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


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

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