LUXEMBOURG INSTITUTE OF HEALTH | CLINICAL AND EPIDEMIOLOGICAL INVESTIGATION CENTRE CIEC

EF GCP

CHL Centre Hospitalier de Luxembourg

INVITATION

Face-to-face Training

Interactive GCP Refresher Training for Investigators & Site Personnel

The planning, preparation and reporting processes of clinical trials are currently undergoing major changes. COVID-19 induced emergency measures towards decentralization of study activities enabled by regulatory guidelines on EU and national levels will partly remain after the end of the pandemic as some of the new processes turned out to be beneficial to the decrease of burden to study participants. The now enforced Clinical Trial Regulation EU 536/2014 will enforce a faster and harmonized clinical trial authorisation system but will also introduce the systematic involvement of patients into the clinical trial activities. Major efforts have been made by the European Commission, EMA, pharmaceutical companies and patient organisations to enable educated patient capacity and governance infrastructure to make such collaboration work efficiently. Also academic institutions need to be aware of these new requirements and work out efficient ways to benefit from such patient input in their resource-constrained research infrastructure.

In this GCP-Refresher course areas of obligatory and voluntary patient involvement in the clinical trial process will be presented. Suitable tools for defining the patient profiles needed and for gathering patient input according to the type of research planned will be explained. An overview on mutually accepted governance and contractual templates as well as strategies for finding suitable and collaborative patients will be explained.

AGENDA

1.00pm	Welcome and Introduction to the patient organisations landscape
1.15pm	Patient involvement: why, when and what?
1.45pm	Consultative and collaborative mechanisms
2.10pm	Key areas for involvement: protocol design, informed consent, lay summary preparation
2.30pm	Defining the patient profiles needed
3.00pm	Helpful patient involvement guidance and governance tools
3.30pm	Coffee Break
3.50pm	Exercise in break-out sessions: How to plan patient involvement in a clinical trial that will start in January 2023?
4.40pm	Plenary discussion of the Exercise results
5.00pm	Final multiple-choice test
5.30pm	Delivery of certifications / End of the Training

FACULTY

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)

Sandrine Lavallé

MSc

Luxembourg Institute of Health (LIH), Engagement and Communication Officer.
EUPATI Board Member, EUPATI Fellow, Luxembourg EUPATI representative

Dates & Time:

June 15, 2022

1pm - 5.30pm

Location: CHL amphithéâtre

Information & Registration:

Tania Zamboni

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