**: 22 days
  - Start: Jul 28 '16
  - Finish: Aug 26 '16
Feasibility Assessment

Conducting assessment in a **truthful**, **thorough**, **consistent** and **systematic** manner that accounts for **real world factors** and supports process improvement.

Operations & Budget
Operational Feasibility

• Inputs from Stakeholders.
  • Biostatistician.

• Sample management.
  • Availability
  • Permit / custom.
  • Cold chain
  • Warehouse
  • Long term storage
Operational Feasibility

• Study Coordinators.
  • Workload / experience
  • Recruitment methodology.

• Site Feasibility Evaluation form
  • Assess feasibility of potential sites.
  • Answer honestly.
  • Involved other stakeholder.
Budget Feasibility

Clinical Trial Budget

- **Internal costs**
  (Budget considered at institution level)

- **External costs**
  (Budget of cost incurred apart from institution)
Budget Feasibility

Time

Cost

Starting the project

Organizing and preparing

Carrying out the work

Closing the project
Budget Feasibility ~ Internal

• Screen failure.
• Investigator fees.
• EC submissions.
• Patient reimbursements.
  • Transport, Drug supplies.
• Lab kits, study related consumables.
• Document archival.
Budget Feasibility ~ External

• Clinical Monitoring.
  • Depth of monitoring.
  • Reports, compliance to GCP.

• Data Management.
  • CRF / eCRF platform.
  • Queries.

• Study Drugs.
  • Placebo.
SCRI PM – Our Difference!

• 20 years of experience!
• Good networking and partners.
• Specialized knowledge in IIT trial.
  – Recruitment 1000 in 3 months.
• Understand the issues faced by IIT.
  • Database of knowledge.
• Experience in handling different trial indication, different phases.
SCRI PM – Our Difference!

• Not too big! Easier to get things done.
• Sample management.
  – China, India, Japan, Korea, Thailand
  – Good understanding of regulatory requirement.
SCRI PM – Our Difference!

• Organizational Process Assets
  – **RAND**.
  – Oracle Clinical.
  – RedCap.
  – Project Registers.
  • Risk registers, lesson learned, stakeholder register, Project files and timeline.
RAND

• A web-based application that allows investigators to screen, randomise patients and keep track of drug inventory.

• It supports configurable study parameters for different types of study design.
Randomisation with drug management process

- With the RAND system in place, the randomisation and drug management processes are streamlined, which eliminates the need for manual and labour-intensive drug management.
SCRI PM – Our Difference!

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  - RAND.
  - Oracle Clinical.
  - RedCap.
  - Project Registers.
    - Risk registers, lesson learned, stakeholder register, Project files and timeline.
THANK YOU!