CRSO Insightalyst

FDA Draft Guidance: ICH E6(R3)

July 17, 2023

On June 6, 2023, The U.S. Food and Drug Administration (FDA) announced the availability of the draft guidance titled "E6(R3) Guideline for Good Clinical Practice." This E6(R3) update aims to provide flexible, modern, and clear Good Clinical Practice (GCP) for conducting clinical research.

The draft guidance is adopted from the International Council for Harmonisation's (ICH) recently updated E6(R3) draft guideline. As a founding member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry.

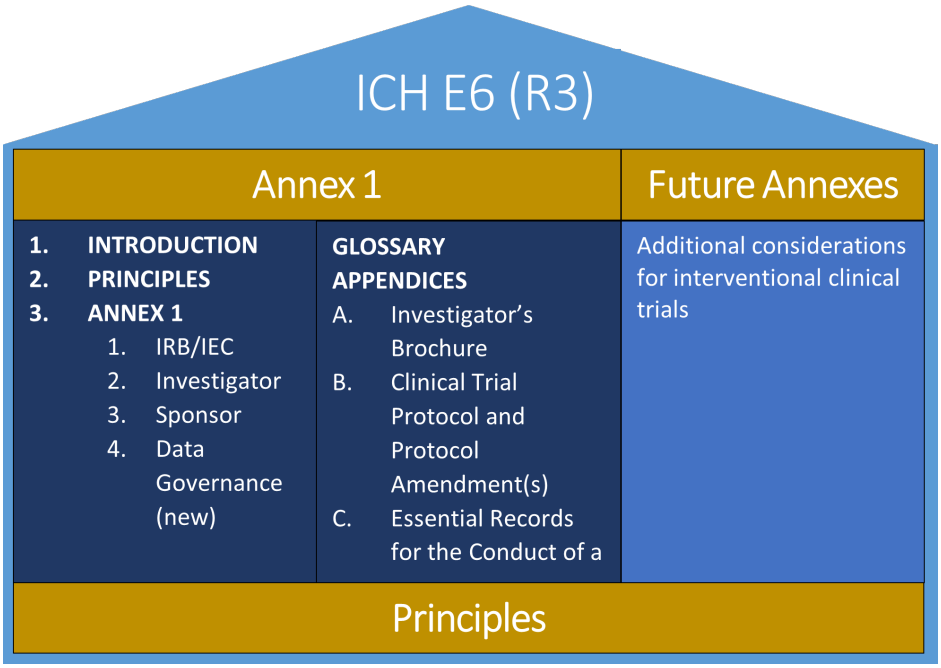
Overview

ICH has created a 9-minute explanatory video to share some of the overarching updates and key concepts. Watch the video to jump-start your review of the E6(R3) guidelines.

Structure

ICH E6(R3) has a new structure to provide clarity and better readability:

- Principles to remain relevant as technology, methods, and study design evolve.
- Annexes and appendices to enable easier and faster updates in the future.



Content

The content has been updated to:

- Provide additional clarity on the scope of the guidance.
- Include language to facilitate innovations in clinical research design, technology, and operational approaches.
- Set expectations around the responsibilities of the sponsor and investigator in a digital ecosystem.
- Encourage approaches that are fit-for-purpose.
- Incorporate learning from innovative clinical trial designs and lessons from public health emergencies/pandemics.
- Encourage transparency by clinical trial registration and result reporting.
- Provide additional language to enhance the informed consent process.

What does it mean for me?

UNC-Chapel Hill applies ICH GCP E6 guidelines to all clinical research. With the evolving clinical research landscape, following GCP is more important than ever to protect participants, yield adequate and reliable results, and ensure that studies are conducted in an efficient manner that reduces burden and unnecessary complexity.

These are some key updates to the investigator section:

- Clarified training requirements for study personnel, that is, training should correspond with role.
- Required investigator supervision of activities that have been delegated.

If you are a UNC-Chapel Hill investigator or clinical research professional conducting clinical research, review the recommendations and consider submitting comments. The guidance is open for public comment until September 5, 2023.

Once the E6(R3) guidelines are finalized, it will update the existing 2018 guidance titled, "E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)."

More Available Information

As a member of the E" Efficiency" family of ICH guidelines, E6(R3) interweaves concepts of "E8(R1) General Considerations for Clinical Studies" to provide a shift toward greater efficiency and risk-based quality management. Click here for CRSO *Insightalyst* on the E8(R1).

The FDA has issued other documents that complement the modernization efforts, including draft guidance on decentralized clinical trials (also discussed in a previous Insightalyst), a Digital Health Technologies (DHT) framework document guiding DHT-derived data in regulatory decision-making for drugs and biological products, and a modernized version of the ClinicalTrials.gov website.

If you have questions about the information presented in this issue of the *Insightalyst*, please contact the CRSO at crso@med.unc.edu.