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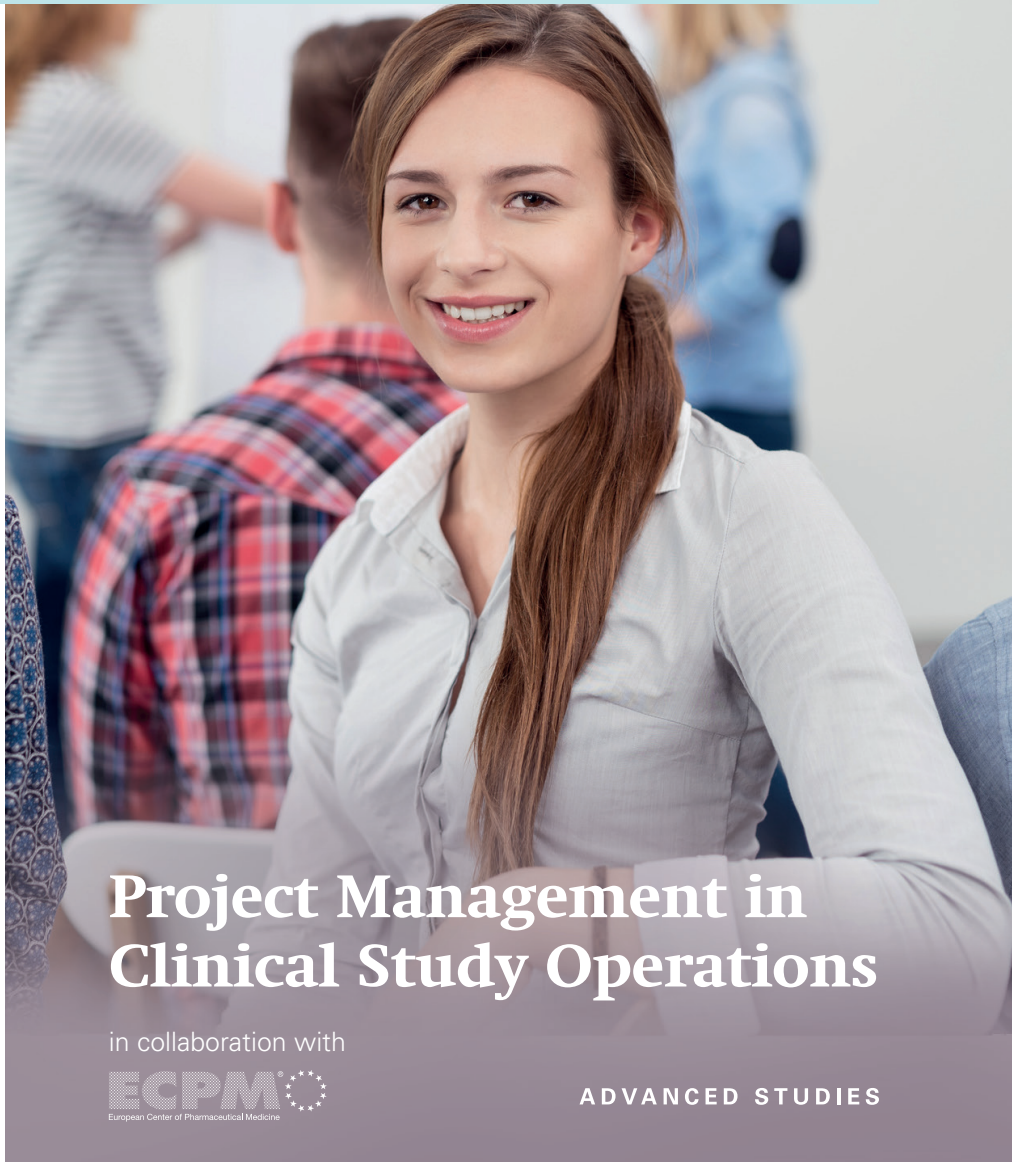

Project Management in Clinical Study Operations

in collaboration with

ADVANCED STUDIES

Course Description

Clinical trials are highly complex enterprises that demand professional management at every stage and level. Project managers in clinical study operations take on many challenges including coordination of multiple stakeholders, budget control and stringent quality and regulatory requirements.

This course teaches the general principles and theory of project management in the context of clinical study operations. In a workshop setting, participants will learn all essential tools for the successful planning, execution, monitoring and controlling of clinical study activities through highly interactive exercises and discussions.

Main topics are: stakeholder management, roles and responsibilities of the project manager and the team, Work Breakdown Structure, project schedule and time management, resource management, quality assurance and quality control, risk management strategies, communication processes.

Target audience

Recommended for everyone working in clinical study operations (physicians, principal investigators, study nurses, study coordinators, study managers, study monitors etc.) in the academic field or a commercial setting wanting to gain proficiency in project management.

Basic knowledge and experience in operational clinical research is highly recommended. No previous knowledge in project management required.

Course fee

CHF 1'500

Fee includes course materials and provision during coffee/tea breaks.

The Department of Clinical Research (DKF) offers training grants for members of DKF clinical research groups. Applications for training grants can be submitted when registering for the program.

Registration

Please visit our websites dkf.unibas.ch/en/projectmanagement or ecpm.ch for further information and to register online.

The number of participants is limited. Applications will be considered based on the date of receipt.

Course structure

3-day classroom training plus pre-reading and homework assignments.

Certificate

Participation in this course results in a certificate issued by Advanced Studies, University of Basel, and accounts for 2 ECTS credit points.

Learning objectives

- Define a project in the context of a clinical trial
- Discuss the role and responsibilities of a project manager and how the role can change
- Define a scope statement as the basis for further project planning, execution and/or monitoring and controlling activities
- Conduct a stakeholder analysis, discuss what is needed to keep stakeholders aligned to support the project and develop reports to keep stakeholders informed
- Organise the team's work by developing and managing a Work Break down Structure (WBS)
- Create and manage a project schedule
- Define roles and responsibilities of team members, estimate the work efforts and discuss procurement options
- Identify the roles and functions of quality assurance and quality control
- Develop a project budget (forecast)
- Address potential threads to a project and develop a risk management strategy and plan
- Manage changes and anticipate how this impacts the schedule, quality, resources and budget
- Discuss the communication process