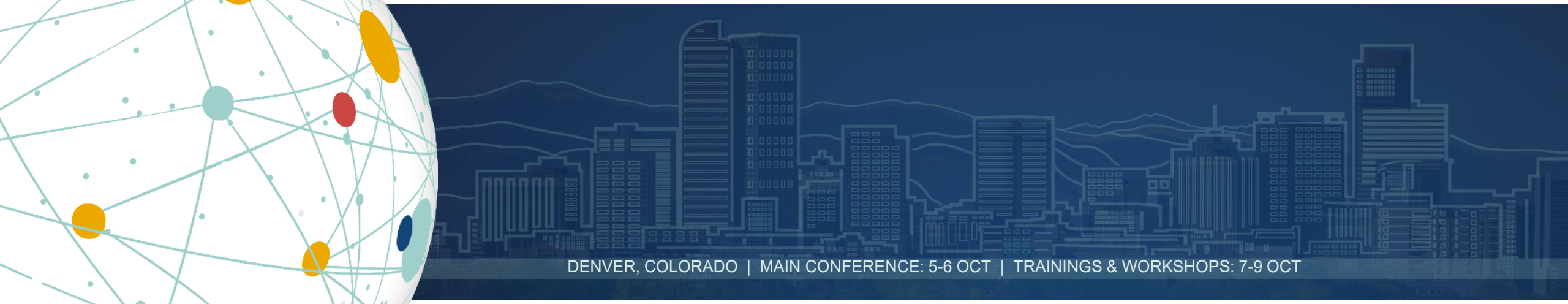
2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION





Panel Discussion: End of Study Quality and Archiving Inspection Findings

Hosted by Chris Sigley, CEO, Arkivum

Speakers

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Disclaimer and Disclosures

The views and opinions expressed in this presentation are those of the panellists and do not necessarily reflect those of the panellists' employers, employer affiliates, or employer management.

Bridging the gap between regulations and inspection findings'

Complying with long-term retention regulations.

1. **Data Integrity MUST be maintained throughout the retention period**, which can be for 25 years or more, for example under EU CTR for essential clinical records. During this time, data MUST remain readable, usable and readily accessible according to the ALCOA+ principles.

2. **Data MUST be inspection ready with immediate and user-friendly access**. Inspectors MUST be able to see (i.e. evidenced) that Data Integrity has been maintained, that no data has been corrupted, lost or altered, and be able to confirm the conduct of the original clinical trial.

3. **Systems used to retain data MUST be demonstrably fit for their intended purpose**. Systems for retention, archiving and preservation MUST have been designed, built, tested and most importantly validated as being fit for the purpose of maintain long-term Data Integrity according to all the ALCOA+ principles.

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Discussion Topic No.1: TMF Retention Requirements - What are we up against?

- FDA:
  - CFR 312.57 – link
  - Original publication – link
- Health Canada
  - Legislation - link
- EU CTR
  - Search for Articles 57 and 58 – link
- MHRA:
  - Current legislation – link
  - March 2023 update – link
- ICH E6 R3
  - Latest draft - link

Region	HA / Regulator	Relevant Regulation(s)/Guideline(s)	Last Updated	What is the retention period?
USA	FDA	CFR 21 Part 312.57	2002 (1987)	"A sponsor shall retain the records and reports required by this part for **2 years** after a marketing application is approved for the drug"
Canada	Health Canada	SOR/2003-196	2022	"The sponsor shall maintain all records referred to in this Part for a period of **15 years**."
EU	EMA	EU CTR (officially EU Reg 536/2014)	2014	Sponsor & investigator retain the TMF for **25 years – readily available for inspection and legible** • W/ exceptions for 30 years • Addtn'l time for market application extensions
UK	MHRA	UK CTR	2026	
Global	ICH	ICH E6 R3	2024	Refer to **local/regional regulators' retention requirements**

Discussion Topic No.2: Challenges of expanding eClinical systems & long-term data integrity

- FINDING 1: A commercial Sponsor's named archivist **did not have oversight of records stored outside of the TMF in other repositories.**

- FINDING 2: A non-commercial Sponsor did not have formal process to ensure;
    - '…that the electronic files, when archived, would not be subject to **software retirement/redundancy** such that they would become **unreadable** during the retention period' and
    - '…relevant **electronic email communication would be retain(ed)** in line with requirements.'

- REALTED ISSUE: Lack of **knowledge regarding data integrity (ALCOA and all +)** over the long-term is causing an increase in regulatory findings:

Sourced from an Arkivum MHRA FOI request

Questions?

Appendix

Resources: Our Gift To The Audience!

Sources

- FDA Warning Letters
  - https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
- MHRA FOI Request
  - https://mhra.disclosurelog.co.uk/disclosures/99b48682-0d79-489e-8716-3a3425129ab5?preserveHistory
- EMA's Annual Report of the Good Clinical Practice (GCP) Inspectors' Working Group (IWG) 2024
  - https://www.ema.europa.eu/en/documents/report/annual-report-good-clinical-practice-inspectors-working-group-2024_en.pdf

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