Small Business and Industry Assistance

# A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Workshop

**FEBRUARY 13 – 15, 2024**
In-Person and Webcast

Version 3 – Updated October 16, 2023

For files and resources, please visit
**The Event Page on SBIAevents.com**
*Add Event to Your Calendar*

# AGENDA

All times are Eastern (UTC-5)

*View Start Time on World Clock*

## DAY ONE: Tuesday, February 13, 2024

8:30 – 8:40

### Welcome

**Brenda Stodart, PharmD, MS, BCGP, RAC**
*Captain* | United States Public Health Service (USPHS)
*Director* | Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:40 – 8:55

### Opening Remarks & Keynote Address

### Your SBIA Host for Day One

**Forest "Ray" Ford, PharmD, BCPS**
*CAPT* | USPHS
*Pharmacist* | DDI | OCOMM | CDER

9:00 – 9:55

### Session 1 – Good Clinical Practice (GCP) Harmonization: Updates to ICH E6(R3)

- Discuss the basis for updates, status, and timeline
- Provide an overview of draft GCP principles and Annex 1 guideline, including a highlight of areas that have been updated/changed from ICH E6 (R2)
- Discuss plans for Annex 2

**10:00 – 10:20: BREAK**

# DAY ONE: Tuesday, February 13, 2024

10:20 – 11:00

## Session 2- Technology in Clinical Trials – Digital Health Technology (DHT)

Discuss important considerations for sponsor for the appropriate management, traceability and security for data derived from DHTs and other computerized systems used to manage the study data, including, but not limited to, considerations for the following:

- Audit trails and metadata maintenance, review, and retention
- Data corrections
- Data transfer, exchange, and migration
- User training and other technical support provided during the trial

11:00 – 12:00

## Session 3 – Trials Incorporating Decentralized Elements or Pragmatic Features

- Discuss decentralized elements and pragmatic features
- Discuss modernization efforts underway in support of innovative trial designs
- Highlight special considerations for use of technology in trials using decentralized elements and pragmatic features

**12:00 – 1:00 PM: LUNCH BREAK**

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# DAY ONE: Tuesday, February 13, 2024

1:05 – 2:05

## Session 4 – Good Data Governance Practice Updates

- Discuss the importance of good data governance practices in the conduct of a clinical trial
- Provide updates to ICH E6R3 related to data governance, including updates to sponsor and investigator responsibilities
- Discuss the risk proportionate management of computerized systems and data governance processes.

2:10 – 3:10

## Panel Discussion (Q&A)

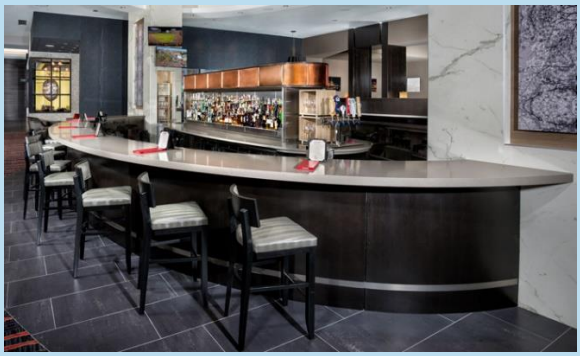
3:15 – 3:35

## Wrap-Up & Closing Remarks

**3:35: ADJOURN DAY ONE**

**4:00 – 5:00 PM: NETWORKING OPPORTUNITY**

Onsite attendees are invited to gather at THE HOTEL's Lobby Bar to continue the conversation with fellow attendees.



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# DAY TWO: Wednesday, February 14, 2024

8:30 – 8:40

## Day Two Welcome

**Forest "Ray" Ford, PharmD, BCPS**
*Captain* | United States Public Health Service (USPHS)
*Pharmacist* | Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:40 – 8:55

## Opening Remarks & Keynote Address

9:00 – 10:00

## Session 1- Sponsor Oversight in Clinical Trials

- Discuss sponsor role and oversight responsibilities in global clinical trials, including those trials incorporating novel designs, operational approaches, and data sources
- Highlight the expanding use of 3rd parties and service providers performing clinical trial-related activities
- Discuss risk proportionate sponsor oversight measures that focus on what is important to ensure reliable trial results, trial participant's safety, and appropriate decision making

**10:00 – 10:20: BREAK**

10:25 – 11:25

## Session 2 – Clinical Trials Post-Pandemic – Positive Disruption to Established Ways of Working?

- Discuss changes in the conduct of clinical trials and inspection activities post-pandemic
- Discuss the adoption of regulatory flexibilities into routine practice
- Insights from inspections on new approaches to clinical trial conduct

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## DAY TWO: Wednesday, February 14, 2024

11:25 – 12:15

**Session 3 - The Future of GCP Inspections**

- Discuss experiences and lessons learned during the pandemic regarding inspections supporting marketing application review
- Discuss the development of the remote regulatory assessments (RRA)/remote inspections (RI) tool
- Discuss current and future use of RRAs/RIs

**12:15 – 1:15: LUNCH BREAK**

1:15 – 2:00

**Session 4- Agency Updates: Policies, Guidance's, and Initiatives**

2:00 – 2:30

**Session 5 – Collaboration Between Agencies and Future Expectations**

2:35 – 3:35

**Panel Discussion (Q&A)**

3:40 – 3:50

**Wrap-up and Closing Remarks**

**3:50: ADJOURN DAY TWO**

**4:30 – 5:30 PM: NETWORKING OPPORTUNITY**

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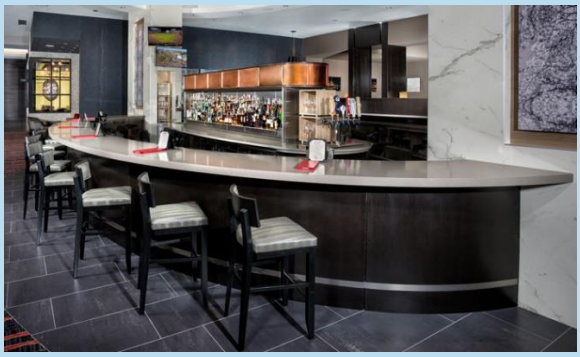

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## DAY THREE: Thursday, February 15, 2024

8:30 – 8:45

### Day Three Welcome

**Forest "Ray" Ford, PharmD, BCPS**
*Captain* | United States Public Health Service (USPHS)
*Pharmacist* | Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) Office of Communications (OCOMM)
Center for Drug Evaluation and Research (CDER)

8:45 – 9:00

### Opening Remarks & Keynote Address

## Morning Sessions: Bioequivalence (BE)

9:00 – 9:30

### Session 1 (BE) - Remote Evaluations

Remote Regulatory Assessments (RRAs) – A valuable tool for OSIS to support drug application review in FDA

9:30 – 10:10

### Session 2 (BE) - Bioanalytical Issues

Bioanalytical Issues from Recent FDA BIMO Inspections and Remote Regulatory Assessments

**10:10 – 10:30: BREAK**

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## DAY THREE: Thursday, February 15, 2024

10:30 – 10:50

**Session 2 (BE)- Bioanalytical Issues** (continued)

- Bioanalytical Issues from Recent FDA BIMO Inspections and Remote Regulatory Assessments

10:50 – 11:05

**Panel Discussion (Q&A)**

11:05 – 11:45

**Session 3 (BE) - Clinical Study Conduct**

FDA perspectives on Clinical Trial conduct

11:45 – 12:00

**Panel Discussion (Q&A)**

**12:00 – 1:00: LUNCH BREAK**

## Afternoon Sessions: Pharmacovigilance (PV) Compliance

1:00 – 1:15

**Pharmacovigilance Compliance Keynote**

1:15 – 2:00

**Session 4 (PV) - International Collaboration**

- How regulatory agencies collaborate to gain an understanding of pharmacovigilance inspections and share information in a global landscape
- Collaboration with international partners
- Health Canada's Joint Inspection Experience

2:00 – 3:00

**Session 5 (PV) - Future of Inspections**

- FDA's Remote Assessments
- FDA's Office of Regulatory Affairs (ORA) Perspective
- Emerging technologies and related advances in pharmacovigilance

**3:00 – 3:15: BREAK**

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## DAY THREE: Thursday, February 15, 2024

3:15 – 4:00

**Session 6 (PV) - Regulatory Updates**

- FDA Office of Combination Products Part 4 Requirements
- FDA Adverse Event Reporting System (FAERS) Updates
- MHRA Regulatory Updates

4:00 – 4:30

**Panel Discussion (Q&A)**

4:30 – 4:45

**Wrap-up and Closing Remarks**

**4:50: ADJOURN WORKSHOP**

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