

DIA/Swissmedic training course: Understanding ICH E6(R3) Annex 2 for Evolving Clinical Trial Designs

24 September 2026 | 09:30-16:30 CEST | Bern, 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



25 September 2026

09:00 REGISTRATION AND WELCOME COFFEE

09:30 WELCOME, HOUSEKEEPING AND INTRODUCTIONS

09:45 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.

10:15 COFFEE BREAK

10:30 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.

11:45 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.

12:45 SANDWICH LUNCH

13:15 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.

14:15 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.

15:15 COFFEE BREAK

15:30 SYNTHESIS, Q&A AND KEY TAKEAWAYS

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

16:20 CLOSING WORDS

16:30 END OF THE TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.



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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.

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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

Swissmedic

Freiburgstrasse 139
3008 Berne

How to get there:

- by tram no. 7 (Bümpliz Süd) or No. 8 (Westside) to the "Steigerhubel" stop
- by train S2 (Laupen), S6 (Schwarzenburg) or S31 (Belp-Thun) to the "Bern-Europaplatz" stop
- by car: exit the motorway A12 Bern-Fribourg at "Bern-Bümpliz", follow directions "Köniz" > "Zentrum"



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.



REGISTRATION FORM

DIA/Swissmedic: Understanding ICH E6(R3) Annex 2 | # 26594
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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	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 600.00 ☐	€ 860.00 ☐
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 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.

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☐ 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

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

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

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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.

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These are available from the office or online by clicking:

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Date

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