

# Good Clinical Practice Day 2

**James Pound**

Deputy Director, Standards & Compliance  
Healthcare Quality and Access  
MHRA

A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Workshop  
February 13, 2024



Medicines & Healthcare products  
Regulatory Agency



Health  
Canada

Santé  
Canada



# Welcome to Day 2

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

**James Pound, BSc, CChem**

Deputy Director | Standards & Compliance  
MHRA

9:00 – 10:00

## Session 1- Sponsor Oversight in Clinical Trials

Moderator: **Adil Nashed, BVSc, DHMS** | Compliance Specialist  
ROEB | HC

- 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

**Adil Nashed, BVSc., DHMS**  
Compliance Specialist | ROEB | HC

**Barbara Wright, BA**

Foreign Cadre Director | Foreign SIMO Cadre  
FDA | ORA

**Jason Wakelin-Smith, BSc**

Expert GCP Inspector and  
Head of the Compliance Expert Circle | MHRA

10:00 – 10:20: BREAK

10:25 – 11:25

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

Moderator: **Iram Hassan, PhD** | LCDR | USPHS | OSI | GCOB |  
FDA

- 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

**Jason Wakelin-Smith, BSc**

Expert GCP Inspector and  
Head of the Compliance Expert Circle | MHRA

**Jennifer Evans, BSc**

Compliance Specialist | ROEB | HC

**Richard Berning**

Foreign SIMO Cadre | ORA | FDA

# Day 2

## Oversight



# Day 2

## Post pandemic



# Day 2

## Collaboration





# Overview

## Today's Agenda:

- Sponsor Oversight
  - Clinical Trials Post Pandemic
  - The Future of GCP Inspections
  - Regulatory Updates and Collaboration
  - Panel Discussion
- 

The slide features decorative geometric patterns on the left and right sides. The left side is a vertical strip composed of various shades of blue and dark blue triangles. The right side features a larger, more complex pattern of orange and light orange triangles, some of which form a staircase-like shape at the bottom right.

**Please enjoy day two of our  
symposium!**

# MHRA Copyright information

© **Crown copyright 2024**

Produced by the Medicines and Healthcare products Regulatory Agency

You may re-use this information (excluding logos) with the permission from the Medicines and Healthcare products Regulatory Agency, under a Delegation of Authority. To view the guideline, visit <https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information> or email: [copyright@mhra.gov.uk](mailto:copyright@mhra.gov.uk).

Where we have identified any third-party copyright material you will need to obtain permission from the copyright holders concerned.

The names, images and logos identifying the Medicines and Healthcare products Regulatory Agency are proprietary marks. All the Agency's logos are registered Trademarks and cannot be used without the Agency's explicit permission.