Session 5: Collaboration Between Agencies and Future Expectations

Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Symposium
February 14, 2024 – 2:10 – 2:40 PM

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Collaboration Between Our Agencies and Future Expectations

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U.S. FOOD & DRUG ADMINISTRATION

Medicines & Healthcare products Regulatory Agency

Health Canada Santé Canada

Overview

- Globalization of Clinical Trials and its challenges
- History of the FDA, MHRA & HC collaboration
- Benefits of the collaboration
- FDA, MHRA, & HC GCP collaboration process
- Future direction of our collaboration
- Update on current thinking and strategy
- Themes / workstreams
- Summary

FDA-MHRA-HC Collaboration
The Past

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Disclaimer

The views expressed in this presentation are those of the speaker and not necessarily those of the Food and Drug Administration.

Sharing of Non-Public Information (NPI)

- **21CFR 20.89**
  Describes conditions under which FDA may share some NPI with foreign counterparts
- Each agency has a current Memorandum of Understanding (MOU), Confidentiality Commitment (CC), or Cooperative Arrangement (CA), which allows us to share NPI.

Clinical Trials around the Globe

- Clinical trial is a global undertaking

- Most approved marketing applications for drugs and biologics contain foreign data

Global Coverage of FDA GCP Inspections

Conducted by FDA/CDER in 2023

Global Coverage of FDA GCP Inspections

Conducted by FDA/CDER in 2022

Challenges in GCP Inspections

- Increasing globalization of clinical trials
  - increase in numbers of non-U.S. based clinical investigators conducting research
- Finite inspection resources
  - Breadth of international inspections coupled with finite inspection resources result in inspection of a limited number of sites

Strategies to Address Issues Posed by Globalization & Finite Resources

FDA/MHRA/HC use diverse approaches to address GCP related challenges :

- Increase collaboration with foreign regulators and other stakeholders
- Develop internationally-harmonized standards & Guidance
- Educate foreign stakeholders about GCP compliance requirements

If regulators work collaboratively, implement information exchanges, then GCP inspection resources can be used more efficiently

History of FDA & MHRA GCP Collaboration

- OSI and MHRA began meeting regularly in 2016
- The key objectives of the collaboration include:
  - exchange GCP-related information including inspection outcomes
  - meet quarterly and as needed to discuss common applications
  - share GCP inspection planning information
  - conduct collaborative GCP inspections
  - keep each other informed of GCP-related legislation, regulatory guidance and related documents

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HC-MHRA-FDA Collaboration- The Present

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National Supervisor
Clinical Trial Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada

Welcoming Health Canada to the Collaboration

- Health Canada (HC) joined MHRA in 2018 and later in 2019 joined FDA- MHRA collaboration
  - FDA-MHRA-HC meets bi-monthly
- HC contributes and provides valuable input
  - Sharing information on inspection
  - Managing common risk files
  - Joint inspection and training

Benefits of Collaboration

- Gain a better understanding of each other's inspection procedures with the objective to harmonize and align processes (have common and predictable expectation from stakeholders)
  - Create greater consistency in regulatory approaches and reduces burden on stakeholders
- Discussing common risk issues and align regulatory actions
  - Clinal trials is a global activity so should be the associated compliance and enforcement
- Optimize inspection coverage to maximize the inspection outcome (avoid duplication and share inspection reports)
- Provide more efficient use of resources and expanded knowledge base

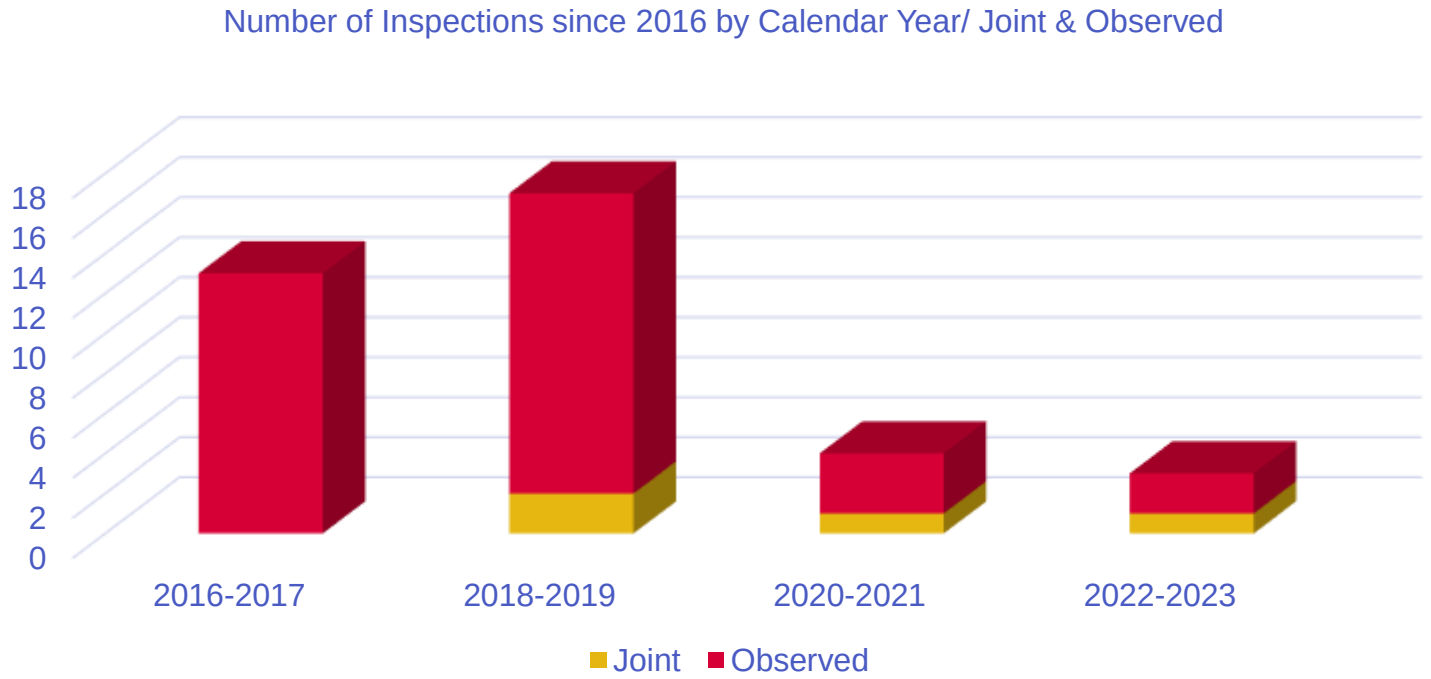
Collaborative Inspections

Observational	Joint
One regulator inspects while the other observes the inspection & highlight similarities & differences	Joint team shares in planning and conducting the inspection
• A confidence building training opportunity • About sharing practices	• Follow their own policies & procedures • Enter their own report into their own review system • Share mutual findings in order to be consistent in the outcome as much as possible

FDA-MHRA-HC Collaboration Process

- Foreign regulators may receive courtesy notifications of our plans to conduct inspections within their territory approximately 30 days prior to the inspection, in accordance with any signed confidentiality commitment/agreement/arrangement between our governments.
- We share inspection planning information and relevant compliance issues
- Educational learning
- Joint Workshops (2018, 2020, 2022, and current 2024)
- Harmonization

What Have We Been Up to Lately?



MHRA-FDA-HC Collaboration- The Future

Mandy Budwal-Jagait
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Collaboration Strategy

- Agree our strategic direction
- Strategy meetings held annually
- Review of current ways of working and new initiatives / workstreams

Future Direction

- Meeting frequency
- Information sharing
- Inspection plans
- Inspector training
- Stakeholder engagement and guidance
- Exploring patient and participant engagement activities
- Exploring use of technology on inspection

Information Sharing

INSPECTION PLANS

INSPECTION OPPORTUNITIES

INTELLIGENCE SHARING

CONTENT – APPLICATIONS, INSPECTION FINDINGS, INTELLIGENCE

Inspections

- Explore joint or observed inspection opportunities
- Training of inspectors
- Common applications
- Common compliance issues

Influencing Compliance

STAKEHOLDER ENGAGEMENT OPPORTUNITIES

KEY MESSAGES

COMMON COMPLIANCE ISSUES

AUDIENCE REACH

FORMAT OF MESSAGING

Summary

- Continue to strengthen our collaboration
- Explore opportunities for alignment and learning from each other.
- Influencing compliance though key messaging
- Training opportunities
- Information exchange
- Inspection opportunities and collaboration

Questions?

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