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## US FDA and Health Canada Regional Public Consultation on ICH

April 29, 2019, 10am to 1pm  
10903 New Hampshire Ave.,  
Bldg. 31 Rm. 1503 (Great Room),  
Silver Spring, MD 20993-0002, U.S.A.

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10:00 - 10:05 AM

### **Welcome**

*William Lewallen, Project Specialist  
Office of the Center Director, Center for Drug Evaluation and Research (CDER),  
US Food and Drug Administration (FDA)*

10:05 - 10:20 AM

### **Overview of ICH**

*Joan Blair, Senior Advisor for International Affairs  
Center for Biologic Evaluation and Research, FDA*

10:20 - 11:40 AM

### **Topics Recently Reaching Step 3 of the ICH Process**

*E8(R1) Revision on General Considerations for Clinical Trials  
Lisa LaVange, PhD, Professor and Associate Chair  
Department of Biostatistics, University of North Carolina*

*E19 Optimization of Safety Data Collection  
Mary Thanh Hai, MD, Director  
Office of Drug Evaluation II, Office of New Drugs, CDER, FDA*

*S11 Nonclinical Safety Testing in Support of Development of Paediatric Medicines  
Karen Davis Bruno, PhD  
Office of New Drugs, CDER, FDA*

*M10 Bioanalytical Method Validation  
Brian Booth, PhD, Deputy Director  
Division of Clinical Pharmacology V, Office of Translational Sciences, CDER, FDA*

11:40 - 12:10 PM

### **Update on Electronic Standards Topics and MedDRA**

*Mary Ann Slack, MS, Director  
Office of Strategic Programs, CDER, FDA*

- E2B(R3) Revision of the Electronic Submission of Individual Case Safety Reports
- M8 Electronic Common Technical Document (eCTD)
- M2 Electronic Standards for the Transfer of Regulatory Information (ESTRI)
- M1 MedDRA Points to Consider

12:10 - 12:40 PM

**Overview of Ongoing Topics**

*Amanda Roache, MPP, Operations Research Analyst  
Office of the Center Director, CDER, FDA*

- E9(R1) Addendum to Defining the Appropriate Estimand for a Clinical Trial/Sensitivity Analyses
- E11A Pediatric Extrapolation
- E14/S7B The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
- E17 Multi-Regional Clinical Trials
- M9 Biopharmaceutics Classification System-based Biowaivers
- M7(R2): Addendum to Assessment and Control of DNA Reactive (Mutagenic) Impurities In Pharmaceuticals To Limit Potential Carcinogenic Risk
- M11 Clinical electronic Structured Harmonized Protocol (CeSHarP)
- S1(R1) Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals Guideline
- S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals
- Q3C(R8) Maintenance of the Guideline for Residual Solvents
- Q3D(R1)/(R2) Maintenance of the Guideline for Elemental Impurities
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management
- Q13 Continuous Manufacturing
- Q2(R2)/Q14 Analytical Procedure Development and Revision of Q2(R1) Analytical Validation

12:40 PM - 12:55 PM

**Public Comment Period**

12:55 PM - 1:00 PM

**Closing Remarks**