Investigator Inspection Readiness for Health Authority Inspections

CRP Information Session

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Agenda

- Background on FDA Bioresearch Monitoring (BIMO) Inspection Program and European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) Inspection Program
- What is “Inspection Readiness”?
- Communication Plan
- Role of Site Investigator and Sponsor
- Inspection Process Overview
- Tips for Interacting with Inspectors
- Inspection Findings and Response

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Purpose of the FDA BIMO Inspection Program

A comprehensive, agency-wide program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research

BIMO Program Objectives

- Protect the rights, safety, and welfare of human research subjects
- Assure the quality, reliability, and integrity of data collected

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Purpose of Good Clinical Practice (GCP) Inspections – EMA CHMP Authorized Inspections

Collectively allows the EMA to:

- Ensure new medicines are approved based on sound scientific data generated from clinical studies
- Ensure data submitted are reliable and accurate
- Determine whether patients' rights are protected
- Ensure regulatory/GCP requirements are fulfilled

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Inspection Readiness Defined

Inspection Readiness is a state of "readiness". It is on-going effectiveness and suitability monitored through periodic review and monitoring of compliance

- Inspection readiness should be a state of being and not a preparation activity
- Principal Investigators and management need to be active participants in a commitment to a culture of compliance

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Communication Plan in the Event of Inspection Notification *cont.*

Alliance and/or its pharmaceutical partner will:

- Provide additional instructions and guidance in preparation for the inspection
- Provide a single point of contact (SPoC) at Alliance for any issues that may arise during the inspection
  - The Alliance SPoC requests to receive a daily report from the site
- The SPoC will assist in the preparation of a response to the inspection results, as needed

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Site Inspection Focus (FDA)

- Site Management
- PI Oversight
- Data
- Investigational Product Management
- Adverse Events

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Inspection Process- Overview

Overall, the HA inspector will set the visit agenda

- Notification of inspection Form 482 will be received
- Opening Meeting
- Interview of site staff
- Review of study-related documentation and source data
- **Exit meeting**
  - Review inspection findings
  - Clarify and/or address issues or concerns
- **Response to the inspection, as needed**

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Role of the Investigator During the Inspection

- Ensure the availability of staff during the inspection
  - Alert other staff members of inspection, so that they know to avoid lingering in areas hosting the inspection and to watch conversations near areas where inspectors are present
- Ensure the availability of study-related records and provide copies to HA as requested
- Answer questions regarding your role and the conduct of the study
- At the end of each day, request a summary from the HA Inspector regarding any issues identified and requests to be fulfilled. Forward summary to the Alliance SPoC and the appropriate study email at the Alliance
- Respond to any inspection findings, as required

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Role of the Alliance During the Inspection

- Assign a SPoC to the Clinical Site
- Provide a daily status report to pharmaceutical partner(s)
- Provide ongoing support to Clinical Site/Investigator before, during, and after the inspection

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Tips for Interacting with the HA Inspectors

When answering questions posed by the inspector:

- Answer as honestly and openly as you can
- Be concise; Answer only the question asked
- Try to be as clear as possible
- Do not argue with the inspector
- Do not answer hypothetical questions
- Do not answer a question until you have heard and understood the whole question
- Beware of pauses – Do not feel like you need to keep on talking

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Inspection Findings

The criticality of the inspection findings will be determined based on whether the deficiencies:

- Affect the rights, safety or welfare of the subjects
- Impact the integrity of the data
- Indicate systemic problems within the study from the Sponsor
- Indicate problems with the investigator/site that may impact other studies

FDA Form 483 "Inspectional Observations" is used to document and communicate concerns discovered during inspections. If received, please forward immediately to the Alliance SPoC.

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Key Points

- Inspection “readiness” at all times. It isn’t a preparation activity but rather a state of “readiness”
- Alliance and the Pharmaceutical Partner(s) are available to assist in the preparation, participation and close out of the inspection process
- Forward any HA communication to the Alliance *IMMEDIATELY*:
  - Contact Trini Ajazi, CAO, at tajazi@uchicago.edu and copy regulatory@alliancenctn.org; Alliance Chicago main line: 773-702-9171
- Understand and prepare for your role in the inspection
- Review the tips for interacting with the inspectors

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Resources

Visit the suggested links to learn more about inspection programs:

- http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf
- http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm
- https://swog.org/Visitors/Spring15GpMtg/Kreis.pdf
- http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000072.jsp&mid=WC0b01ac05800268ad
- https://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf

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Q & A

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Thank you for your participation!

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