PROJECT MANAGEMENT
FOR CLINICAL RESEARCH PROFESSIONALS

Synopsis

This workshop provides an overview of project management and offers practical tools and techniques that are applicable to the research teams. Tailored to clinical trials, learn about project lifecycle and key knowledge areas of project management including scope, time and risk management. With the increasing globalization and complexity of clinical trials, it is important that researchers and the supporting team are well-equipped, and at minimum, aware of the necessary tools to manage trial sites and manage projects on time and within budget.

AGENDA

Date	Time	Topic
Day 1 20 Oct 2021	8:45am	**Registration**
	9:00am	**Lecture 1 - Introduction to Clinical Research: Clinical Trial Phases and Design** • Definition of Clinical Research & Clinical Trials • Importance of Research • Different Types of Clinical Trials • Different Clinical Trial Phases • Players in Clinical Trials
	9.30am	**Lecture 2 - Introduction to Project Management Processes and Project Lifecycle** • Define Project Management Framework and Terminology • Define the Project Management Process Groups • Assessment of project performance at regular intervals
	11.00am	*Tea Break*
	11:15am	**Lecture 3 – Project Scope and Project Scheduling** • Define Project Scope • Define project deliverables and activities • Defining Project milestones • Develop a project plan and create teams, assigning roles • Managing a scope change
	12.15pm	**Workshop - Project Plan** • **Review and critique** • **Project plan development**
	1:15pm	*Lunch*

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Date	Time	Topic
Day 1 Cont'd	2:00pm	**Lecture 4 - Developing a Project Budget Plan** • Developing a realistic budget plan • Developing a tracking system for investigator budget and project budgets • Managing pitfalls in budget estimations
	3:00pm	**Workshop - Project Budget Plan** • Developing a budget plan for a case scenario
	4:00pm	**Tea Break**
	4:15pm	**Lecture 5 - Establishing Effective Communication Paths** • Managing team dynamics • Identifying and managing project stakeholders • Successful negotiation • Developing an effective communication plan • Useful communication and reporting tools for project • Managing communication in a multi-centred trial
	5:45pm	**End of Day 1**

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Date	Time	Topic
Day 2, 21 Oct 2021	8:45am	**Registration**
	9:00am	**Lecture 6 - Assessing Site Feasibility and Selecting Study Sites** • Importance of Site Feasibility • Consideration from Sponsor and Study Site • Criteria for site selection
	9:45am	**Lecture 7 - Developing an Effective Recruitment & Retention Strategy** • Review of subject recruitment methods • Devising a recruitment strategy • Advertising campaigns in the local context • Identifying what to do when enrollment is not progressing
	10:45am	**MCQ Self Test**
	11am	*Tea Break*
	11:15am	**Workshop - Devising Subject Recruitment Methods and Strategies** • Devise subject recruitment methods • Devise a recruitment strategy • Designing an Advertisement Campaign • Contingency planning
	12.00pm	*Lunch*
	1:00pm	**Lecture 9 - Developing a Risk Management Plan** • Identification, assessment, planning and management • Maintaining regulatory compliance • Identifying and prioritizing financial, technical and legal risks to ensure project success • Establishing a monitoring & reporting system
	2:00pm	**Workshop – Risk Management Plan** Application of risk management to case scenarios
	2.30pm	**MCQ Self Test and Q&A**

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Date	Time	Topic
Day 2 Cont'd	3.00pm	**Lecture 8 - Study Monitoring** • Effective monitoring strategies • Proper documentation to ensure data quality • Decreasing protocol deviations and handling outstanding and missing data
	4.30pm	**Tea Break**
	4.45pm	**Lecture 6 - Surviving an Audit / Inspection** • Reasons for Regulatory Inspections / Audits • Preparation of an announced Inspection / Audit • Briefing of study team (Principal Investigators & Site Staff) • Practical tips for site pre-inspection / audit preparation
	6:00pm	**End of Day 2**

Note: Information is accurate at time of print. Agenda is subject to changes without prior notice.

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