

SYLLABUS

CLINICAL PROJECT MANAGEMENT TRAINING AGENDA

Module 1:

Review the Nature of a Project and Project Management in Clinical Research

- Project management principles
- Clinical project management challenges
- Portfolio and programme management
- Drug development timeline
- Project life cycle
- Clinical project management roles and responsibilities

Module 2:

Defining a Mission for the Project and Performing an Analysis of Stakeholders, Risks and Benefits

- Clinical project management documentation:
 - Project charter
 - Project plan
 - Trial master plan
- Clinical protocol
- Standard operating procedures
- Stakeholder engagement
- Project outcomes
- Benefits and risks
- Business cases

Module 3:

Structure and Organise a Clinical Research Project and/or a Clinical Study

- Project needs
- Objectives and requirements
- Work breakdown structure
- Responsibility matrix

Module 4:

Planning an Estimation of Time and Cost (Schedule and Budget)

- Art (participative method) and science (techniques) of estimating effort and durations
- Planning work packages and activities from the Work Breakdown Structure
- Defining dependencies, milestones and deadlines
- Calculating the critical path
- Probabilistic analysis and critical chain

Module 5:

Setting Up a Project Baseline

- Risk management
- Decision making
- Setting up the project baseline (scope, time, cost)
- Managing the project baseline

Module 6:

Managing Suppliers (Contract Resource and Site Management Organisations)

- Appropriate contracting arrangements between clients and suppliers
- Trust-based approaches for setting up a good working relationship
- Patient recruitments challenges, remedies and good practices

Module 7:

Skills and Methods to Improve and Speed Up Your Projects

- Teamwork
- Project communication
- Conflict management
- Motivation
- Time management

Module 8:

Closing Out the Project, Learning from Failures and Building from Successes

- Project progress
- Project results management
- Project close-out
- Learning and improvement processes