

PM Tools and Techniques applied in Clinical Research



Module 8 Topic 7

Project Management Techniques

Critical Path Analysis

Event Driven Analysis

Patient/Treatment Pathways

WBS

Rolling Wave Planning

Bottom up Estimate

Alternative Analysis

Contract and Contract Change Control System



Project Management Techniques (contd)

Variance/Trend Analysis

Analogous Estimate

Histogram

Process analysis/Quality Audits

Issue/Action item log

Risk log

RACI Chart

Assumption Analysis

Survey/Interviews

Project Information System



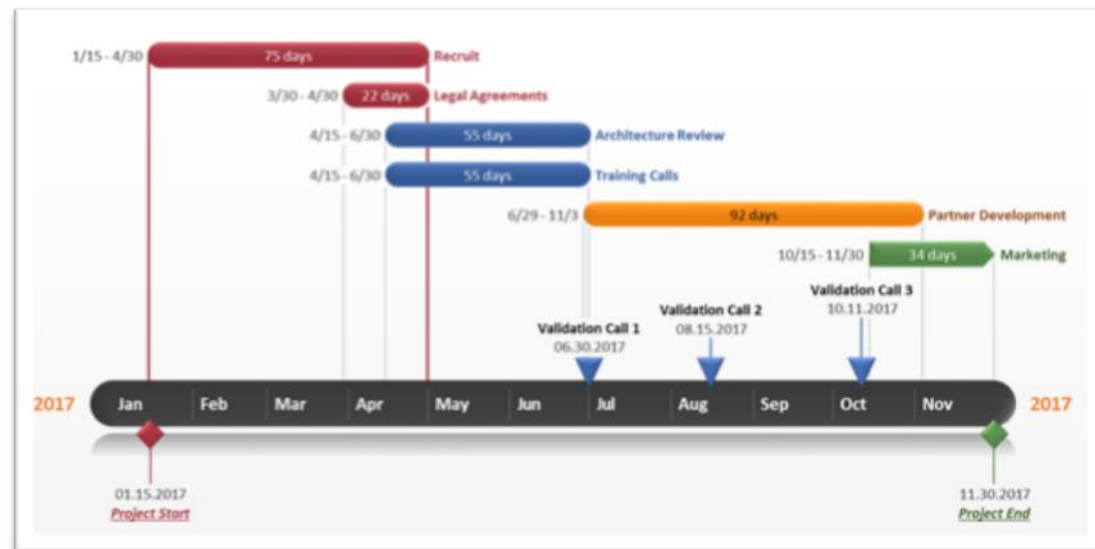
Project Management:Tools

- Project Management Software - MS-Project
- Planning software
- PERT charts
- Gantt (bar) charts
- Dashboards
- Budgets
- Decision trees & network
- Meeting minutes
- Spreadsheets



Gantt Charts

- Gantt template is the most commonly used chart for communicating any project to any audience
- Gantt charts are the most frequently used visual when planning, scheduling or reporting on a project
- They provide a quick snap shot of what needs to be done and by when



Trackers- For Better Monitoring and Control

ACTION ITEMS						
Site #	Action Item	Responsible Person(s)	Target Completion Date	Date Completed	Follow-up Comments	Source of Action
502						



Project Systems

Communication

- E-mail/mobile/telephone/fax/podcast
- Sharepoint/WebEx

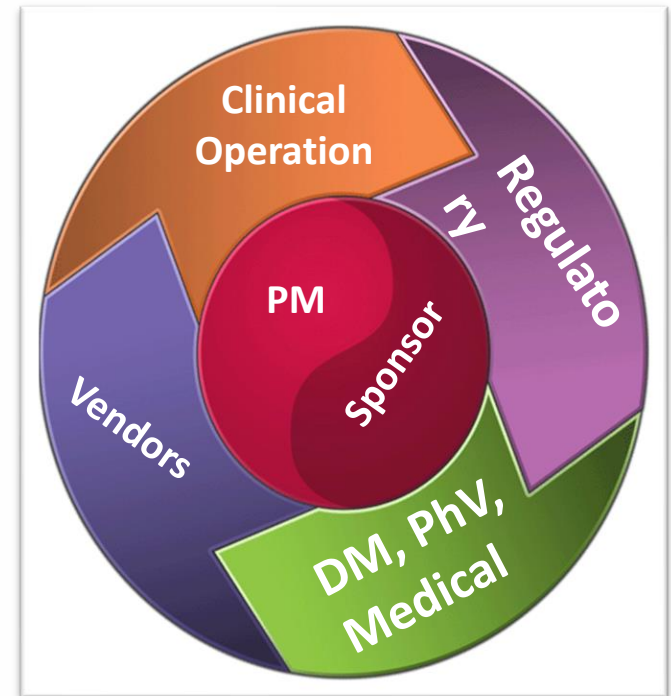
Data Reporting/Analysis/Archival

- e-CRF/IVRS/IXRS/Web portal
- Clinical Trial Management System (CTMS)
- e-Dairy/Patient cards
- Electronic File Management System



Project Management Plan

- Scope/Budget/Milestones
- Regulatory strategy
- Patient recruitment
- Risk management
- Quality management
- Vendor management



Study Milestones

- Project Charter Approval
- Kick-off Meeting
- Final Protocol Ready
- First Site Selection
- Investigator's Meeting
- First Site Activation
- First Patient In (FPI)
- Last Patient In (LPI)



Study Milestones (contd)

- Last Patient Out (LPO)
- Database Lock
- Draft Table and Figure Listing
- Draft Clinical Study Report
- Final Clinical Study Report
- Last Site Close out
- Archival of Study Document
- Project closure



Country/Site Strategy

Country Strategy

- Regulatory Agency
 - Sequential submission (Long start up time)
 - Parallel submission (Short start up time)
- Central Ethics Committee/Local/Institutional Ethics Committee
- Contract with Investigators/Institutes

Site Strategy

- Patient pool
- Relationship/past performance



Patient Recruitment

Recruitment Expectations/Planning/Contingency

- **Challenges and Risk**
 - Potential and Actual Barriers from the Country's/Site's/Patient's Perspective
- **Recruitment Plan**
 - Country/site identifications/selection
 - Recruitment projection/adjustments
 - Pre-initiations activities
 - Recruitment tools and methods



Patient Recruitment: Methods and Tools

- Site staff training/contacts
- Referral Network/Database search
- Advertisement and other recruitment aids
- Investigator /SC Teleconferences
- Web based study-specific patient recruitment tools



Recruitment Toolkit

Patient Facing Tools

- Patient flyer/ brochure
- Informed consent flipchart
- Newspaper/ Social media ad

Site Facing Tools

- Study reference cards
- Mini protocols/ Resources CD
- Physician slide deck

Patient Compliance

- Welcome binder/ Thank you card
- Visit reminder card
- Patient drug instruction card



An educated patient is more retainable and compliant

Recruitment Contingency

- Booster visits
- Activate back-up sites/countries
- Implement Escalation Plan for slow/non-enrolling sites

