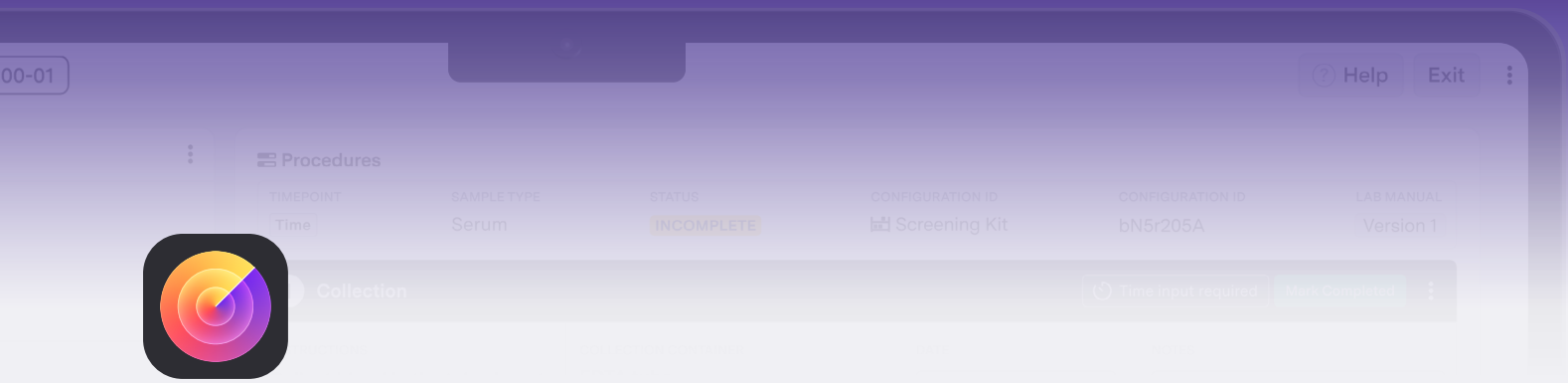

Biospecimen360™: Your Key to ICH E6(R3) Compliance

Are you prepared to navigate new regulatory requirements that impact biospecimen management?

The updated ICH E6(R3) guidelines emphasize **risk-based quality management, robust data governance**, and **enhanced oversight**—placing greater accountability on sponsors and directly affecting the processes that govern samples and their associated data.

For teams managing biospecimens, these changes raise the stakes for data integrity, sample traceability, and regulatory compliance. Slope's Biospecimen360™ (B360™) software and professional services are designed to help you meet these evolving requirements with confidence.

Learn how Slope ensures ICH E6(R3) compliance. Read more >

SLOPE

1 Risk-Based Quality Management

ICH E6(R3) emphasizes a proactive, risk-based approach to ensure quality across clinical trial processes.

Impact to Biospecimens

Biospecimen management is deemed a critical and high-risk activity given the value biospecimens provide, and must be prioritized even higher now in risk-based quality systems. Risks to address include sample mishandling and lapses in chain of custody.

What the ICH E6(R3) Guidelines Say

"The essential records are used as part of the… sponsor oversight (including monitoring) of the trial. These records are used…**during inspections** by regulatory authority(ies) **to assess the trial conduct and the reliability of the trial results.**" C.1.3

"An essential record: (t) Documents the **collection, chain of custody, processing, analysis and retention or destruction** of biological samples;" C.3.1.t

"Quality control should be applied using a risk-based approach **to each stage of the data handling** to ensure that data are reliable and have been processed correctly. Within clinical trials, **monitoring** and **data management processes** are the main quality control activities." 3.11.3

"The sponsor and investigator/institution should maintain a record of where essential records are located, including source records. The storage system(s) used during the trial and for archiving (irrespective of the type of media used) should provide for **appropriate identification, version history, search and retrieval of trial records.**" C.2.4

How Slope Ensures Compliance

Essential Sample-Related Records

B360™ automates, streamlines, and centralizes robust documentation of collection, chain of custody, processing, storage, and retention/ destruction to meet compliance requirements.

Risk-Based Sample Tracking

B360™'s sample compliance dashboard, chain-of-custody tracking, and automated quality controls prevent sample integrity failures before they impact trial outcomes.

Operational Efficiency & Quality Assurance

B360™'s integration of inventory tracking, automated resupply, guided sample collection, and real-time monitoring ensures sites remain in compliance with study requirements — mitigating deviations and reducing costly delays.

Audit-Ready Documentation & Traceability

B360™'s audit trails, sample journey views, and downloadable reports provide full traceability to support regulatory compliance to maintain complete, searchable records for biospecimens.

2 Data Governance & Integrity

ICH E6(R3) mandates that clinical trial data must be complete, accurate, and protected across the entire lifecycle.

Impact to Biospecimens

Biospecimen management, a critical component of clinical trials, is now explicitly subject to comprehensive data governance principles as they pertain to computerised systems — impacting technology used for sample management, sample trackers, and more. Every stage of sample handling — including collection, storage, transportation, and more — requires adherence to strict data integrity protocols.

What the ICH E6(R3) Guidelines Say:

"**Documented procedures** should be in place to ensure the appropriate use of **computerised systems** in clinical trials for essential activities related to **data collection, handling and management.**" 4.3.1

"Validation: (g) The responsible party should ensure that the computerised systems are validated as **fit for purpose** for use in the trial, including those developed by other parties. They should ensure that **validation documentation is maintained and retained**." 4.3.4,g

"The trial data and relevant metadata should be archived in a way that allows for their **retrieval and readability** and should be **protected from unauthorised access and alterations** throughout the retention period." 4.2.7

"The following key processes should address the **full data life cycle** with a focus on the criticality of the data and should be implemented proportionately and **documented appropriately**: Processes to support key decision making, such as data finalisation prior to analysis…changes in clinical trial design…" 4,d

How Slope Ensures Compliance

Eliminating Data Gaps and Inconsistencies

B360™ standardizes sample metadata capture and streamlines data reconciliation through integrations with labs and EDC to prevent missing, inaccurate, or inconsistent sample metadata — ensuring compliance with ICH's heightened data governance standards around accuracy.

End-to-End Traceability

B360™ provides an end-to-end audit trail, capturing every biospecimen touchpoint from collection to final lab destination, ensuring complete traceability and transparency for regulatory compliance.

Streamlined Compliance with Validation Standards

B360™ supports sponsor validation with a rigorous UAT process and a robust validation package, eliminating the risk of non-compliance that comes with unvalidated spreadsheets or manual tracking methods.

Continued: How Slope Ensures Compliance through Data Governance & Integrity

Secure Sample Metadata Governance

B360™ ensures that data is protected with robust user access controls and permissions management, meeting ICH's requirement for safeguarding against unauthorized access and alterations.

Sample Metadata Retention and Retrieval Compliance

B360™ guarantees that all biospecimen-related metadata remain intact, readable, and retrievable throughout the required retention period, eliminating risks associated with data loss or degradation.

Replacing Risk-Prone, Outdated Processes

The new ICH guidelines reinforce that spreadsheets and non-validated tracking methods are no longer sufficient unless they are compliant with rigorous data governance standards. B360™ provides a purpose-built, regulatory-compliant solution that meets modern study demands.

3 Enhanced Sponsor Oversight

Sponsors now hold explicit responsibility for ensuring stakeholder compliance and oversight throughout the clinical trial. This includes ensuring every vendor and system used in the trial is validated, evaluated as fit for purpose via formal user acceptance testing, etc.

Impact to Biospecimens

The updated guidance reinforces accountability in biospecimen management by clearly defining and documenting oversight responsibilities across multiple roles — explicitly putting the onus for all biospecimen-related conduct on sponsors. This requires enhanced operational practices, including improved training, advanced monitoring tools, and greater stakeholder collaboration to ensure ethical compliance and scientific rigor.

What the ICH E6(R3) Guidelines Say

"The **sponsor** should ensure that data acquisition tools are **fit for purpose** and designed to capture the information required by the protocol. They should be **validated** and ready for use prior to their required use in the trial. The sponsor should ensure that **documented processes** are implemented to ensure the **data integrity** for the **full data life cycle** (see section 4.2)." `3.16.1, d & e`

"The **sponsor** should implement an appropriate system to **manage quality** throughout **all stages** of the trial process. Quality management includes the design and implementation of efficient clinical trial protocols, including tools and procedures for trial conduct (including for **data collection and management**), in order to ensure the protection of participants' rights, safety and well-being and the reliability of trial results." `3.10`

How Slope Ensures Compliance

Supporting Sponsor Accountability for Biospecimen Oversight

B360™ provides the necessary infrastructure to ensure biospecimen-related processes meet regulatory and scientific standards by providing real-time monitoring tools, traceability, and compliance-driven workflows.

Formal User Acceptance Testing Process to Ensure Fit-for-Purpose

Slope supports formal UAT for sponsors to help them ensure B360™ is purpose-built for biospecimen lifecycle management, offering a validated system that meets regulatory expectations for data integrity and traceability.

Full Visibility into Sample Metadata

Sponsors must implement systems that ensure quality across all stages of trial execution, including data collection and management. B360™'s data insights dashboard, real-time sample tracking, and audit trails empower sponsors with the visibility they need to fulfill their oversight duties.

Enhanced Documentation and Training Essential for Compliance

The new oversight framework demands robust documentation of roles and responsibilities. B360™ supports this requirement by providing onboarding, consulting, and training resources to ensure compliance with regulatory expectations.

Lab Vendor Oversight

Sponsors must ensure proper selection, oversight, and alignment of vendors managing biospecimens. Slope's lab vendor oversight services and vendor-agnostic data-sharing capabilities help sponsors maintain quality standards across all stakeholders.

Reduced Trial Integrity Risk

Without clear oversight and fit-for-purpose tools, sponsors risk regulatory noncompliance, protocol deviations, and compromised trial data. B360™ mitigates these risks by ensuring biospecimen workflows are compliant, validated, and transparent from collection to analysis.