Are you ready?

Inspections … they may be coming … and they are different than monitoring visits

Jared Baeten

ASPIRE Protocol Chair

Think ahead to 2016

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But then…

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Office of Regulatory Affairs
Office of Regional Operations
Division of Foreign Field Investigations
International Operations Branch
BIMO Program

12420 Parklawn Drive
ELEM 2015
Rockville, MD 20857
Phone: 301-796-8179
Fax: 301-827-9791
Tania.mercado@fda.hhs.gov

May 15, 2016

IPM

Dear IPM:

The purpose of this letter is to announce and request confirmation of the routine bioresearch monitoring (BIMO) Clinical Investigator inspections to be conducted by the US Food and Drug Administration to determine if the following facilities and operations of the clinical investigators and/or sites are in accordance with the Current Good Clinical Practice Regulations.

Why inspections? Why?

An inspection is an 'evidence gathering activity'

- Not always because something was done wrong

- Protect the rights, safety, and welfare of human research subjects
- Assure adherence to regulations & guidelines
- Validate the quality , reliability and integrity of data collected

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What are inspectors interested in seeing?

- Adherence to protocol requirements
- Investigator oversight
- SOP implementation
- Signed and dated ICFs
- Participants case histories
- Sponsor/IRB/regulator correspondence
- Drug accountability
- AE and EAE accountability
- May review any information

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It is how these pieces all tie together that really makes an inspection visit.

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What are inspectors *not* interested in doing?

- Trapping you
- Fighting with you
- Finding unnecessary fault
- Ruining your day…

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So that this is the outcome…

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