White Paper

Beyond Compliance:
How Sponsors Can Drive Success with Central eSource at Investigator Sites

INTRODUCTION

Running efficient, high-quality clinical trials is paramount in drug development. Too often, sponsors and CROs face opposition when evaluating tools that defy the status quo, thinking that regulatory guidance does not support novel and innovative methods in clinical research.

Luckily, your experts from CRIO have scrutinized relevant regulations and guidelines to debunk just that.

We've analyzed ICH E6(R3), ICH E8(R1), and 21 CFR 312 to provide the reader with a clear understanding on how these regulations align with the central electronic source (eSource) approach. Central eSource is the concept of providing clinical research sites with centrally developed protocol driven eSource forms to ensure consistent and compliant data collection that also enables centralized monitoring and better sponsor oversight, while at the same time reducing site burden.

A key takeaway from these guidelines is the emphasis on building quality into both the scientific and operational design of trials. This is precisely where deploying a central eSource data collection tool to clinical investigator sites becomes not just acceptable, but a highly beneficial strategy for sponsors.

Ensuring Reliable Results with Fit-for-Purpose Systems

ICH E6(R3) principle 9 stresses the importance of generating reliable results in clinical research. To achieve this, the guideline highlights that systems and processes for data capture and management must be fit for purpose, capture data required by the protocol, and be implemented proportionate to risks and importance of the data in question.

A central eSource solution directly addresses these points. By developing and deploying a standardized source documentation tool, sponsors ensure that:

- **Data capture is consistent:** The system is designed to collect precisely the data needed according to the protocol, reducing variability and improving data quality across all sites.
- **System design is optimized for quality:** Sponsors can build in features that promote data integrity, traceability, and protect personal information from the ground up, as mandated by ICH E6(R3) 9.3 and 9.4.
- **Essential records are secure and accessible:** Centralized systems facilitate secure retention of essential records, making them readily available for regulatory authorities, monitors, auditors, and IRBs/IECs, as required by ICH E6(R3) 9.5.

Empowering Investigators and Fulfilling Responsibilities

Investigators have clear responsibilities to comply with the protocol, GCP, and applicable regulatory requirements (21 CFR 312.62, ICH E6(R3) 2.5.2). What better way to ensure this compliance than by providing them with a source documentation tool developed by the same experts who crafted the protocol?

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Furthermore, ICH E6(R3) 2.12.4 states that ***"The investigator should ensure that data acquisition tools and other systems deployed by the sponsor are used as specified in the protocol or trial-related instructions."*** A central eSource solution directly facilitates this, offering a clear, pre-defined method for data entry and management, reducing ambiguity and promoting protocol adherence.

Sponsor Oversight and Quality Management

Sponsors bear significant responsibility for the quality of the trial design, conduct, and generated data (ICH E6(R3) 3.9.1, 3.10).

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ICH E6(R3) 2.12.4

By implementing a central eSource system, sponsors can proactively embed quality throughout all stages of the trial process.

Key considerations are outlined below:

- **Risk mitigation:** Quality management, including efficient tools and procedures for data collection, is crucial for protecting participants and ensuring reliable results (ICH E6(R3) 3.10). A centralized eSource system inherently incorporates risk mitigation activities into its design and implementation (ICH E6(R3) 3.10.1.3).
- **Enhanced monitoring:** Centralized eSource allows for **remote and secure, direct read-only access to source records** (ICH E6(R3) 3.11.4.1 (c)), enabling more efficient and targeted monitoring activities.
- **Data integrity and confidentiality:** Sponsors are responsible for ensuring the integrity and confidentiality of generated and managed data (ICH E6(R3) 3.16.1 (a)). A centralized system offers robust controls and processes to safeguard data throughout its lifecycle (ICH E6(R3) 3.16.1 (e), (v)).
- **Pre-specified data collection:** With a central eSource, sponsors can **pre-specify data to be collected and the method of its collection** directly within the tool, ensuring that data acquisition is fit for purpose and validated before use (ICH E6(R3) 3.16.1 (c), (d)).
- **Investigator access and endorsement:** Despite central deployment, sponsors must ensure investigators have **timely access to collected data** for critical decision-making (ICH E6(R3) 3.16.1 (k)) and seek their endorsement of reported data at milestones (ICH E6(R3) 3.16.1 (o)). A well-designed central eSource system will facilitate these requirements without giving the sponsor direct control of data, preventing undetectable changes (ICH E6(R3) 3.16.1 (l)).

Incorporating Quality by Design (ICH E8(R1))

ICH E8(R1) reinforces the concept of Quality by Design, emphasizing that study designs should be operationally feasible and avoid unnecessary complexity. Centralized eSource solutions embody this principle by:

- **Streamlining data collection:** Protocols and data collection methods should enable efficient study conduct and avoid unnecessary data collection (ICH E8(R1) 3.3). A centralized eSource tool is designed to collect only the data needed to meet study objectives, promoting efficiency.
- **Enhancing data quality attributes:** The use of standards for data recording and coding within a central system directly supports data reliability, consistency, accuracy, and completeness (ICH E8(R1) 5.7).
- **Facilitating protocol adherence:** A well-implemented central eSource system ensures the protocol is operationally feasible and makes adherence throughout the study more likely (ICH E8(R1) 6.1.1).

What Does This Mean For Sponsors And CROs?

In essence, deploying a central eSource data collection tool isn't just about efficiency; it's about embedding quality, compliance, and reliability into the very fabric of clinical trial operations.

Deploying a centralized eSource solution at investigator sites does not remove the investigator of site autonomy—it's a partnership. By providing an eSource tools and a centralized template, which the sites can build upon, sponsors give investigators a turnkey system that aligns with the principles and responsibilities outlined in ICH E6(R3), ICH E8(R1), and 21 CFR 312.

In an era where trial efficiency, participant safety, and data reliability are paramount, central eSource is not just acceptable—it's the embodiment of Good Clinical Practice for the next generation of global trials.

SOURCES

ICH E6(R3) GUIDELINE FOR GOOD CLINICAL PRACTICE - 2025
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

ICH E8(R1) GENERAL CONSIDERATIONS FOR CLINICAL STUDIES - 2021
https://database.ich.org/sites/default/files/E8-R1_Guideline_Step4_2021_1006.pdf

U.S. Code of Federal Regulations § 312.62 Investigator recordkeeping and record retention.
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-D/section-312.62

ABOUT CRIO

CRIO is a leading provider of eSource solutions for clinical research. Our platform streamlines data collection and management, ensuring protocol compliance and reducing errors. By eliminating paper binders and automating workflows, we help clinical sites and sponsors save time and money, improve data quality, and enhance patient safety.