PM Tools and Techniques applied in Clinical Research

KLINTEC Academy

Module 8 Topic 7

Project Management Tools/Techniques

Project Management Software - MS-Project

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 Tools/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

What is Project Management?:Tools

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

What is Project Management?:Tools (contd)

- E-Mail
- Word processor
- Teleconference
- Videoconference

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 in Clinical Research

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

Country/Site Strategy (contd)

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

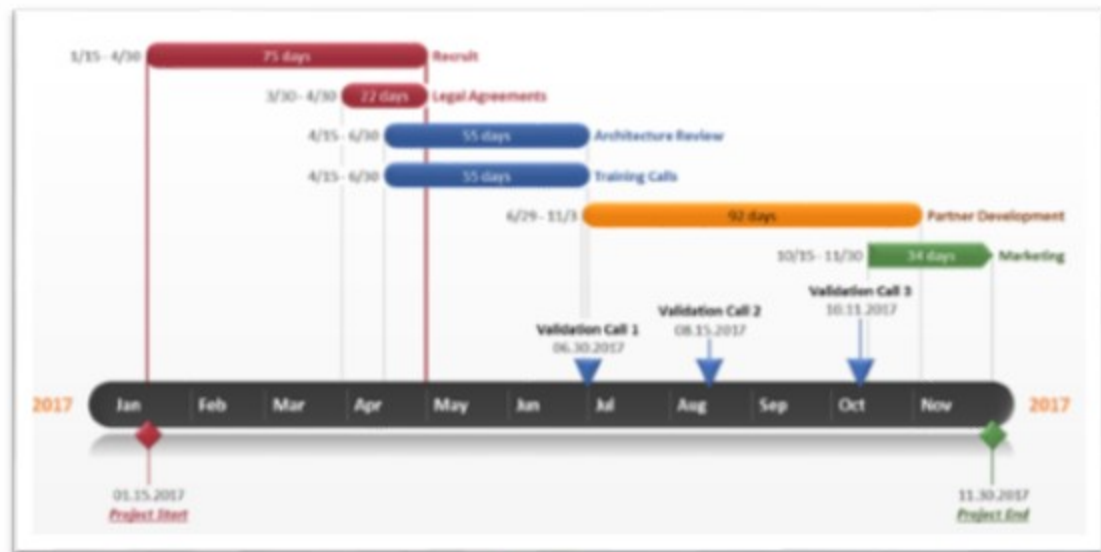**An educated patient is more retainable and compliant**

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Recruitment Contingency

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

Gantt Charts

- Gantt template is the most commonly used chart for communicating any project to any audience

- Gantts 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						