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Preparing for ICH E6(R3): Toward a Unified Global Standard in Clinical Research

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidance is designed to provide a **unified standard** for the **European Union, Japan, and the United States**. This harmonization is essential for enabling regulatory authorities in these regions to **mutually accept clinical trial data**—streamlining approvals, reducing duplication, and strengthening opportunities for global collaboration in medical research.

FDA Announcement on E6(R2)

The **U.S. Food and Drug Administration (FDA)** recently announced the availability of a guidance entitled *"E6(R2) Good Clinical Practice: Integrated Addendum to E6(R1)."*

- This guidance, prepared under the auspices of the ICH (formerly the International Conference on Harmonisation), is not yet formally adopted by the FDA.
- The purpose of E6(R2) is to modernize trial expectations by promoting more efficient design, conduct, oversight, and reporting of trials.
- It also includes updates related to electronic records and essential documentation.

While this announcement does not represent official adoption, it signals the FDA's alignment with global efforts to move toward harmonized standards.

Looking Ahead: E6(R3)

The next version, *E6(R3)*, further builds on these principles and reflects evolving approaches in clinical research. On **July 23, 2025**, the CITI Program updated all of its relevant GCP training courses to incorporate E6(R3) content.

- Some FDA-specific training modules still reference E6(R2), as the FDA has not yet adopted E6(R3).
- However, most GCP modules now reflect the updated standards to help prepare the research community.
- Learners who have completed past training can review updated content by selecting the **"Review/Retake Module"** option in CITI.

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Why This Matters

For our hospital research community, these updates mean that our training, practices, and documentation will remain aligned with international best practices—even before official FDA adoption. By staying current, we ensure that:

- Our data can be trusted and recognized across borders.
- Our participants remain protected under the highest ethical and scientific standards.
- Our teams are well-positioned for future regulatory transitions.

What You Can Do Now

- **Check your training status:** Log into CITI and review the updated GCP modules. Good Clinical Practice (GCP) | CITI Program

- **Stay informed:** Read the current guidance document and watch for FDA's forthcoming adoption of E6(R3). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1

- **Apply standards today:** Incorporate GCP best practices into study design, oversight, and documentation to ensure readiness.