Update on the University of Calgary's Adoption and Implementation of ICH GCP E6 (R3)

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This presentation is not training for ICH GCP E6 (R3).

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Objectives

1. General overview of the ICH GCP E6 (R3) guideline
2. Understand the anticipated timeline for adoption
3. Updates on available training and other tools
4. Review the anticipated impact on Industry Sponsored & Investigator-Initiated trials

ICH GCP E6 (R3) guideline

Reorganization

- New section: Data Governance
- Protocol, Investigator Brochure and Essential Record Sections from R2 are now appendices in R3

ICH GCP E6 (R3) guideline

Updated focus

- Data Life Cycle
  - Electronic systems
  - Risk proportionality in data management
  - Blinding
- Risk proportionality
  - Quality by Design (QbD)
  - Critical to Quality Factors (CtQ)
- Responsibility
  - Added responsibilities to both sponsor & investigator

Adoption Timeline

- Health Canada is adopting the guideline E6 R3 on April 1, 2026.
- University of Calgary is “soft” adopting the guideline Jan 2026
  - Documents and tools will be updated per R3
  - Audits & monitoring conducted per R3 as of January in anticipation for April 1, 2026

Training Requirements (IITs)

- R2 to R3 Comparison Session conducted by N2 will be recognized as bridging training until R2 GCP certificate expires
  - Recording expires Dec 31, 2025
  - Self-attestation
- Optional CITI R3 GCP available today
- Industry sponsored trials – take direction from Sponsor

Training

- CITI R3 GCP update is available October 27 (today)
- N2 training sessions
  - Oct 1, 2025 & self attestation form available *(bridging training)
- ICH E6(R3) training
  - Module 1 (Intro & Foundations)posted in October
  - Modules 2-5 coming soon
- Health Canada training sessions
  - Started hosting sessions in Fall & more coming
- Practical training during audits & monitoring
- Study-specific guidance available as needed

Tools & Templates

- Website & resource updates
  - Risk assessment & management
  - CtQ resources
  - Protocol deviation criteria
  - N2 resources updated soon
- N2 SOP V11 coming soon

Industry Sponsored Trial Impact

- Take direction from sponsor on training requirements
  - Investigators familiarize yourself with the updated responsibilities
- Request CtQs to be shared
- Monitoring should be risk-based and focussed on CtQs

Investigator Initiated Trial Impact

- CtQs will be required to be integrated into new protocol submitted to Health Canada
  - Health Canada has not yet commented on the requirement for currently active trials
  - ICH M11 protocol template
- Risk management plan (including CtQs)
- Multi-site
  - Sponsor responsibility to identify & share CtQs with subsites

Questions?

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