LUXEMBOURG INSTITUTE OF HEALTH | CLINICAL AND EPIDEMIOLOGICAL INVESTIGATION CENTRE CIEC

EF GCP where science and ethics meet

Save the Date
ONLINE TRAINING

Interactive Training in Applied GCP for Investigators & Site Personnel

Performance of clinical trials according to the Good Clinical Practice (GCP) standard has been introduced as a European regulatory requirement for clinical trials with medicines but as this is a globally agreed best practice standard for clinical research involving human subjects, it is an ethical obligation for clinical researchers to apply this standard to all type of studies to ensure optimal protection of participants and generation of reliable results. It is the basis for enabling funding, acceptance of publications and for patients' access to new treatments. This standard has implications for all stakeholders and processes in clinical trials. However, despite overall commitment and best intentions to apply to these requirements, monitoring, audits and inspections regularly find deficiencies of different levels of severity.

In this interactive 3 lunchtime lectures current experience and requirements of GCP-conform set-up and performance of clinical studies will be presented, practical implications and examples discussed and pragmatic solutions for your daily practice elaborated.

GCP certificate obtained after attending the 3 modules & passing the test at the end of the 3rd session
Otherwise certificate of attendance

GCP Basics (online webinar)
8th, 14th, 16th March 2023
1pm - 3pm

GCP Advanced (on site)
7th June 2023
1pm - 5pm

TRAINER

Ingrid Klingmann
MD, PhD, FFPM, FBCPM
Expert in Drug Development Planning and Site Management Support, Pharmaplex bv, Brussels, Belgium & Chairman of the Board of European Forum for Good Clinical Practice (EFGCP)

Information & Registration:

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8th March
Ethical Principles

1.00pm Welcome and Introduction

1.05pm Ethical Principles in the Declaration of Helsinki, Questions & Answers

1.30pm ICH-E6(R2): Good Clinical Practice Principles and Guideline Content, Questions & Answers

2.15pm The Informed Consent Process, Questions & Answers

2.35pm Ethical Aspects in Recruitment, Questions & Answers

3.00pm End of Part 1

14th March
Principal Investigators' Responsibilities for a Clinical Trial at his/her Site

1.00pm Welcome and Introduction

1.05pm Set-up of a Clinical Trial at the Site, Questions & Answers

1.30pm Compliance in Document Management, Questions & Answers

2.20pm Critical Elements in Conducting Clinical Trials, Questions & Answers

2.35pm PI's responsibilities in Safety Reporting in Clinical Trials, Questions & Answers

3.00pm End of Part 2

16th March
Risk-adapted Quality Management in Clinical Trials

1.00pm Welcome and Introduction

1.05pm Risk-adapted Management of Clinical Trials, Questions & Answers

1.45pm Exercise: Critical Review of GCP Conditions Presented in a Publication

2.20pm Multiple Choice Test

3.00pm End of Part 3

TRAINING AGENDA