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Project Management in Medicines Development

A training program offered by the Clinical Trial Unit (CTU) Basel
and the European Centre of Pharmaceutical Medicines (ECPM)



ADVANCED STUDIES

Theory put into practice

Several proven project management approaches are currently used by different industries. Amongst the ones used most widely is PMBoK (Project Management Body of Knowledge), a tool specifically customized to reflect not only the general concepts of project management but also the specific aspects of pharmaceutical projects like the development cycle of a medicinal molecule or the management of a clinical trial.

This course focuses on the principles of PMBoK and project management in general, and will at the same time have a workshop character with highly interactive elements. Using your own project or a model project provided by the course instructors, all templates and tools for planning, executing, managing&controlling as well as closing a project will be developed. Examples and exercises will guide participants through the practical implementation of project management.

Target audience

This course is recommended for everyone working in clinical development (physicians, nurses, study coordinators, study managers, etc.) either in

the academic field or in the commercial setting who wants to gain proficiency in all aspects of project management. Basic knowledge and experience in operational clinical research is highly recommended. No previous knowledge in project management is required.

Course fee

CHF 3'000

The course fee contains all course materials and provision during tea/coffee breaks.

The Department of Clinical Research at the University of Basel supports all members of registered clinical research groups by granting reduction in course fees. Please find more information on our website dkf.unibas.ch/ausundweiterbildung.

Registration

Please visit our websites dkf.unibas.ch/ausundweiterbildung or ecpm.ch/cpd 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

This course consists of two parts of 3 days each. A variety of teaching methods including lectures, exercises and interactive group discussions will be applied. Mandatory home assignments will complete the learning portfolio.

Learning objectives

- To understand the tasks and responsibilities of a project manager
- To know the major project documents required for conduction projects successfully
- To be acquainted with the tools to manage all knowledge areas throughout all project phases
- To be familiar with the interactions needed with different project stakeholders
- To have a series of templates and tools at hand
- To be able to use and/or adapt these templates and tools within individual projects
- To know how to practically apply the PMBoK project management standards to all kinds of pharmaceutical development projects

Certificate

Participation in this course results in a certificate issued by Advanced Studies, University of Basel, and accounts for 4 ECTS credit points.

Course content

- Using PMBoK as a guide and support when managing projects or building organisation-specific project management processes
- Discussion of all project phases (initiation, planning, execution, monitoring&controlling, closure) and knowledge areas (management of scope, time, cost, quality, team, communication, risk, procurement, stakeholders)
- Development of a project plan, starting from a project charter
- Creation of documents and worksheets for managing clinical trials or other projects relating to pharmaceutical development
- Discussion of Key Performance Indicators to judge the status of the project
- Discussion of CAPAs to prevent the project from getting off track