

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

- Declaration of Helsinki

<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

- ICH-Guidelines: refresh your mind on E6 R2 (GCP) and E8

<https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice-scientific-guideline>
<https://www.ema.europa.eu/en/ich-e8-general-considerations-clinical-studies-scientific-guideline>

- Familiarize yourself with the specific topics covered in the EU-CTR

<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation>

- GDPR (European General Data Protection Regulation), sections concerning clin. examinations)

- Familiarize yourself with the topics covered in EMA 'Guideline on computerised systems and electronic data in clinical trials' (EMA/INS/GCP/112288/2023);

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-electronic-data-clinical-trials_en.pdf

- Glossary on terms and definitions (EMA)

- FIH Guideline / FDA guidance documents for first-in-human dose

- Pre-course reading on marketing authorisation:
 - How are medicines evaluated at the EMA? booklet available from EMA
 - Clinical Trial Route Map – NIHR

<http://www.ct-toolkit.ac.uk/routemap>

- All documents for the mock submission dossier

- Blinded Tegenero informed consent form

programme modifications reserved - status 12/2024

FACULTY MEMBERS

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INFORMATION

Venue Digital part via Microsoft Teams.
Guests receive personal login data.

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

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Zimmersmühlenweg 35

61440 Oberursel (Germany)

(A room block is prereserved - please inform yourself when you register and call for a room yourself)

Dates

Halfday 1:	5 March and
Halfday 2:	7 March 2025
<i>(2 half days online)</i>	
Day 3- 5:	10 - 12 March 2025
<i>On-site (face-to-face, 3 full days in Oberursel/Germany)</i>	
Halfday 6:	20 March and
Halfday 7:	21 March 2025
<i>(2 half days online)</i>	

Test: 24 March 2025 (Activation 5 to 7 pm)

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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Registration <https://forms.office.com/e/k90q0dRun4>



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

5 and 7 March 2025, online

10-12 March 2025, on-site (face-to-face)

20-21 March 2025, online

24 March 2025, online test

Day 1 · WEDNESDAY, 5 March 2025 (halfday, online)

14:30 - 14:45	Introduction of faculty and participants <i>Sybille Baumann, Kerstin Breithaupt-Grögler, Ingrid Klingmann</i>
14:45 - 15:30	Historical development of ethical standards: Nuremberg Code, DoH, ICH-GCP, CIOMS <i>Nadja Faisst</i>
15:30 - 16:45	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. <i>Ingrid Klingmann</i>
16:45 - 17:00	Break
17:00 - 18:15	The structure of clinical trial legislation in the EU, UK, CH, and USA CTD, CTR, MHRA, Swissmedic, FDA; legal texts and guidelines <i>Birka Lehmann</i>
18:15 - 18:30	EudraLex Vol. 1,2,3,4,9,10 <i>Nadja Faisst</i>

Day 2 · FRIDAY, 7 March 2025 (halfday, online)

14:30 - 15:45	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 <i>Kerstin Breithaupt-Grögler, Michael Haberl</i>
15:45 - 16:00	Break
16:00 - 17:30	What is a quality management system in early phase clinical trials? - An introduction to Sponsor procedures and QMS requirements at the site. How to prepare the regulatory infrastructure for an early phase trial including risk assessment and management? <i>Karin Köhler-Hansner</i>
17:30 - 18:00	Case discussion: Informed consent process in Phase I - Tegenero ICF will be discussed (Pre-reading of Tegenero case is mandatory!) <i>Kerstin Breithaupt-Grögler, Ingrid Klingmann</i>
18:00 - 18:30	Principles of EU-Clinical Trials Regulation <i>Ingrid Klingmann</i>

Day 3 · MONDAY, 10 March 2025 (face-to-face)

09:00 - 10:00	Regulatory development strategy options incl. central approval or country-specific approval, pre-approval scientific advice with EMA and/or FDA, abbreviated marketing authorisation (conditional approval, rolling review), interaction with CA and ECs, paediatric development obligations in EU and USA (PIP) <i>Birka Lehmann</i>
10:00 - 11:00	Principles of clinical trial authorization according to the EU-CTR, German Research facilitation Act ('Medizinforschungsgesetz') <i>Ingrid Klingmann</i>
11:00 - 11:15	Break
11:15 - 12:15	An introduction to the CTR-related pharmaceutical regulatory framework for investigational medicinal products (IMPs, small molecules) in early phase clinical trials <i>Susanne Trumm</i>
12:15 - 13:00	Translational considerations of non-clinical experience to human studies incl. M3, safety, bioavailability, pharmacokinetics, and metabolism <i>Diana Sims-Silbermann</i>
13:00 - 14:00	Break
14:00 - 15:00	First-in-human guideline with focus on determination of first dose, process for dose escalation decisions, stopping rules, clinical safety (AE/SAEs), trend assessment processes' regarding safety, PK and PD, independent data monitoring committee; FDA guidance documents for first-in-human dose <i>Kerstin Breithaupt-Grögler</i>
15:00 - 15:15	Break
15:15 - 16:45	Trial preparation in Phase 1: the CTA application dossier (protocol, IB, IMPD), site selection, contracting and management of suppliers, investigator agreement, insurances <i>Diana Sims-Silbermann</i>
16:45 - 17:15	Q&A on today's topics

Day 4 · TUESDAY, 11 March 2025 (face-to-face)

09:00 - 11:15	Which documents are required for clinical trial authorisation application? Cover letter, trial protocol, informed consent, IB, IMPD, manufacturing authorization, site suitability template, recruitment arrangements, proof of insurance, financial arrangements, proof of payment, compliance statement GDPR <i>Maria Anschutz, Kerstin Breithaupt, Nadja Faisst, Sylvia Grebe, Burkhard Kerlin</i>
11:15 - 11:30	Break

11:30 - 12:15	Clinical trial authorisation application: redaction and deferrals <i>Burkhard Kerlin</i>
12:15 - 13:15	Break
13:15 - 15:00	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
15:00 - 15:15	Break
15:15 - 18:30	CTIS Training module: - Explanation of CTIS structure, available trainings, timelines, organisational aspects between regulatory and operations departments - Upload of a mock CTA submission dossier according to the EU CTR - Documents to be uploaded following the end of trial (e.g., upload of scientific results summary, lay summary of results) <i>Maria Anschutz, (Sybille Baumann), Kerstin Breithaupt-Grögler, (Nadja Faisst), Sylvia Grebe, Burkhard Kerlin, Ingrid Klingmann, Diana Sims-Silbermann</i>
19:00	Joint Dinner with participants and faculty

Day 5 · WEDNESDAY, 12 March 2025 (face-to-face)

09:00 - 10:15	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) <i>Sybille Baumann</i>
10:15 - 11:00	Discussion / Short case study <i>Sybille Baumann</i>
11:00 - 11:15	Break
11:15 - 12:45	Standard operating procedures in an early phase trial unit SOP system from recruitment to sample management, 'Mind Map' <i>Ingrid Klingmann</i>
12:45 - 13:45	Break
13:45 - 15:00	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) <i>Kerstin Breithaupt-Grögler</i>

15:00 - 15:15	Break
15:15 - 15:45	Clinical trial transparency: Registration of clinical trials in EU and globally, reporting of results in data bases <i>Burkhard Kerlin</i>
15:45 - 16:15	Joint discussion Challenges of transparency in Phase 1 trials
	Home work 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.
Day 6 · THURSDAY, 20 March 2025 (halfday, online)	
14:30 - 15:00	Feedback from home work on trial protocol adaptation
15:00 - 16:30	Pharmacovigilance in clinical trials (Safety reporting, Serious breaches, MedDRA coding, SUSAR reporting in Eudra-Vigilance, IND safety reporting, DSUR, periodic safety reports) <i>Maria Weber</i>
16:30 - 16:45	Break
16:45 - 17:45	Validation - PK and PD assessments, bioanalytical methods, computerised systems and data capture <i>Karl Kleine</i>

Day 7 · FRIDAY, 21 March 2025 (halfday, online)

13:00 - 14:00	Document management TMF, ISF, archiving conditions <i>Diana Sims-Silbermann</i>
14:00 - 14:45	Sponsor's study oversight including cross-discipline due diligence and monitoring for all protocol-contracted out services, outsourcing of sponsor obligations, 'vendor assessment' <i>Karin Köhler-Hansner</i>
14:45 - 15:00	Break
15:00 - 16:00	How to prepare audit and inspection readiness at the trial site? Examples regarding Inspection Findings <i>Karl Kleine</i>
16:00 - 17:00	Audit, audit response (CAPA), inspection <i>Karl Kleine</i>
17:00 - 17:15	Feedback

17:00 - 19:00 MONDAY, 24 March - Final Test (mandatory)