

TRAINING AGENDA

GOOD CLINICAL PRACTICE

How to write a clinical research protocol for a successful project.

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- 09:30 - 10:15** **Ethics of Clinical Research questions and study designs**
Heather Sampson
University of Toronto, Office of Research Toronto East General Hospital
- Ethical boundaries of clinical research questions (integrating research ethics into protocol design – a scientific imperative – and easy to do)
 - The investigator's and sponsor's ethical obligations in clinical trials (research integrity – what to do with 'unintended consequences')
 - Ethical clinical trials in the regulatory constraints (engaging your regulatory oversight before they engage you)
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- 10:15 - 11:00** **From research question to a GCP-conform protocol**
Ingrid Klingmann, MD, PhD
Chairman, European Forum for Good Clinical Practice (EFGCP)
- The SPIRIT guideline and protocol template
 - Developing the study concepts
 - Defining the study conditions
 - Writing the protocol
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- 11:00 - 11:15** **Coffee break**
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- 11:15 - 12:30** **Statistical concepts to answer protocol scientific questions**
Michel Vaillant, PhD,
Researcher at Competence Center in Methodology and Statistics (LIH)
- Overall structure - protocol standards (content)
- In line with statistical analysis
 - Importance of providing statistical analysis with historical data
 - Better understanding of the statistics and methodology section
 - Superiority / non inferiority
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- 12:30 - 13:30** **Lunch**
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- 13:30 - 13:45** **Introduction & instructions for the breakout sessions**
Ingrid Klingmann, MD, PhD
Chairman, European Forum for Good Clinical Practice (EFGCP)
WG facilitators: Ingrid Klingmann, Heather Sampson, Michel Vaillant, Anna Chioti, Manon Gantenbein
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- 13:45 - 15:30** **Parallel breakout sessions**
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- 15:30 - 16:00** **Synthesis from breakout sessions**
Michel Vaillant & Heather Sampson
Scientific, methodology and ethical take home messages.

DATE
28th May 2016
9:30 - 16:00

VENUE
**Centre Hospitalier
Luxembourg (CHL)**
Amphithéâtre
4, rue Barblé
L-1210 Luxembourg

INFORMATION
www.luxclin.lu
tania.zamboni@lih.lu

IN COLLABORATION WITH

