PROJECT MANAGEMENT

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Project Manager

INNOVATION IN
CLINICAL RESEARCH
FOR THE NATION

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

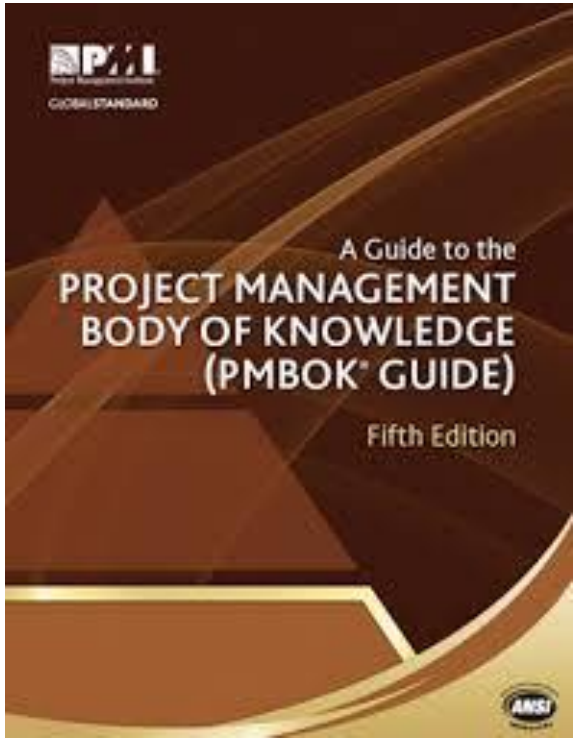
Manage Stakeholder engagement

Control stakeholder engagement

SCRI Singapore Clinical Research Institute

PM Knowledge Area

Project Management Institute



10 Knowledge Areas.
47 Processes.

PM Knowledge Area

Knowledge Areas	Initiating	Planning	Executing	Monitoring & Controlling	Closing
Integration	1-Develop Project Chart	2-Develop Project Management Plan	3-Direct and Manage Project Execution	4-Monitor and Control Project Work 5-Perform Integrated change control	6-Close Project or Phase
Scope		1-Collect Requirements 2-Define Scope 3-Create WBS		5-Verify Scope 6-Control Scope	
Time		1-Define activities 2-Sequence Activities 3-Estimate activity resources 4-Estimate activity durations 5-Develop Schedule		6-Control Schedule	
Cost		1-Estimate Cost 2-Determine Budget		3-Control Cost	
Quality		1-Plan Quality	2-Perform Quality Assurance	3-Perform Quality Control	
Human Resources		1-Develop Human Resources Plan	2-Aquire Project Team 3-Develop Project Team 4-Manage Project Team		
Communication	1-Identify Stakeholders	2-Plan Communications	3-Distribute Information 4-Manage Stakeholders Expectations	5-Report Performance	
Risk		1-Plan Risk Management 2-Identify Risks 3-Perform Qualitative Risk Analysis 4-Perform Quantitative Risk Analysis 5-Plan Risk Responses		6-Monitor and Control Risks	
Procurement		1-Plan Procurements	2-Conduct Procurements	3-Administer Procurements	4-Close Procurements

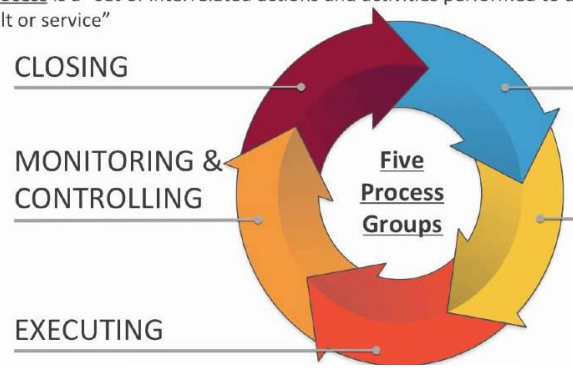
Project Management Process Groups

Based on the PMBOK® Guide - 4th Edition, http://www.pmi.org
http://selharti.wordpress.com/category/project-management

Mapping Project Management Process Groups to Knowledge Areas

The Five Process Groups

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



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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

		Task Name	Duration	Start	Finish	Predeces
1		Study Setup Phase	162 days	Jan 1 '15	Aug 14 '15	
2		CTA and Budget	91 days	Jan 1 '15	May 7 '15	
10		Protocol	31 days	Jan 1 '15	Feb 12 '15	
13		CRF	25 days	May 8 '15	Jun 11 '15	
17		eCRF	46 days	Jun 12 '15	Aug 14 '15	
20		Randomization	26 days	May 8 '15	Jun 12 '15	
26		Informed Consent Form	15 days	May 8 '15	May 28 '15	
30		IRB	51 days	May 29 '15	Aug 7 '15	
34		Regulatory Authority	51 days	May 29 '15	Aug 7 '15	
38		Study Operations Manual	26 days	Jun 12 '15	Jul 17 '15	
43		Monitoring Plan	26 days	Jun 12 '15	Jul 17 '15	
48		Investigational Product Manual	41 days	Jun 5 '15	Jul 31 '15	
53		Study recruitment	174 days	Aug 10 '15	Apr 7 '16	
67		Database Lock	101 days	Apr 8 '16	Aug 26 '16	
72		Study Close-Out	15 days	Jul 28 '16	Aug 17 '16	
76		Final Statistical Analysis	22 days	Jul 28 '16	Aug 26 '16	

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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

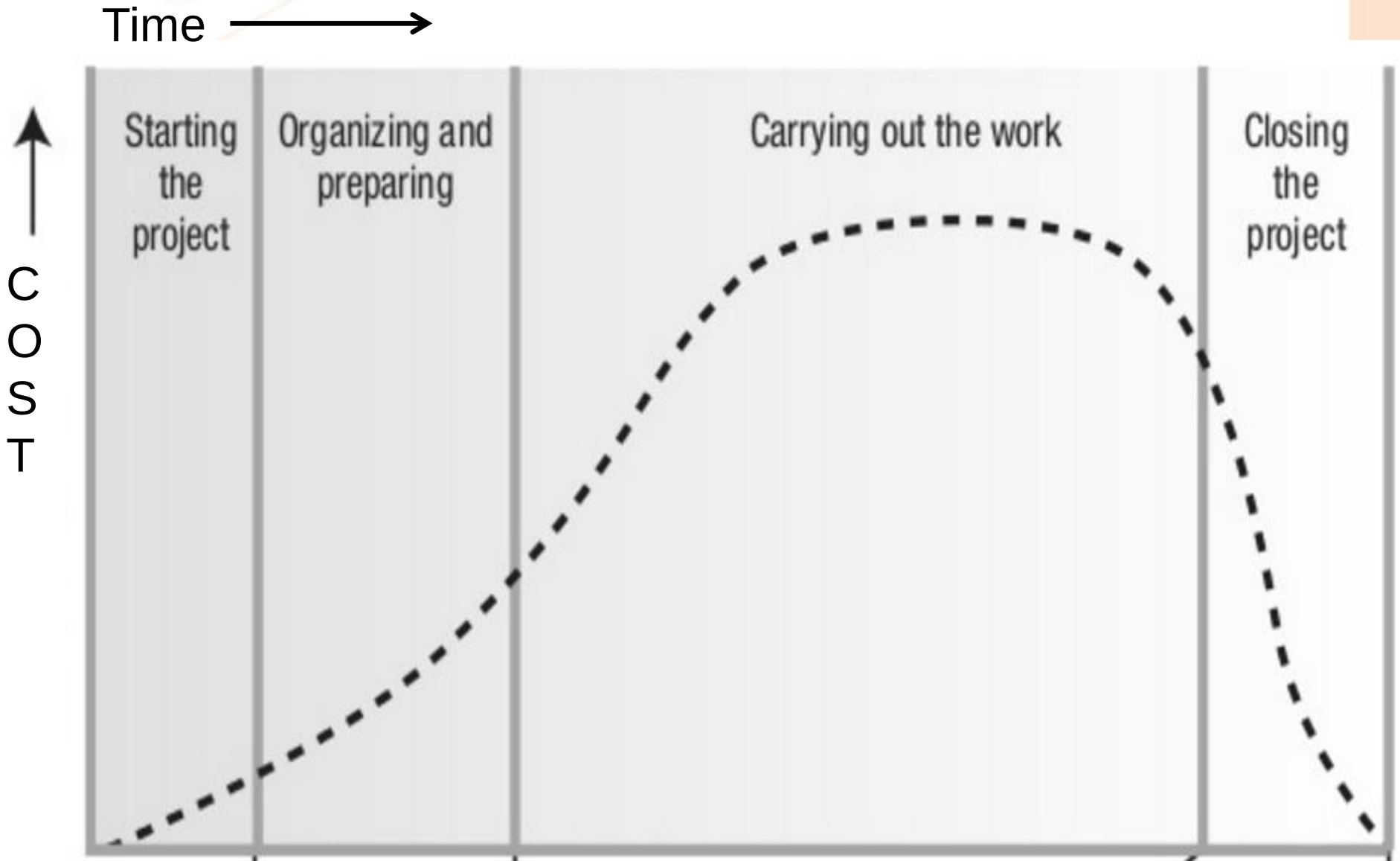
Internal costs

(Budget considered at institution level)

External costs

(Budget of cost incurred apart from institution)

Budget Feasibility



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

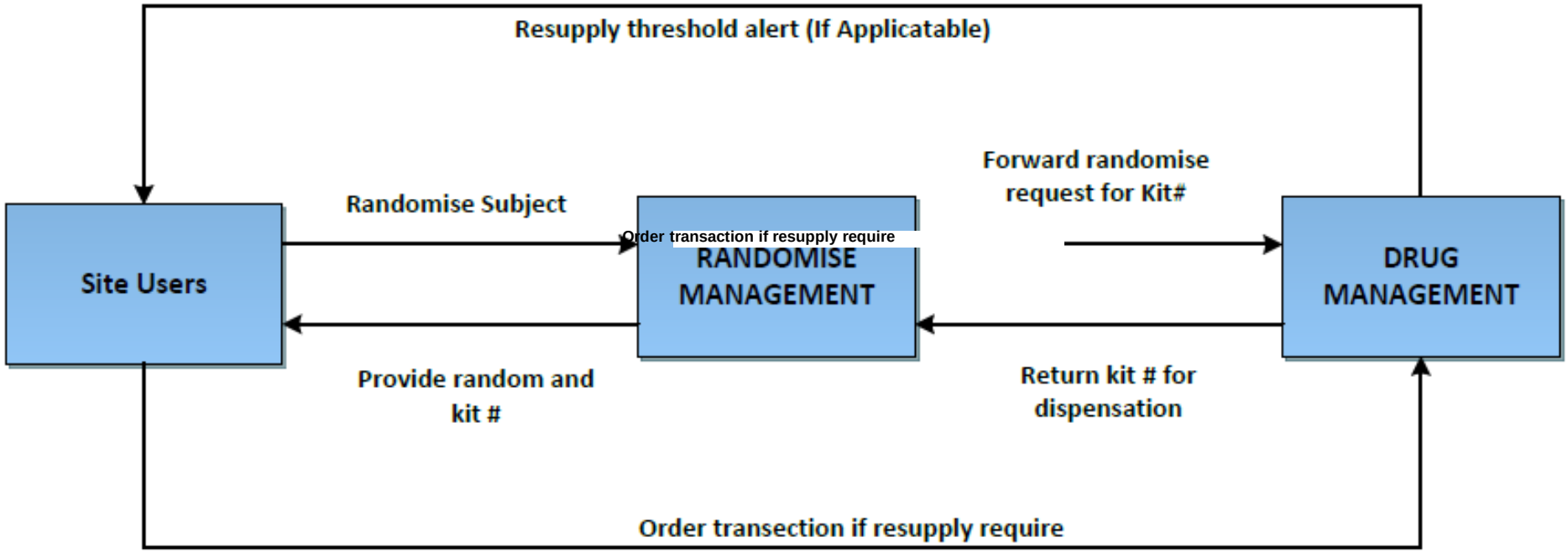
- A web-based application that allows investigators to screen, randomise patients and keep track of drug inventory.

- It supports configurable study parameters for different types of study design.

RAND

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.



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THANK YOU!

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