

CITI Program Updates Curriculum in Response to ICH E6(R3) Guideline

CITI Program updates GCP curriculum and launches new course in response to ICH E6(R3) to support clinical trial compliance and training.

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*Eric Kupferberg, Associate
Director of Clinical Research
Education*

trusted leader in research ethics and compliance education, has updated its Good Clinical Practice (GCP) curriculum in response to the finalization of the ICH E6(R3) Guideline for Good Clinical Practice, issued by the International Council for Harmonisation (ICH) on January 6, 2025. The updated guideline marks a pivotal shift in how clinical trials are designed and conducted. It introduces enhanced flexibility, a greater emphasis on quality and risk management, and recognition of digital health technologies and decentralized trial models. It also reflects a more participant-centered approach and prepares the research community for future innovations.

“CITI Program is committed to equipping the research community with high-quality, up-to-date training that reflects global regulatory developments. Our updated GCP curriculum ensures that sponsors, investigators, IRBs, and clinical teams can confidently align with the expectations set by ICH E6(R3),” said Eric Kupferberg, Associate Director of Clinical Research Education at CITI Program.

Highlights of CITI Program’s Response

CITI Program has revised the relevant courses in its Good Clinical Practice (GCP) curriculum to align with the changes introduced in ICH E6(R3). Learners will gain an understanding of how the guideline shapes the expectations and responsibilities of those who conduct, monitor, report, and document clinical trials.

To further support the research community during this transition, CITI Program has launched a new video-based course, ICH E6(R3): An Introduction. This course offers CME/CEU credits and provides a clear, practical overview of the updated GCP principles, Annex 1, and Annex 2.

For current CITI Program courses recognized as meeting the minimum criteria for mutual recognition established by TransCelerate Biopharma, the updated course reflecting ICH E6(R3) also meet the minimum criteria, ensuring consistency and acceptance across participating organizations.

As the U.S. Food and Drug Administration (FDA) has not yet adopted ICH E6(R3), CITI Program's GCP FDA Basic and Refresher courses still refer to E6(R2). These courses will be updated once the FDA issues its implementation timeline.

In addition, the GCP ICH Refresher for Canada is scheduled for revision in Fall 2025 to reflect Canada-specific regulatory guidance and developments related to E6(R3).

Explore the Updated Curriculum

To learn more about the updated GCP offerings and the new ICH E6(R3): An Introduction course, [visit CITI Program's Good Clinical Practice \(GCP\) Series](#). For more information about TransCelerate Biopharma mutual recognition, [visit our Support Center](#).

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