Clinical Investigator Inspections: What to Expect

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Discussion Topics

- Inspection types
- Inspection process
- What happens after the inspection

Inspection Types

- Routine
- For-cause (directed)

Inspection Process

- Form FDA 482 (Notice of Inspection)
- Inspection
- Form FDA 483 (Inspectional Observations)
- Establishment Inspection Report

What happens after the inspection ends?

- Responses to Forms FDA 483
- Establishment Inspection Report (EIR)
- Center review and classification

Inspection Classifications

- No Action Indicated
- Voluntary Action Indicated
- Official Action Indicated

Letter Types

- Untitled
- Warning Letter
- Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)
  - Notice of Opportunity for Hearing (NOOH)

Questions?

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