

ICH E6 Guideline for Good Clinical Practice (GCP) Update on Progress - Public Web Conference

Provided by the International Council for Harmonization (ICH)

Tuesday, May 18, 2021 8 AM – 11 AM EDT,¹ 2PM – 5 PM CEST, 9 PM – 12 PM JST
Wednesday, May 19, 2021 5 AM – 8 AM EDT, 11 AM – 2 PM CEST, 6 PM – 9 PM JST

AGENDA

[CTTI Announcement; Registration](#)

Background materials: [ICH E6\(R3\) Draft Principles](#)

Tuesday, May 18, 2021

TIME	PRESENTATIONS
Session 1 – General Introduction	
8:00 AM EDT 2:00 PM CEST 9:00 PM JST	A – Welcome, Opening Remarks <ul style="list-style-type: none">M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States B – ICH Guideline Development Process and the Initial Approach to ICH E6(R3) <p>This video session will explain the ICH guideline development process and provide a brief description of the approach to updating the ICH E6(R3) Good Clinical Practice (GCP) guideline.</p> <ul style="list-style-type: none">Nitin Bagul, TGA, AustraliaM. Khair ElZarrad, FDA, United StatesGail Francis, PIC/SKanako Ito, PMDA, JapanCarole Légaré, Health Canada, CanadaMiriam Onishi, ANVISA, BrazilSumitra Sachidanandan, HSA, SingaporeRebecca Stanbrook, EFPIAFergus Sweeney, EC, Europe
Session 2 – ICH E6(R3) GCP Expert Working Group (EWG) Vision & Engagement	
8:20 AM EDT 2:20 PM CEST 9:20 PM JST	A – Vision and Goals for the Work to Update ICH E6(R3) GCP Guideline <p>In this session, the general goals and vision for this revision of ICH GCP guideline will be outlined.</p> <ul style="list-style-type: none">Fergus Sweeney, ICH E6(R3) Regulatory Chair, EC, Europe

¹ EDT = Eastern Daylight Time (Washington DC); CEST = Central Europe Summertime (Brussels); JST = Japan Standard Time (Tokyo)

B – Lessons Learned from Public Input & Stakeholder Feedback

The work that the Expert Working Group has carried out to collect and analyze input from all stakeholders will be described. Also, the ICH GCP stakeholder engagement plan and related activities will be presented.

- Dianne Paraoan, FDA, United States
- Lisbeth Bregnhøj, EC, Europe
- Rebecca Stanbrook, EFPIA

C – Questions & Answers

9:20 AM EDT

3:20 PM CEST

10:20 PM JST

Break

Session 3 – Principles & Stakeholder Reflections

9:30 AM EDT

3:30 PM CEST

10:30 PM JST

A – Draft “Work-in-Progress” Principles

In this session, the Expert Working Group members will present the published draft principles and highlight key points.

- Celia Witten, FDA, United States
- Carole Légaré, Health Canada, Canada
- Sumitra Sachidanandan, HSA, Singapore
- Gail Francis, PIC/S
- Miriam Onishi, ANVISA, Brazil
- M. Khair ElZarrad, FDA, United States

B – Stakeholder Reflections and Vision

In this session, experts and advocates will provide their vision and aspirations on the clinical trial enterprise in general.

- Dr. Marco Greco, European Patients Forum, Europe
- Dr. Kenichi Nakamura, National Cancer Center Hospital, Japan
- Ms. Janette Panhuis, Population Health Research Institute, Canada

Questions & Answers for Stakeholders

10:50 AM EDT

4:50 PM CEST

11:50 PM JST

Closing Remarks & Summary

- M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States

11:00 AM EDT

5:00 PM CEST

12:00 AM JST

Adjournment