

**Skills for Monitoring Non-Commercial Clinical Trials
(for the UK Sector)**
Contact Siobhan Lim at Siobhan@acrpnnet.org for training dates

Course Description:

This two-day course will provide an introduction to the skills required for monitoring research in the UK non-commercial sector. The course will focus on monitoring of clinical research trials of medicinal products. The course is designed for all staff involved in monitoring, or supervising monitoring of clinical research e.g. R&D Managers, research governance staff, study coordinators, and investigator site staff.

Learning Objectives:

On successful completion of this course, participants should be able to:

- Understand the purpose and scope of monitoring
- Be familiar with the Good Clinical Practice and UK regulations of clinical research
- Be familiar with the life cycle of a clinical research project of a medicinal product
- Understand the responsibilities of individuals associated with monitoring activities
- Be able to perform essential skills required for monitors
- Be able to write effective monitoring reports and identify the follow up actions

Minimum Qualifications to Train the Course:

- At least 5 years clinical research experience which includes monitoring
- At least 3 years experience of training clinical research professionals including physicians
- ACRP certified preferred
- Monitoring of non-commercial clinical trials is preferred
- Credentialed trainer preferred.

**Good Clinical Practice (GCP)
(for the UK Sector)**

Contact Siobhan at Siobhan@acrpnnet.org for training dates

Course Description:

This is an intensive training course designed to boost knowledge and understanding of GCP and locally applicable regulations and guidelines such as the European Directives and the International Conference on Harmonisation (ICH). It is intended for clinical research physicians, investigators, study coordinators or other members of the study team. It contains interactive exercises, lectures and question-and-answer forums that will suit attendees of any level of experience.

Learning Objectives:

Upon successful completion of this course, participants should be able to:

- Review the evolution of GCP, from its origins to currently acceptable standards and the imperative of keeping abreast of changing practices and regulations.
- Define the major steps and phases of the drug development process.
- Describe the main regulations governing the practice of clinical research and other applicable guidelines, including the EU Directive and ICH.
- Examine the legal, professional and ethical constraints on various clinical research processes, such as the management of informed consents, IECs, disclosures of financial interests and electronic signatures.
- Identify the tools and techniques for successfully managing and executing trials.
- Analyze the international principles of ethical conduct and subject protection together with examples of acceptable and non-acceptable norms.

Minimum Qualifications to Train the Course:

- At least 5 years clinical research experience
- At least 3 years experience of training clinical research professionals including physicians
- ACRP certified (CRA or CRC) preferred
- Credentialed trainer preferred.