

---

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

April 6, 2018, 10am to 1pm  
10903 New Hampshire Ave.  
Building 32 Rm 1503 (Great Room)  
Silver Spring, MD 20993

---

- 10:00 - 10:05 AM     **Welcome**  
*Amanda Roache, MPP, Operations Research Analyst, FDA, Center for Drug Evaluation and Research (CDER), Office of Strategic Programs*
- 10:05 - 10:20 AM     **Overview of the ICH**  
*Theresa Mullin, PhD, Associate Director for Strategic Initiatives, FDA, CDER*
- 10:20 - 10:40 AM     **Update on Electronic Standards Topics and MedDRA**  
*Mary Ann Slack, MS, Director (Acting), Office of Strategic Programs*
- E2B Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
  - M8 Electronic Common Technical Document (eCTD)
  - M2 Electronic Standards for the Transfer of Regulatory Information
  - MedDRA and MedDRA Points to Consider
- 10:40 – 11:40 AM     **Topics Recently Reaching Step 3 of ICH Process**
- Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management  
*Ashley Boam, MSBE, Director, FDA, CDER, Office of Pharmaceutical Quality, Office of Policy for Pharmaceutical Quality*
- E9 (R1) Addendum: Statistical Principles for Clinical Trials  
*Thomas Permutt, PhD, Associate Director for Statistical Science and Policy, FDA, CDER, Office of Translational Sciences, Office of Biostatistics*
- S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals  
*Ronald Wange, PhD, Associate Director, FDA, CDER, Office of New Drugs, Pharmacology/Toxicology Staff*

11:40 – 12:20 AM **Selected Topics Recently Reaching Step 4**

E17 General Principles on planning/designing Multi-Regional Clinical Trials  
*Douglas Pratt, MD, MPH, Branch Chief, FDA, Center for Biologic Evaluation and Research, Office of Vaccines Research & Review, Division of Vaccines and Related Product Applications*  
*Aloka Chakravarty, PhD, Director (Acting), FDA, CDER, Office of Translational Sciences, Office of Biostatistics*

E11(R1) Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population  
*Lynne Yao, MD, Director, FDA, CDER, OND, Division of Pediatric and Maternal Health*

12:20 – 12:40 PM **Overview of Ongoing Topics**

*Amanda Roache, MPP, Operations Research Analyst, FDA, CDER, Office of Strategic Programs*

- E19 Optimization of Safety Data Collection
- E8(R1) Revision on General Considerations for Clinical Trials
- E11A Pediatric Extrapolation
- E14/S7B Discussion Group on Clinical and non-Clinical Evaluation of QT/QTc Interval Prolongation
- M9 Biopharmaceutics Classification System-based Biowaivers
- M10 Bioanalytical Method Validation
- S1(R1) Revision on Rodent Carcinogenicity Studies for Human Pharmaceuticals
- S5(R3) Revision on Detection of Toxicity to Reproduction for Human Pharmaceuticals
- S9 Q&A on Nonclinical Evaluation for Anticancer Pharmaceuticals
- S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines
- Q3C(R7) Impurities: Guideline for Residual Solvents
- Q3D(R1) Guideline on Elemental Impurities

12:40 PM – 12:55 PM **Public Comment Period**

12:55 PM – 1:00 PM **Closing Remarks**