INTRODUCTION AND LEARNING OUTCOMES

The training course is intended for physicians, biopharmaceutical scientists and healthcare professionals working in exploratory medicines development research as well as investigators and research staff performing early phase clinical trials.

Learning Outcomes

At the end of this course participants will be able to address and apply the ethical, regulatory and quality requirements of early phase clinical trials in their daily work. They will be familiar with the required measures for risk identification, assessment, mitigation and management in the early phase clinical trial activities presented in this course. Participants will know how to prepare the single dossier documentation and how to interact with the Clinical Trial Information System (CTIS) within the new Clinical Trial Regulation framework. They will understand the organizational and quality requirements when preparing a Phase I unit for inspection readiness. Case studies and a home work will provide the opportunity to discuss and apply the theoretical background provided in the lectures.

Case studies

- Review of the Informed Consent Form-blinded Tegenero case (homework and virtual Day 1)
- Prepare a mock submission dossier according to EU CTR (on site on Day 3 at f2f meeting)
- Homework: Review an 'old' protocol according to the new EU-CTR (between Day 4 and 5)
- Homework: Pre-reading and reading in-between course days; preparation of test

Pre-reading

Prior to starting the course, participants will profit by refreshing their knowledge on good clinical practice and related guidelines. A pre-reading list will be provided to the participants.

programme modifications reserved. status 09/2023

FACULTY

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Simply Quality - Dr. Karl Kleine, Weilheim

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Pharmaplex BV, Brussels

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AH Clinical Trials Services GmbH, Niedernhausen

Dr Birka Lehmann
Senior Expert for Drug Regulatory Affairs, Bonn

Dr Thomas Schillinger
CRS Clinical Research Services GmbH, Wuppertal

Dr Diana Sims-Silbermann
Düsseldorf

Dr Maria Weber
Boehringer Ingelheim International GmbH, Ingelheim

INFORMATION

Venue
Virtual via Microsoft Teams.
Guests receive personal login data.

Requirement
A Download of the MS Teams Desktop-App is highly recommended.

and

H+ Hotel Bad Soden
Königsteiner Straße 88
65812 Bad Soden, Germany
(A room block is reserved - pleas feel free to book during your registration

Dates

Day 1	10 November 2023 - Online -
Day 2-4	13-15 November 2023 Bad Soden (Germany)
Day 5	20 November 2023 - Online -

Fees

1.900 EUR	Guest
1.500 EUR	Member*

*of ACRON, AGAH, AHPPI, AFPT-CPI HEALIXIA, POLFEMED

CONTACT AND FURTHER INFORMATION

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AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

Regulatory, ethical and quality requirements in today's early phase clinical trials

Module 3, EUFEMED Diploma Course in Human Pharmacology

10 November 2023
-online-

13 - 15 November 2023
Bad Soden, Germany

20 November 2023
-online-

EUFEMED

Day 1 · FRIDAY, 10 November 2023 (online)

09:00 - 09:15 **Introduction of faculty and participants**
Sybille Baumann, Kerstin Breithaupt-Grögler, Ingrid Klingmann

09:15 - 10:00 **Historical development of ethical standards:** Nuremberg Code, DoH, ICH-GCP, CIOMS
Nadja Faisst

10:00 - 10:45 **What needs to be regulated in a clinical trial?** Clinical Trial Approval application dossier with protocol, IB, IMPD, etc., approval by CA and EC, Substantial modifications, IMP, Safety info, annual updates, results publication, QA, etc.
Ingrid Klingmann

10:45 - 11:00 Break

11:00 - 12:15 **The structure of clinical trial legislation in the EU, UK, CH, and USA:** CTD, CTR, MHRA, Swissmedic, FDA; legal texts and guidelines
Birka Lehmann

12:15 - 12:30 **EudraLex Vol. 1,2,3,4,9,10**
Nadja Faisst

12:30 - 13:15 Break

13:15 - 14:30 **What is GxP?** Overview of key elements of GCP (Good Clinical Practice) and GMP (Good Manufacturing Practice) GLP (Good Laboratory Practice), GcLP (Good clinical Laboratory Practice) including sample management
Kerstin Breithaupt-Grögler (GCP)
Karl Kleine (GLP, GcLP)
Kerstin Breithaupt-Grögler (GLSP, GVP, GMP)

14:30 - 14:45 **Discussion on the principles of GxP**

14:45 - 15:15 Break

15:15 - 16:30 **Principles of CTD, EU-CTR and transition period**
Ingrid Klingmann

16:30 - 16:45 Break

16:45 - 17:30 **Case discussion:** Informed consent process in Phase I - informed consent form from Tegenero trial will be discussed (Pre-reading of Tegenero case is mandatory!)
Kerstin Breithaupt-Grögler, Ingrid Klingmann

Day 2 · MONDAY, 13 November 2023 (face-to-face)

09:00 - 09:45 **Regulatory development strategy options** incl. central approval or country-specific approval, pre-approval scientific advice with EMA and/or FDA, abbreviated marketing authorisation, interaction with CA and ECs, paediatric development obligations in EU and USA
Birka Lehmann

09:45 - 10:30 **From Phase 1 to marketing authorisation:** formulations, PIP, interaction studies, conditional marketing authorisation options (small molecules)
Ingrid Klingmann

10:30 - 10:45 Break

10:45 - 12:00 **CTR-related pharmaceutical regulatory framework for investigational medicinal products** (IMPs, small molecules)
Rango Dietrich

12:00 - 12:45 **Translational considerations of non-clinical experience to human studies** (incl. M3, safety, bioavailability, pharmacokinetics, and metabolism)
Diana Sims-Silbermann

12:45 - 13:45 Break

13:45 - 14:45 **First-in-human guideline** with focus on assessments of determination of first dose, process for dose escalation decisions, stopping rules, clinical safety (AE/SAEs), 'trend assessment processes' regarding safety, PK and PD, institution of independent data monitoring committee
Kerstin Breithaupt-Grögler

14:45 - 15:15 **FDA guidance documents for first-in-human dose**
Kerstin Breithaupt-Grögler

15:15 - 15:45 Break

15:45 - 17:30 **Trial preparation in Phase 1:** the CTA application dossier (protocol, IB, IMPD), site selection, contracting and management of suppliers, investigator agreement, insurances
Diana Sims-Silbermann

17:30 - 18:00 **Q&A on today's topics**

Day 3 · TUESDAY, 14 November 2023 (face-to-face)

09:00 - 10:45 **Which documents are required for Clinical Trial Authorisation Application?**
Cover letter, trial protocol, informed consent, IB, IMPD, manufacturing authorization, site suitability template, labelling, recruitment arrangements, proof of insurance, financial arrangements, proof of payment, compliance statement GDPR, to be checked versus Annex I EU-CTR Trial protocol, patient informed consent, IB, IMPD, proof of insurance (adapted study nurse documents):
Kerstin Breithaupt-Grögler, Burkhard Kerlin
Nadja Faisst
Manufacturing authorization, recruitment arrangements, compliance statement, Labelling:
Maria Anschütz, Sylvia Grebe
Site suitability template: *Kerstin Breithaupt-Grögler*

10:45 - 11:00 Break

11:00 - 11:45 **Clinical trial authorisation application: redaction and deferrals**
Burkhard Kerlin

11:45 - 13:00 **Which information needs to be redacted?**
Break-out groups: redaction of trial protocol, informed consent, IB/IMPD, site suitability document, taking into account the respective chapters of EU-CTR (Q&A Document, Eudralex guidances)

13:00 - 14:00 Break

14:00 - 17:00 **CTIS Training module:**
- Explanation of CTIS structure, available trainings, timelines, organisational aspects between regulatory and operations departments
- Upload of the mock CTA submission dossier according to the EU CTR; use of CTIS Sandbox
- Documents to be uploaded following the end of trial
Maria Anschütz, Sybille Baumann, Kerstin Breithaupt-Grögler, Nadja Faisst, Sylvia Grebe, Burkhard Kerlin, Ingrid Klingmann, Diana Sims-Silbermann

Day 4 · WEDNESDAY, 15 November 2023 (face-to-face)

09:00 - 10:10 **Organisation and responsibilities of an early phase trial unit:**
Set-up of Phase I unit, infrastructure, how to be ready for a pre-qualification visit, subject recruitment, data protection, informed consent, housing conditions, ethical and technical aspects of assessments, data management, remuneration, follow-up (FiH guideline in practical application, Eudralex guidance for inspections)
Sybille Baumann

10:10 - 10:30 **Discussion / Short case study**
Sybille Baummann

10:30 - 11:00 Break

11:00 - 12:30 **How to prepare the regulatory infrastructure for an early phase clinical trial incl. risk assessment and management? How to prepare inspection readiness?**
Thomas Schillinger
(perspectives of trial site)
Karin Köhler-Hansner
(perspectives of sponsor)

12:30 - 13:30 Break

13:30 - 14:00 **Clinical trial transparency: Registration of clinical trials in EU and globally and reporting of results in data bases**
Nadja Faisst

14:00 - 15:30 **Evaluation and reporting of a Phase 1 trial in the EU (Statistical analysis plan, Clinical study report, Start-End, Summary of clinical trials, Lay summary)**
Kerstin Breithaupt-Grögler

15:30 - 16:00 Break

16:00 - 16:30 **Joint discussion:** Challenges of transparency in Phase 1 trials

Home work day individually or as group work with up to 4 participants: Check the trial protocol that was developed under the EU Directive versus the requirements of the EU Clinical Trials Regulation and identify the required changes (document from study nurse group).

Day 5 · MONDAY, 20 November 2023 (online)

09:00 - 09:30 **Feedback from home work on trial protocol adaptation**

09:30 - 10:45 **Pharmacovigilance in clinical trials** (Safety reporting, Serious breaches, MedDRA coding, SUSAR reporting in EudraVigilance, IND safety reporting, DSUR, periodic safety reports)
Maria Weber

10:45 - 11:00 Break

11:00 - 12:00 **Quality management in Phase 1 trials**
Thomas Schillinger

12:00 - 13:00 **Validation** (PK and PD assessments, bioanalytical methods, computerised systems and data capture)
Karl Kleine

13:00 - 13:45 Break

13:45 - 14:15 **Document management** (TMF, ISF, archiving conditions)
Diana Sims-Silbermann

14:15 - 14:45 **Sponsor's study oversight** including cross-discipline due diligence and monitoring for all protocol-contracted out services, risk-based monitoring
Karin Köhler-Hansner

14:45 - 15:00 Break

15:00 - 16:30 **Audit, audit response (CAPA), inspection and inspection readiness Auditor, Inspector, Quality Working Party**
Karl Kleine

16:30 - 17:00 Feedback

17:00 - 18:00 Final Test