Feedback from the ACT EU workshop on ICH E6 (R3)

Joint Patients' and Consumers and Healthcare Professionals working parties meeting

1 April 2025

Presented by

Peter Twomey, Head of Inspections and ICH E6 R3 (principles and Annex 1) Reg Chair

Kim Pietsch, Seconded National Expert (DE-PEI), ACT EU PA coordinator, Inspections

- Update to ICH E6 R3
- 19-20 Feb 2025 ACT EU Workshop on ICH E6 (R3)
  - Presentations, recordings, meeting report
  - Feedback from attendees
- Implementation

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Update to ICH E6 R3

- **ICH E6 first released in 1996**, now at R3
- **Extensive stakeholder engagement** and input, **including HCPs and patients/patient representatives**
- **R3 is a major rewrite** to position the guideline for alternative trial types and new technologies, reduce unnecessary burden, clarify roles and responsibilities (incl. investigator oversight)
- Guideline **focuses on what is most important** to **patient safety** and **data reliability**
  - Proportionality, risk-based approaches, good trial design and building quality in up front
  - Encouragement of engagement with patients and other interested parties
- **Principles and Annex 1** finalised in January 2025, in EU, guideline comes into effect on **23 July 2025**
- **Annex 2 (focusing on alternative trial types and technologies)** being further drafted in line with public comments – **aim to finalise second half of 2025**

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ACT EU workshop on ICH E6 (R3) Agenda

- Overview of Renovation and Key concepts
- Investigator oversight
- Informed consent
- Draft ICH E6 (R3) Annex II
- Community Advisory Boards
- Panel and Audience discussions
- Interactive Q&A session
- Sponsor oversight
- Data Governance
- Essential Records and Safety Management

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ACT EU Workshop on ICH E6(R3)

Key points

- Event page updated with recordings and presentations
- Attended by 2000 participants (online and on site) from 50 different countries
- Areas include overview of changes, Annex 2, investigator and sponsor oversight, informed consent, data governance, essential records and safety management
- Meaningful perspectives from E6 Expert Working Group Members, investigators and patients/patient representatives
- High level of engagement and so far, very positive feedback received from the attendees
- A meeting report will be published in due time.

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Extracts from the post workshop survey

Over 90% were (very) satisfied; 2% were unsatisfied; 0% were very unsatisfied

Over 95% found the content as (very) relevant to their needs or interests)

95% rated the overall quality of the presentations as excellent or good

99% excellent or good rating of the expertise of the speakers/panellists

98% would recommend this workshop to a colleague or peer

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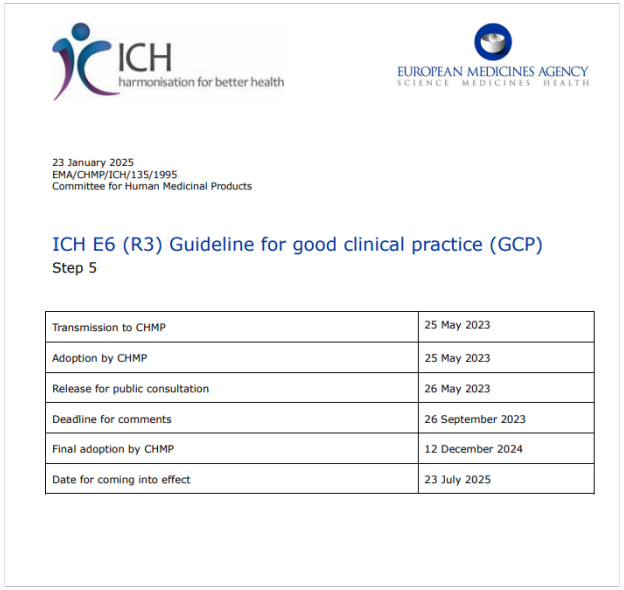
Implementation

- In EU, guideline comes into effect on **23 July 2025**
- **Training**
  - ACT EU ICH GCP E6 (R3) workshop on 19-20 Feb 2025
  - **Online training** being developed at global ICH level
  - Network engaged in **regional workshops**
  - **Training of regulators** (e.g. GCP IWG Cyprus workshop in Oct 2024, more to come)
- **Impact analysis of ICH E6 (R3) guideline** against other guidelines/papers



ICH harmonisation for better health

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 January 2025
EMA/CHMP/ICH/135/1995
Committee for Human Medicinal Products

ICH E6 (R3) Guideline for good clinical practice (GCP)
Step 5

Transmission to CHMP	25 May 2023
Adoption by CHMP	25 May 2023
Release for public consultation	26 May 2023
Deadline for comments	26 September 2023
Final adoption by CHMP	12 December 2024
Date for coming into effect	23 July 2025

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Thank you

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