Public Meeting on ICH E8(R1)- General Considerations for Clinical Studies

FDA Great Room, Building 31, Room 1503
10903 New Hampshire Avenue, Silver Spring, MD 20993, USA

October 31, 2019

AGENDA

Meeting Website: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/ich-global-meeting-ich-e8r1-guideline-general-considerations-clinical-trials-10312019-10312019

8:30 a.m. **Welcome, Opening Remarks**

8:45 a.m. **Session I: The role of E8 as part of the ICH GCP Renovation and next steps** **45 minutes**

Chairs:
- *Dr. Lisa LaVange, E8 Expert Working Group (EWG) Rapporteur - FDA, United States*
- *Dr. Fergus Sweeney, E8 EWG Regulatory Chair - EC, Europe*

Presentation:
1. Introduction to ICH and its Global Footprint – *Ms. Amanda Roache, ICH Coordinator – FDA, United States (10 min)*
2. ICH E8(R1) Role in GCP Renovation – *Dr. Lisa LaVange, E8 EWG Rapporteur, FDA, United States (10 min)*
3. Overview of ICH E8(R1) – *Dr. Andreas Kirisits, E8 EWG Representative – EC, Europe* (10 *min)*
4. Response to public consultations: first impressions and next steps – *Dr. Carole Légaré, EWG Representative, Health Canada, Canada (10 min)*

Public Comment/Questions *(5 mins)*

9:30 a.m. **Session II: Drug Development Plan** **75 Minutes**

Chairs:
- *Dr. Joanne Palmisano, EWG Representative – PhRMA*
- *Dr. Gregory Golm, EWG Representative – BIO*

Presentation:
Overview presentation – *Dr. Joanne Palmisano, EWG Representative – PhRMA (10 minutes)*

Panelist Perspective –
- Prof. Louise Bowman, European Society of Cardiology/University of Oxford
- Dr. Harumasa Nakamura, Director, Department of Clinical Research Support, National Center of Neurology and Psychiatry, Japan
- Dr. John Buse, Division Chief and Director, Diabetes Center, UNC
- Mr. John Adams, Best Medicines Coalition of Canada
- Dr. Marco Greco, European Patients Forum

Public Comment/Questions *(15 mins)*

10:45 a.m. **Break**

11:00 a.m. **Session III: Components of Study Design** **75 minutes**

Chairs:
- *Dr. Andreas Kirisits, EWG Representative – EC, Europe*
- *Dr. Sigrid Balser, EWG Representative – IGBA*

Presentation:
Overview presentation *(10 minutes)- Dr. Sigrid Balser, EWG Representative – IGBA*

Panelist Perspective -
- Ms. Shachi Vyas, Sr. Clinical Trial Manager, JDRF
- Dr. Michele Jonsson-Funk, Director, Center for Pharmacoepidemiology, UNC
- Ms. Tracy Temple, Associate Director, Clinical Trials, CVC/University of Alberta
- Dr. Rosa Giuliani, European Society for Medical Oncology
- Dr. Leonard Lichtenfeld, Deputy Chief Medical Officer, American Cancer Society

Public Comment/Questions *(15 mins)*

12:15 p.m. **Lunch** **60 minutes**

1:15 p.m. **Session IV: Quality by Design/ Critical to Quality Factors** **75 minutes**

Chairs:
- *Dr. Kerstin Koenig, EWG Representative – EFPIA*
- *Dr. Mutsuhiro Ikuma, EWG Representative – MHLW/PMDA, Japan*

Presentation:
Overview presentation *(10 minutes)- Dr. Fergus Sweeney, E8 EWG Regulatory Chair - EC, Europe*

Panelist Perspective -
- Dr. Christine Kubiak, European Clinical Research Infrastructure Network
- Mr. Francois Houyez, European Organisation for Rare Diseases (Eurordis)
- Ms. Janette Panhuis, Chief Operating Officer, Population Health Research Institute
- Dr. Janet Wittes, Statistics Collaborative Inc.
- Dr. Victoria Manax, Pancreatic Cancer Action Network

Public Comment/Questions *(15 mins)*

2:30 p.m. **Break**

2:45 p.m. **Session V: Data sources** **75 minutes**

Chairs:
- *Dr. Byron Jones, EWG Representative – EFPIA*

- *Dr. Osamu Komiyama, EWG Representative – JPMA*

Presentation: *Overview (10 minutes)- Dr. Byron Jones, EWG Representative – EFPIA*

Panelist Perspective –
- Mr. Prasanna Shirol, Parent and Co founder, Organisation for Rare Diseases, India
- Ms. Abby Bronson, Parent Project Muscular Dystrophy
- Dr. Frank Rockhold, Professor of Biostatistics and Bioinformatics, Duke Clinical Research Institute
- Dr. PJ Devereaux, Director of the Division of Perioperative Care, McMaster University
- Prof. Steven Le Gouill, European Hematology Association

Public Comment/Questions *(15 mins)*

4:00 p.m. **Open Comment**

4:45 p.m. **Closing Remarks**

5:00 p.m. **Adjournment**