

## 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,<sup>1</sup> 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](#)

### Wednesday, May 19, 2021

TIME	PRESENTATION
<b>Session 1 – General Introduction</b>	
5:00 AM EDT 11:00 AM CEST 6:00 PM JST	<b>A – Welcome, Opening Remarks</b> <ul style="list-style-type: none"><li>M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States</li></ul> <b>B – ICH Guideline Development Process and the Initial Approach to ICH E6(R3)</b> <p>This <a href="#">video session</a> 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"><li>Nitin Bagul, TGA, Australia</li><li>M. Khair ElZarrad, FDA, United States</li><li>Gail Francis, PIC/S</li><li>Kanako Ito, PMDA, Japan</li><li>Carole Légaré, Health Canada, Canada</li><li>Miriam Onishi, ANVISA, Brazil</li><li>Sumitra Sachidanandan, HSA, Singapore</li><li>Rebecca Stanbrook, EFPIA</li><li>Fergus Sweeney, EC, Europe</li></ul>
<b>Session 2 – ICH E6(R3) GCP Expert Working Group (EWG) Vision &amp; Engagement</b>	
5:20 AM EDT 11:20 AM CEST 6:20 PM JST	<b>A – Vision and Goals for the Work to Update ICH E6(R3) GCP Guideline</b> <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"><li>Fergus Sweeney, ICH E6(R3) Regulatory Chair, EC, Europe</li></ul> <b>B – Lessons Learned from Public Input &amp; Stakeholder Feedback</b>

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

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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**

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6:20 AM EDT  
12:20 PM CEST  
7:20 PM JST

**Break**

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## Session 3 – Principles & Stakeholder Reflections

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6:30 AM EDT  
12:30 PM CEST  
7:30 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
- Nitin Bagul, TGA, Australia
- 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

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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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8:00 AM EDT  
2:00 PM CEST  
9:00 PM JST

### Adjournment

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