

INVITATION / ONLINE TRAINING

GOOD CLINICAL PRACTICE

How to write a clinical research protocol for a successful project

The protocol is the most important document of a clinical research project and the key of the success of your research project. This course will teach you how to write a protocol and will give you all the basic elements according to good Clinical Practice to write a protocol in the respect of ethical rules and participant protection. After successful completion of a test at the end of the training, the participants will obtain a certificate that will document their knowledge of GCP.



TRAINER

Ingrid Klingmann

MD, PhD, FFPM, FBCPM

Expert in Medicines Development Planning and Site Management Support, Chairman,
European Forum for Good Clinical Practice (EFGCP)

1.00pm Introduction

1.10pm From research question to protocol

Definition of

- > Regulatory elements
- > Ethical elements
- > Statistical and data management elements
- > GCP elements
- > Study medication elements
- > Efficacy elements
- > Safety elements
- > Organisational elements
- > Publication elements

3.00pm Break

3.20pm Joint Exercise

- > Introduction to the research question of a real case
- > Jointly defining the study condition elements

5.10pm Final multiple-choice test

5.30pm End of training

DATE & TIME

16th of September 2020

From 13:00 till 17:30

ONLINE WEBINAR

INFORMATION & REGISTRATION

Registration: gcptraining.lih.lu

> Training will be held in English

CONTACT

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Organized by **Clinical and Epidemiological Investigation Center**
in collaboration with: