DIA LEARNING

Understanding ICH E6(R3) Annex 2 for Evolving Clinical Trial Designs

15 March 2027 | 11:00-18:00 CET | Basel, CH

Overview

As clinical trial designs continue to evolve, ICH E6(R3) Annex 2 provides essential considerations for trials that incorporate pragmatic and decentralised elements, make use of Real-World Data (RWD), or rely on Digital Health Technologies (DHTs).

A clear understanding of Annex 2 has become increasingly important for all stakeholders involved in clinical research – including regulators, ethics committees, industry, academia and service providers – to ensure proportionate, scientifically sound and operationally feasible approaches.

This course offers practical guidance on applying Annex 2 across the clinical trial lifecycle, including expectations for investigator and sponsor oversight, safety data collection in pragmatic, decentralised and technology-enabled settings, and the assessment of RWD fitness-for-purpose and access pathways.

Participants will gain a structured understanding of how Annex 2 supports evolving clinical trial designs and aligns with the overarching principles of ICH E6(R3).

Learning Objectives

The objective of this course is to equip participants with a comprehensive and practical understanding of the expectations outlined in Annex 2, enabling them to apply decentralised, pragmatic, RWD-related and technology-enabled approaches – including oversight and safety considerations – in a proportionate and scientifically robust manner across evolving clinical trial designs.

Who Will Attend

This course is designed for professionals involved in:

- Clinical operations
- Clinical research
- Clinical safety and pharmacovigilance
- Regulatory affairs
- Quality assurance and quality control

Faculty

Rebecca Stanbrook
EFPIA ICH E6(R3) Expert Working Group Member
RESaltas GmbH, Switzerland

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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

15 March 2027

10:30 REGISTRATION AND WELCOME COFFEE

11:00 WELCOME, HOUSEKEEPING AND INTRODUCTIONS

11:15 SESSION 1

WHERE ANNEX 2 SITS IN ICH E6(R3) AND ITS SCOPE

- Focus: Establishing Annex 2 as an integral, proportionate extension of the main guideline. Focuses on risk proportionality, fit-for-purpose oversight, and determining trial scope.
- Interactive Element: Opening poll.

11:45 SESSION 2

SPONSOR CONSIDERATIONS: TRIAL ELEMENTS THAT CAN BE DECENTRALISED

- Focus: Practical implementation of remote activities (remote consent, eSource, direct-to-participant delivery, and remote oversight). Focuses on sponsor planning, validation, and vendor oversight.
- Interactive Element: Small group planning exercise.

13:00 SANDWICH LUNCH

13:45 SESSION 3

SPONSOR CONSIDERATIONS: PRAGMATIC TRIAL ELEMENTS

- Focus: Designing trials that operate within usual care settings and routine clinical infrastructure. Focuses on protocol design, risk-proportionate monitoring, and participant protection.
- Interactive Element: Oncology case scenario discussion.

14:45 SESSION 4

SPONSOR CONSIDERATIONS: USE OF AND ACCESS TO RWD IN THE CLINICAL TRIAL CONTEXT

- Focus: Supplementing clinical trials with real-world data. Focuses on data quality, provenance, governance, and assessing fitness-for-purpose for electronic health records or registry data.
- Interactive Element: Data scenario discussions.

15:40 COFFEE BREAK

15:55 SESSION 5

INVESTIGATOR CONSIDERATIONS

- Focus: The shifting role of the investigator in distributed settings. Focuses on delegation and oversight of external healthcare providers, remote participant oversight, and safety monitoring.
- Interactive Element: Investigator dilemma scenarios.

16:55 SYNTHESIS, Q&A AND KEY TAKEAWAYS

- Focus: Consolidating course themes, addressing common implementation pitfalls, and open audience Q&A.

17:45 CLOSING WORDS

18:00 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. 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.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

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

Course Venue

Congress Center Basel
Messeplatz 21, 4058 Basel, Switzerland
Tel: +41 58 206 28 28
Email: basel@messe.ch
www.messe-basel.com/en

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.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

REGISTRATION FORM

Understanding ICH E6(R3) Annex 2 for Evolving Clinical Trial Designs | # 27594
15 March 2027 | 11:00-18:00 CET | Basel, CH

DIA LEARNING

REGISTRATION FEES

Registration fee includes full admission to the course, electronic access to training course materials, refreshment breaks and sandwich lunch.
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 18 Jan 2027	MEMBER valid from 19 Jan 2027	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 540.00 ❑	€ 600.00 ❑	€ 860.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 300.00 ❑	€ 560.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats is limited.			

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.

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