Good Clinical Practice

ICH E6(R3) update from ACT EU (PA4)

Annual Workshop of the European network of paediatric research at the EMA

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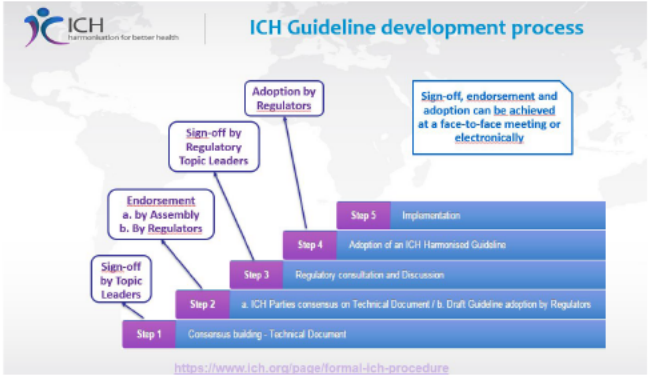
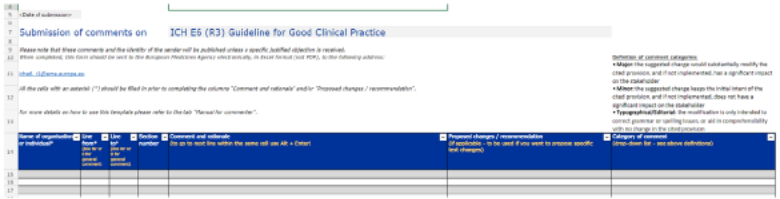
Disclaimer

The views expressed in this presentation are the personal views of the author(s) and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency (EMA) or one of its committees or working parties *or* the Paul-Ehrlich-Institut (PEI).

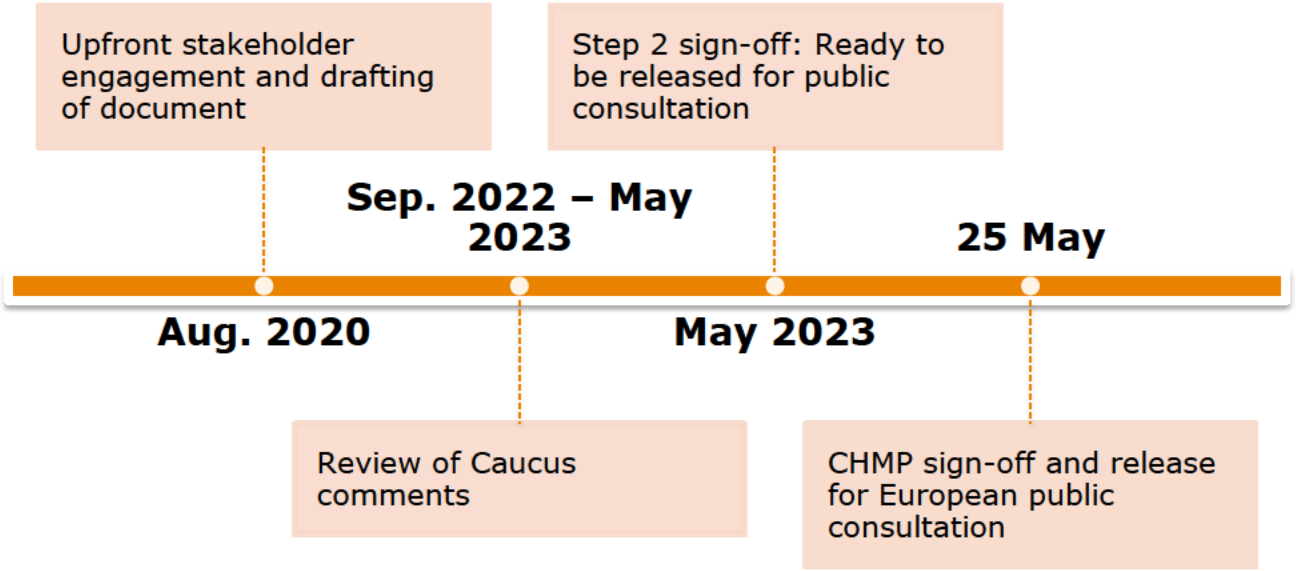
Roadmap and timeline towards ICH E6(R3)

- Consultation dates: 26 May to 26 Sep 2023 (principles and Annex 1).
- Anticipating finalization as a step 4 document to be implemented in the local regional regulatory system: Sep/Oct 2024
- Source: https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step2_Presentation_2023_0613.pdf





Progress so far (Principles and Annex 1)



Source: ICH E6 (R3) workplan

Next steps (Principles and Annex 1)

26 Sep 2023: Closing date for comments to the European group

Nov 2023: Begin review of public comments from all regions

Aug/Sep 2024: Step 3 sign off of technical document

Sep/Oct 2024: Step 4 adoption of technical document

Thank you for your interest in ICH E6(R3) Good Clinical Practice.

ICH E6(R3) Guideline Availability Notice

Thank you for your interest in ICH E6(R3) Good Clinical Practice.

The ICH E6(R3) Expert Working Group (EWG) has developed and drafted a revised guideline while considering a variety of clinical trial designs and settings. The EWG intends to encourage the use of innovation and technologies that have the potential to make clinical trials more efficient.

We greatly appreciate your comments. As we anticipate an extraordinarily large number of comments, we strongly encourage you to consider the following when drafting your comments:

- Prioritizing or highlighting key comments.
- Correlating your comment with the corresponding line number of the draft guideline to make it easier for us to identify relevant text.
- Providing justification and any relevant examples to support suggested changes.
- Consolidating comments from the same organisation, if appropriate.

We are requesting inputs across all topics addressed in this draft guideline, but please focus on key issues and consider providing insights on:

- Areas that may need additional clarity or language that may be susceptible to misunderstanding.
- Areas that may not accommodate technological innovations and design elements that are being explored to make clinical trials more efficient (we welcome examples to help inform us).
- Training components that should be included to make global GCP training useful as the EWG is planning to develop training materials for ICH E6(R3).

E6(R3) Guideline Availability Notice.pdf (ich.org)

What is unique about E6(R3) structure and content?

New structure to provide clarity and better readability

- Principles to remain relevant as technology, methods, and trial design evolve
- Annexes and appendices (better flow and a strategy intended to enable easier and faster updates in the future)

Focused **scope**

Language to **facilitate innovations** in trial design & technology

- Enabling DCTs and PoCs among other design elements
- Expect the use of DHTs, healthcare infrastructure, and other design elements & tools to recruit/retain, capture data, monitor, and to analyze results

Link to the recording and summary of records of the ACT EU PA4 workshop on ICH E6(R3) public consultation

- 13-14 July 2023
- Link to the eventpage: ACT EU PA04 - Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation | European Medicines Agency (europa.eu)
- ICH step 2b presentation: ICH-E6(R3)

Brief update on comments received during the PC in the EU

Over 60 stakeholders

Over 1500 comments in total

Too early to share further details on the comments received

- All comments received will be published in accordance with existing polices.

Next steps:

Identify major trends/themes and bring forward to the ICH E6(R3) EWG for further discussion and consideration.

According to the published ICH E6(R3) EWG work plan step 4 adoption of draft guideline (principles and Annex 1) is anticipated for Jun/Jul 2024

EUROPEAN MEDICINES AGENCY

E6 (R3) Draft Guideline

E6 (R3) draft guideline subject to public consultation consists of parts I, II, III (composed of 4 sections), glossary, and appendices.

Open for public consultation now

- **I. INTRODUCTION**
- **II. PRINCIPLES OF ICH GCP**
- **III. ANNEX 1**
  1. Institutional Review Board/Independent Ethics Committee (IRB/IEC)
  2. Investigator
  3. Sponsor
  4. Data Governance – Investigator and Sponsor
- **GLOSSARY**
- **APPENDICES**
  - Appendix A. Investigator's Brochure
  - Appendix B. Clinical Trial Protocol and Protocol Amendment(s)
  - Appendix C. Essential Records for the Conduct of a Clinical Trial

Work Started on E6(R3) Annex-2

Expected finalisation: TBA

The proposed development of Annex 2 will include additional considerations on how GCP principles may be applied across a variety of trial designs and data sources, where applicable. This will include:

1- Decentralised elements, where some or all trial-related activities occur at locations other than traditional clinical trial sites, such as patient homes, mobile trial units, or local clinics, and data collection may occur remotely.
2- Pragmatic elements, reflecting trials that closely resemble routine clinical practice.
3- Real-world data (RWD) sources[2], for example, the use of registries, electronic health records (EHR), hospital data, pharmacy and medical claims data or wearables.

ACT EU PA4 – Modernisation of GCP

Homepage (europa.eu) – Accelerating Clinical Trials in the EU

- The Accelerating Clinical Trials in the European Union (ACT EU) initiative will support smarter clinical trials through regulatory, technological and process innovation.

Our vision is to transform the EU into a region that supports **clinical trial development** and enables **collaboration and innovation** at all stages of the clinical research lifecycle.

Seamless coordination among stakeholders, regulators and ethics committees will lead to more cross-border collaboration.

The result will be better, more impactful clinical trials, **benefitting patients and healthcare in Europe** in the process.

The new work plan is currently drafted and discussed

We will keep you informed

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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