DIA LEARNING

ICH GCP: 1 year on – practical tips on implementation

20-21 April 2027 | London, UK

Overview

This intensive, highly interactive two-day training course is designed to bridge the gap between regulatory theory and real-world clinical trial execution under the ICH E6(R3) guideline. One year into its implementation, this course provides a timely look at how the interplay between core principles and the annexes alters day-to-day operations.

Led by European Commission and EFPIA ICH E6(R3) Expert Working Group representatives, the program abandons rigid, check-the-box training in favour of risk-proportional, practical application. Through a series of workshops, interactive panel discussions, and a progressive case study utilising a synthetic protocol, participants will learn how to:

- Operationalise Critical to Quality (CTQ) factors during protocol development. Monitor then throughout the course of the trial.
- Manage modern data governance complexities, including computerised systems and automated data flows.
- Adapt to contemporary trial designs, directly addressing Annex 2 elements such as Decentralised Clinical Trials (DCTs), pragmatic trial elements, and the utilisation of Real-World Data (RWD).

Ample time is foreseen for Q&A. The faculty invites participants to submit related questions to training.emea@diaglobal.org**.**

Learning Objectives

By the end of this two-day training course, participants will be able to:

- Deconstruct the ICH E6(R3) Framework: Understand the structural interplay between the core principles and the annexes to apply them seamlessly to ongoing and future clinical programs.
- Implement Critical to Quality (CTQ) Factors: Identify, assess, and prioritize CTQs and their associated risks during the protocol development phase using a practical risk-proportional approach.
- Optimise Oversight & Responsibilities: Define and execute modern investigator and sponsor oversight responsibilities, with specific practical strategies for re-consenting and the management/oversight of service providers.
- Modernise Monitoring and Auditing: Design risk-based monitoring strategies, implement centralised monitoring approaches, and manage non-compliance effectively.
- Navigate Data Governance & Systems: Map complex clinical data flows, evaluate the "fitness for purpose" of computerised systems, and manage expectations around database locks and statistical programming.
- Apply Annex 2 Principles to Modern Trials: Confidently evaluate the quality, governance, and GCP compliance of trial designs incorporating decentralised (DCTs), pragmatic elements, and real-world data (RWD).
- Redefine Essential Records: Transition away from the rigid "before, during, and after" tables of R2 to build a risk-proportional essential records strategy.

Faculty

Instructor invited
EC ICH E6(R3) Expert Working Group Member

Instructor invited
EFPIA ICH E6(R3) Expert Working Group Member

Target Audience

This course is specifically tailored for mid-to-senior level clinical research professionals who are actively involved in the planning, conduct, and oversight of clinical trials and need to operationalise ICH E6(R3) in their day-to-day operations.

It is highly relevant for international professionals across sponsors (pharma/biotech), CROs, and investigative sites, including:

- Clinical Operations Directors, Managers, and Leads
- Clinical Trial Protocol Developers and Medical Writers
- Quality Assurance (QA) Auditors and Quality Management Professionals
- Clinical Monitoring Managers and Centralised Monitoring Specialists
- Data Governance Officers and Clinical Data Managers
- Regulatory Affairs Specialists
- Principal Investigators, Sub-Investigators, and Clinical Research Directors looking to understand updated oversight expectations.

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DAY 1

08:30 REGISTRATION AND WELCOME COFFEE

09:00 INTRODUCTION OF THE COURSE, FACULTY AND PARTICIPANTS

09:45 SESSION 1

THE ICH E6 (R3)

Scene setting presentation to enable the participants to understand the interplay between the principles and the annexes.

10:45 COFFEE BREAK

11:15 SESSION 2

DEVELOPING THE PROTOCOL: THE INTRODUCTION OF CRITICAL TO QUALITY FACTORS

In this session the attendees will have a short presentation on the understanding of what are critical to quality factors and their risks and then move into an exercise to determine what are the critical to quality factors of the synthetic protocol.

12:45 LUNCH BREAK

13:45 SESSION 3

INVESTIGATOR ROLES AND RESPONSIBILITIES, OVERSIGHT

This presentation will focus on the investigator section. It will be an interactive session with a workshop specifically looking into the concept of reconsenting.

14:45 COFFEE BREAK

15:15 SESSION 4

SPONSOR ROLES AND RESPONSIBILITIES, OVERSIGHT

This session will focus on the trial conduct phase and 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. You have identified your CTQs and the risks, how do you ensure the ongoing assessment and oversight. In this session oversight of service providers will be included.

16:15 Q&A AND RECAP OF DAY 1

17:00 END OF DAY 1

17:30 JOIN THE COURSE FACULTY AND OTHER PARTICIPANTS FOR A SELF-FUNDED DINNER

DAY 2

08:30 INTRODUCTION OF DAY 2

08:35 SESSION 5

SPONSOR MONITORING AND AUDITING

This session will focus on monitoring strategies, risk based auding and non-compliance, including material for a breakout session to discuss approaches to centralised monitoring.

09:30 SESSION 6

DATA GOVERNANCE

This session will explore what is expected of both investigators and sponsors in terms of data governance, including considerations for handling different types of data sources such as decentralised trial elements, pragmatic elements, and real-world data as referenced in Annex 2.

Basic principles and responsibilities.

10:30 COFFEE BREAK

11:00 SESSION 7

CASE STUDY 1

The delegates will split into groups, utilising the synthetic protocol, discuss data flows and assess where critical to quality factors fit in. Work out data flow diagram.

12:00 LUNCH BREAK

13:00 SESSION 8

COMPUTERISED SYSTEMS USED IN CLINICAL TRIALS

This session will cover fitness for purpose of computerised systems and tools. In addition, considerations for database lock, statistical programming activities, and systems used in decentralised trial elements (as discussed in Annex 2) will be addressed.

14:00 SESSION 9

CASE STUDY 2 - PRAGMATIC ELEMENTS, DECENTRALISED CLINICAL TRIALS, AND REAL-WORLD DATA

In this practical workshop, participants will explore pragmatic elements, decentralised clinical trial design, and the role of real-world data in modern trials. Small groups will assess a trial scenario, discuss how these elements align with GCP principles, and consider fitness-for-purpose and governance considerations raised in Annex 2.

15:00 COFFEE BREAK

15:30 SESSION 10

WHAT MAKES AN ESSENTIAL RECORD?

With the removal of the before, during and after tables from the essential documents section 8 in R2, what should sponsors consider as an essential record? Risk proportionality will help drive what documents are seen as essential.

16:00 PANEL DISCUSSION AND Q&A

17:00 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

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

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

Hilton London Olympia
380 Kensington High StreetLondon W14 8NLUnited Kingdom
Tel: +44 20 7603 3333
Email: reservations.olympia@hilton.com
Website: https://www.hilton.com/en/hotels/lhrolhn-hilton-london-olympia/

Bedroom reservations
DIA has blocked a limited number of bedrooms for the course participants at the rate of GBP 148.48 per Classic Double room per night for single use. The rate includes VAT, free Wi-Fi and extensive breakfast.

Information on how to book will be available shortly.

Continuing Education

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.

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CENTRE RECOGNITION

REGISTRATION FORM

ICH GCP: 1 year on | # 27530
20-21 April 2027 | London, UK

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 23 Feb 2027	MEMBER valid from 24 Feb 2027	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 1'260.00 ❑	€ 1'400.00 ❑	€ 1'660.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 700.00 ❑	€ 960.00 ❑
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.

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