ICH E6(R3) Guideline for Good Clinical Practice
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) Principles

DAY 1

TIME	PRESENTATIONS
Session 1 – General Introduction	
8:00 AM EDT 2:00 PM CEST 9:00 PM JST	**A – Welcome, Opening Remarks** • M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States **B – ICH Guideline Development Process and the Initial Approach to ICH E6(R3)** Video link will be available approximately 48 hours before the meeting. This 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. • Nitin Bagul, TGA, Australia • M. Khair ElZarrad, FDA, United States • Gail Francis, PIC/S • Kanako Ito, PMDA, Japan • Carole Légaré, Health Canada, Canada • Miriam Onishi, ANVISA, Brazil • Sumitra Sachidanandan, HSA, Singapore • Rebecca Stanbrook, EFPIA • Fergus Sweeney, EC, Europe
Session 2 – E6(R3) EWG Vision & Engagement	
8:20 AM EDT 2:20 PM CEST 9:20 PM JST	**A – Vision and Goals for the Work to Update E6 Guideline** In this session, the general goals and vision for this revision of ICH GCP guideline will be outlined • 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.

- Lisbeth Bregnhøj, EC, Europe
- Dianne Paraoan, FDA, United States
- 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. • Gail Francis, PIC/S • Carole Légaré, Health Canada, Canada • Miriam Onishi, ANVISA, Brazil • Sumitra Sachidanandan, HSA, Singapore • Celia Witten, 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, The Clinical Research Core Hospital, Japan • Ms. Janette Panhuis, Population Health Research Institute, Canada **C – Questions & Answers**
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**

DAY 2

TIME	PRESENTATION
Session 1 – General Introduction	
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6:20 AM EDT 12:20 PM CEST 7:20 PM JST	**Break**

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7:50 AM EDT 1:50 PM CEST 8:50 PM JST	**Closing Remarks & Summary** • M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States
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