

Stakeholder Engagement on ICH E6 Guideline for Good Clinical Practice

Public Web Conference

Organized by the U.S. Food and Drug Administration

in Collaboration with the Clinical Trials Transformation Initiative (CTTI)

Thursday, June 4 and Friday, June 5, 2020

10:00 a.m. – 1:00 p.m. (EST)

AGENDA

Meeting website: <https://www.fda.gov/drugs/news-events-human-drugs/stakeholder-engagement-ich-e6-guideline-good-clinical-practice-web-conference-06042020-06052020>

Thursday, June 4, 2020

10:00 a.m. Welcome, Opening Remarks

- Pamela Tenaerts, Moderator, Executive Director, CTTI, United States
- M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States

10:10 a.m. Session I: ICH Process & Updating ICH E6 GCP Guidelines

- Theresa M. Mullin, FDA, United States – Introduction to the ICH Process
- M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States – Revision of ICH E6 Good Clinical Practice Guideline
- Fergus Sweeney, ICH E6(R3) Regulatory Chair, EC, Europe – Stakeholder Engagement for ICH E6

10:35 a.m. Session II: CTTI ICH E6 Survey and Stakeholder Input

- Amy Corneli, CTTI, United States

10:50 a.m. Session III: Perspectives from EWG Members

- Carole Légaré, Health Canada, Canada
- Deborah Driscoll, PhRMA, United States
- Carla Brichesi, ANVISA, Brazil
- Celia Witten, FDA, United States

11:25 a.m. BREAK

11:35 a.m. Session IV: Perspectives from Clinical Investigators

- Roger Lewis, Harbor-UCLA Medical Center, Society for Clinical Trials, United States
- Otávio Berwanger, Hospital Israelita Albert Einstein, Brazil
- Marianne Chase, Healey Center for ALS, Massachusetts General Hospital, United States

- 12:10 p.m. Session V: Perspectives from Patient Organizations**
- John Adams, Canadian PKU and Allied Disorders, Best Medicines Coalition, Canada
 - Jane Perlmutter, The Gemini Group, CTTI, United States
 - Antoine Daher, Casa Hunter, Brazilian Federation of Rare Disease Associations (Febrararas), Brazil

- 12:45 p.m. Closing Remarks, Plans for Day 2**
- M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States

Friday, June 5, 2020

- 10:00 a.m. Welcome, Recap Thursday Discussion**
- Pamela Tenaerts, Moderator, Executive Director, CTTI, United States
 - M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States

- 10:05 a.m. Session I: Stakeholders Perspectives**
- Murray M. Lumpkin, Bill and Melinda Gates Foundation, United States
 - Martha F. Jones, Partners HealthCare, United States
 - Thierry Lacaze, Maternal Infant Child and Youth Research Network (MICYRN), Canada
 - Charles Preston, Pan American Health Organization (PAHO), United States

- 10:50 a.m. Session II: Moderated Discussion of Themes from Stakeholders**
- Panel Moderator: Celia Witten, FDA, United States
 - Panelists
 - Carla Brichesi, ANVISA, Brazil
 - Deborah Driscoll, PhRMA, United States
 - Ni Khin, FDA, United States
 - Carole Légaré, Health Canada, Canada
 - Pamela Tenaerts, CTTI, United States

11:50 a.m. BREAK

- 12:00 p.m. Session III: Stakeholder Comments**
- Pre-registered stakeholders

- 12:45 p.m. Closing Remarks, Adjournment**
- M. Khair ElZarrad, ICH E6(R3) Rapporteur, FDA, United States