

# Clinical Study Protocol Writing

The aim of the course is to introduce participants in how to write a clinical study protocol including study synopsis.

## Description

- Clinical plan, product development
- Study design
- Laws, rules and guidelines
- Content according to ICH guidelines
- Objectives, patient population
- Investigational medicinal product
- Registration of efficacy/safety
- Cooperation with data management/biostatistics
- Quality control and quality assurance

## Target group

The course is designed for anybody who is planning to or already has started to write clinical study protocols. The course will also benefit anybody involved in the review of clinical study protocols e.g. project managers, clinical research managers, monitors, investigators and other site personnel.

## Course leader

- Siw Anehus, PhD, Global Training Manager

## Cost

The cost for the course is EURO 375 + VAT when applying one month prior to the date of the course. An application after that date costs EURO 400 + VAT. The price includes morning and afternoon coffee as well as lunch.

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