ASSESSING NEW INSPECTION TRENDS

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Understanding ICH E6(R3)

ICH E6(R3) Recognizes Records, Rather than Documents

"It didn't make sense to keep the word *documents* because that implies that it can be printed to a PDF or even to paper and filed in a paper file. … The language now suits the modern clinical trial with its increased technology."

Andrew Fisher, Lead Senior GCP Inspector, MHRA

Source: FDA-MHRA-HC 2024 Joint Symposium

TMF Changes Coming with ICH E6(R3)

Expands on how to take a **thoughtful risk-based approach to clinical trials**, including TMF management

New **expectations for essential and potentially essential records**

Explicitly **introduces the role of computerized systems** in clinical trials

Refers to **local laws for rules on document retention**

Source: Veeva Blog

Group Discussion

- Has your company provided input on ICH E6(R3)? Why or why not?
- Do you feel prepared to respond to the changes in ICH E6(R3)? Why or why not?
- What other recent changes in regulations/guidelines are most impactful for your company?

New Inspection Approaches

Increasing Global Regulator Collaboration

- **Regulatory agencies collaborate**, including sharing inspection plans and findings
- **Observational**: One regulator inspects; other regulators observe
- **Joint** team plans and conducts inspection

Source: FDA-MHRA-HC 2024 Joint Symposium

TMF Inspection Trends

Remote/hybrid inspections continuing	Increasing specialization among inspectors	Mock inspections still an important preparation mechanism
Some regulators, including Swiss Medic, prefer over-the-shoulder inspections	Increasing focus on audit trails, data integrity, and traceability	SMEs still must be prepared with a war room and playbook

Group Discussion

Inspection Experiences

- If you've recently experienced an inspection, what learnings can you share?
- Do you prepare differently depending on the inspection type (e.g., hybrid)?
- How do you prepare for new inspection trends, like increasing audit trail focus?
- How does your company approach mock inspections?

Mock Inspection Questions

- How are revisions and updates to ICFs tracked and documented?
- How are adverse events documented and tracked within the eTMF?
- How is drug accountability maintained within the eTMF to ensure accurate records of drug shipments, dispensations, returns, and destructions?
- How are electronic signatures managed within the eTMF?