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The Precision Medicine Intelligence Company

What's your ICH E6(R3) Readiness Score?

The new ICH E6(R3) GCP guideline, impacting clinical studies starting 23 July 2025, introduces significantly more detailed requirements around the integrity and governance of data assets and trial records, including biospecimens, their derivatives, and all associated clinical and assay data generated during trials.

To help you meet these new requirements, we've developed a compliance checklist.

Using QuartzBio's Precision Medicine AI Agent Platform, with our solutions for Sample Intelligence and Biomarker Intelligence, can help you implement these checklist items and ensure compliance by July.

Document procedures for handling trial records, including biospecimens.

Required documentation should detail procedures for:

- Chain of Custody; collection, processing, shipment, and storage conditions
- Recording retained samples
- Recording and reporting noncompliance
- Data finalization, including query resolution, reconciliation, quality control, and generation of output datasets

Establish Essential Records Table

Prior to study start, have in place a list of essential trial records, including documented procedures for biospecimen chain of custody.

Implement data lifecycle procedures

Establish procedures covering the full data lifecycle, including data capture, validation, review, and correction.

Ensure metadata management

Evaluate and manage relevant metadata, ensuring systems maintain logs of user actions and data changes.

Maintain audit trails

Ensure audit trails are enabled, interpretable, and support review without being modified.

Automate data validation checks

Implement automated data validation checks at the point of data capture based on risk.

Maintain review of data and metadata

Plan and conduct risk-based reviews of trial-specific data, audit trails, and metadata.

Correct data errors

Establish processes for timely correction of data errors, ensuring corrections are documented and justified.

Secure data transfers

Validate processes for data transfer, exchange, and migration to maintain data integrity and confidentiality.

Archive data and metadata

Plan and conduct risk-based reviews of trial-specific data, audit trails, and metadata.

Manage system security

Implement and maintain security controls for digital systems, including user authentication and data backup.

Validate systems

Validate digital systems based on risk assessment, ensuring they meet requirements for completeness, accuracy, and reliability.

Provide training

Ensure users of digital systems are appropriately trained in their use.

Establish contingency procedures

Develop contingency procedures to prevent data loss or inaccessibility due to system failures.

Document user management

Maintain records of authorized users, access permissions, and any updates to user roles and permissions.

Define roles and responsibilities

Document roles, responsibilities, and procedures for access to unblinded information.

What's your Score?

Rate your readiness:

0-5

Still using spreadsheets and emails? It's not too late – QuartzBio's technology can make digital transformation easy, accurate and fast.

6-11

You most likely have an ecosystem of point solutions to manage your data assets, but it can be a headache to ensure all these solutions are compliant.

Let's connect your point solutions across the precision medicine value chain for a scalable, platform approach to compliance.

What's your Score?

Rate your readiness:

12-16

Congratulations, you have a strong foundation of data integrity and governance! You're ready to optimize risk-based management, leveraging insights across clinical programs, including from closed studies.

Learn how QuartzBio's platform accelerates your data-to-insights lifecycle by 2X or more.

Get in touch for personalized recommendations and a demo of our Precision Medicine AI Agent Platform:

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