DIA LEARNING

ICH GCP Guideline Rewrite - The Future is Now

Face-to-Face Training Course
3-4 June 2025 | Amsterdam, NL

Overview

With the recent implementation of the revised ICH E6 (R3) guidelines, this course offers a practical overview of the rationale and key implications of this revision - the most significant in over two decades.

Participants will explore the driving forces behind these changes, including technological advances, the latest developments in alternative clinical trial designs and the use of real-world data sources.

By the end of the course, participants will understand how the revised guideline provides a framework that supports fit-for-purpose clinical trial design, the use of new technologies and alternative operational strategies. They will also gain a thorough understanding of the key principles and expectations for proportionate, risk-based quality management of clinical trials and return to their roles with practical, concrete solutions for effective implementation of this revised guideline.

The course is delivered by GCP experts from both regulatory authorities and industry, who bring deep insight into the current clinical trial landscape. Drawing on their expertise, they explore the practical application of GCP across a range of scenarios from trial design to trial reporting.

Learning Objectives

Participants will be guided in understanding:

- the new structure of ICH E6 and the reasons for the changes that have been made,
- how to conduct clinical trials using the Quality by Design and Fitness for Purpose approaches,
- the implications of the GCP revision and how to implement the changes in a way that is appropriate to the investigational product and the trial's underlying scientific questions, potential trial participants, investigators, and sponsors and their service providers,
- the implications of the major changes compared to version R2.

The overall objective of the seminar is to enable participants to make informed decisions to protect the rights, safety and well-being of trial participants and to ensure the reliability of trial results, and to understand what sponsor and investigator oversight means in practice.

They will also learn to think cross-functionally and consider how actions affect other parties involved in conducting clinical trials.

Who Will Attend

- Clinical Operations, including trial leads, monitors, data scientists, data managers, statisticians etc.
- Clinical Development
- Quality Assurance
- Service Providers
- Investigators
- Ethics Committee members

In fact, anyone involved in the conduct of interventional clinical trials on investigational product.

Faculty

Lisbeth Bregnhoj
EC ICH E6(R3) Expert Working Group Member

Susanne Norskov
EFPIA ICH E6(R3) Expert Working Group Member

Gabriele Schwarz
EC ICH E6(R3) Expert Working Group Member

Rebecca Stanbrook
EFPIA ICH E6(R3) Expert Working Group Member

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

DAY 1

08:30 REGISTRATION AND WELCOME COFFEE

09:00 INTRODUCTION OF FACULTY AND PARTICIPANTS

09:30 SESSION 1

BACKGROUND TO ICH E6 (R3) REVISION

Gabriele Schwarz

This session will enable all participants to understand the background of the GCP revision.

This will tell the story of GCP and the update to R3. It will also ensure that participants internalise that ICH E6 should not be interpreted in isolation, but in the context of other ICH Efficacy Guidelines referred to in E6(R3).

10:15 COFFEE BREAK

10:45 SESSION 2

SPECIFIC PRESENTATION ON E6 (R3)

Rebecca Stanbrook

Building on the presentation from Gabriele will start with the structure and main approaches of E6 (R3) followed by time for discussion.

11:30 Q&A

12:00 LUNCH BREAK

13:00 SESSION 3

BREAKDOWN OF THE GUIDELINE: PLANNING

Lisbeth Bregnhoj

In this session, the participants will learn more about what is expected from the sponsors during the planning phase of a clinical trial. This includes e.g. expectations for the involvement of stakeholders. The concept of quality by design, the feasibility of clinical trials and the selection of investigators and service providers will be given special attention.

14:00 SESSION 4

INVESTIGATOR ROLES AND RESPONSIBILITIES, OVERSIGHT

Susanne Norskov

This session considers the role and responsibilities of the investigator in contemporary clinical trials with decentralised and pragmatic elements, and the involvement of service providers in the performance of investigator tasks.

14:45 COFFEE BREAK

15:15 SESSION 5

SPONSOR ROLES AND RESPONSIBILITIES, OVERSIGHT

Rebecca Stanbrook

This session will focus on the trial conduct phase and, in particular, on what the guideline requires sponsors to undertake to ensure that the clinical trial is conducted in accordance with the protocol, GCP and the applicable regulatory requirements.

16:15 SESSION 6

ESSENTIAL RECORDS – NOT AN ARCHIVE

Gabriele Schwarz

This session will talk about what constitutes an essential record and who should retain it.

17:15 Q&A

17:45 RECAP OF DAY 1

18:00 WELCOME RECEPTION

19:00 END OF DAY 1

Schedule-At-A-Glance

DAY 2

09:00 SESSION 7

DATA GOVERNANCE PART 1

Lisbeth Bregnhoj

This session will explore what is expected of both investigators and sponsors in terms of data governance throughout the various data lifecycle steps from data capture to data disposal.

09:45 SESSION 8

CASE STUDY 1 - GROUP WORKS

Lisbeth Bregnhoj and Susanne Norskov

The delegates will split into groups, be provided with a protocol, discuss data flows and assess where critical quality factors fit in. Work out data flow diagram.

10:30 COFFEE BREAK

11:00 SESSION 8 CONT.

CASE STUDY 1 - RESULTS AND DISCUSSION

Lisbeth Bregnhoj and Susanne Norskov

11:45 SESSION 9

DATA GOVERNANCE PART 2

Lisbeth Bregnhoj

This session will continue to explore responsibilities for key data governance activities, including responsibility and fitness for purpose assessments for computerised systems in clinical trials.

12:45 LUNCH BREAK

13:45 SESSION 10

ANNEX 2

Gabriele Schwarz and Rebecca Stanbrook

This session will provide additional information on the considerations when using decentralised, pragmatic elements and/or different types of data sources in clinical trials.

14:45 Q&A

15:15 COFFEE BREAK

15:45 PANEL DISCUSSION AND Q&A

16:45 END OF THE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company (excludes government/academia/non-profit). Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

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Or explore eLearning to allow self-paced learning.

For more information please contact basel@diaglobal.org

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

Venue Information

Mercure Hotel Amsterdam City
Joan Muyskenweg 10, 1096 CJ Amsterdam, The Netherlands
Tel: +31 20 721 917
Email: H1244@accor.com
Website: https://www.mercureamsterdamcity.com/

Bedroom reservations
DIA has blocked a limited number of hotel bedrooms for the course participants from 2nd to 4th June 2025 at the rate of EUR 239.00 per standard/classic double room for single use per night including breakfast, excluding taxes and city-tax. In order to book a hotel bedroom, please fill out the booking form that is available on the DIA website and send it by email to Diego.Fort@accor.com.
The room rate is available until 4th April 2025 or until the room block is sold-out, whichever comes first.

Continuing Education

Please note: Most EU countries accept direct submission, by the participant, of training courses, conferences and other educational opportunities with the aim of obtaining CPD (Continuous Professional Development) points. Please do not hesitate to contact DIA directly if you need any further documentation to conclude your submission.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.50 credits.

REGISTRATION FORM

ICH GCP Training Course # 25531
3-4 June 2025 | Amsterdam, NL

DIA LEARNING

REGISTRATION FEES

Registration fee includes admission to the course, refreshment breaks and lunches, and electronic access to training course materials.
Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER EARLY-BIRD valid until 8 Apr 2025	MEMBER valid from 9 Apr 2025	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'420.00 ❑	€ 1'580.00 ❑	€ 1'840.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 790.00 ❑	€ 1'050.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature