UNIVERSITY OF CALGARY

CUMMING SCHOOL OF MEDICINE

Calgary Centre for Clinical Research
3280 Hospital Drive NW
Calgary, AB, Canada T2N 5A1
ucalgary.ca

University of Calgary E6 (R3) Transition Training

As part of our ongoing commitment to ensuring research teams are aligned with current regulatory standards, the Calgary Centre for Clinical Research (CCCR) is implementing interim training to bridge the transition from ICH E6 (R2) to ICH E6(R3).

Background

- ICH GCP E6(R3) was released in early 2025.
- The European Medicines Agency (EMA) has already adopted R3, while both the FDA and Health Canada are in the process of adopting this standard.
- Currently, CITI-GCP Canada training program does not yet include ICH E6(R3) content
- The upcoming Network of Networks webinar "R2 to R3 Comparison Sesson" being held on Oct 1, 2025, provides essential insights into the key differences between R2 and R3 and their impact on clinical research operations.
- This webinar will serve as a bridge for staff engaged in regulated clinical trials to ensure preparedness until formal GCP (R3) training is fully available.

Institutional Decision

- Attendance at the ""R2 to R3 Comparison Sesson" webinar will be recognized by CCCR as bridging training between ICH E6(R2) and ICH E6(R3). Click here to register for the webinar.
- Attendance confirmation certificates will be available for the live viewing session.
- For those unable to attend the live session, the webinar recording will be made available. Research team members and investigators must make a personal commitment to review the webinar recording in full and create an internal record confirming completion. They are encouraged to engage with the CCCR team with any questions or clarifications arising from the material.

Harmonized Research Training Framework and Requirements

- This interim training will serve as a bridge until staff are due for GCP renewal, at which time updated GCP(R3) training will be required through formal programs such as CITI-GCP once the content is available.

  Note: Until the CITI-GCP Canada course content is updated to include R3, continue to take and refresh your CITI-GCP(R2) as per the Harmonized Research Training Framework.

Next Steps

All research team members and investigators in clinical trials are strongly encouraged to complete this training — either by attending the live session or by carefully reviewing the recording and documenting self- training — to remain current with the evolving GCP framework.

If institutes or centers have identified alternative approaches or training modules for bridging R2 to R3, these should be submitted to the Lead Regulatory Officer – Clinical Research for review and confirmation to ensure that they meet the required fundamental competencies.

For any questions regarding this interim training recognition or documentation, please contact Jenna Dobry-Dub jldobry@ucalgary.ca .

Jenna Dobry-Dub, MSc (Law), CCRP *(She/Her)*
Lead Regulatory Officer – Clinical Research
Calgary Centre for Clinical Research | Cumming School of Medicine
E jldobry@ucalgary.ca
cumming.ucalgary.ca/research/cccr

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