# How the Shared Investigator Platform enables compliance with ICH E6(R3) guidelines

As the clinical research landscape evolves, the release of the ICH E6(R3) guideline for Good Clinical Practice (GCP) marks a pivotal shift toward more participant-centric, risk-based and quality-driven clinical trials. Cognizant® Shared Investigator Platform (SIP), a collaborative digital ecosystem used by sponsors, CROs and clinical trial sites, is uniquely positioned to support and accelerate compliance with these new expectations.

## Understanding ICH E6(R3): A new era of GCP for trial governance

The ICH E6(R3) guideline introduces a modular structure and emphasizes:

- Varied, innovative clinical trial design
- Comprehensive management of essential records and data integrity
- Quality by Design (QbD)
- Risk-based quality management (RBQM)
- Participant safety and ethical oversight
- Collaborative sponsor-site relationships
- Inspection readiness

These principles require both sponsors and clinical trial sites to adopt more proactive, technology-enabled and transparent practices.

## SIP's role in enabling ICH E6 (R3) compliance

### 1. Allowing flexibility in clinical trial design

ICH E6(R3) recognizes the increasing use of decentralized elements in clinical trial designs. The guideline encourages the use of innovative trial designs, documented monitoring plans and technologies.

SIP supports various facets of decentralized and hybrid clinical trials by:

- Allowing trial sites to seamlessly transition into multisite models with satellite study locations, based on participant recruitment strategy
- Providing flexibility to monitors to remotely oversee protocol-specific site profile, delegation logs, and assign and track training related to site staff
- Enabling sponsors to securely share workflow-driven, protocol-specific documents, including safety notifications—with investigators and site staff, who can respond directly within the system using e-signatures, acknowledgements or comments as needed
- Helping sponsors identify potential sites where the patient population closely aligns with the protocol's diversity goal

This allows sponsors to engage more efficiently with research sites through centralized tracking of regulatory documents and training activities. At the same time, sites can recruit a broader, more diverse participant population, enhancing the relevance and scope of trial outcomes.

**2. Ensuring data integrity and maintaining essential records**

ICH E6(R3) mandates that sponsors and investigators have direct access to all "essential records" as opposed to "essential documents." Essential records include digital formats and metadata.

As a centralized data management and exchange system, SIP is well suited to support this guidance by:

- Maintaining audit-ready, time-stamped records
- Enforcing access controls and electronic signatures
- Ensuring version control and traceability of all site documents
- Capturing a broad range of information beyond formal documents, including electronic data and metadata of investigator profiles, study-specific site profiles and protocol details
- Comprehensive tracking of communication logs between sponsors and sites with end-to-end audit features

This ensures all data is accurate, complete and verifiable —critical elements to maintaining regulatory compliance.

**3. Facilitating quality by design**

The first step in applying a quality by design (QbD) approach is defining factors that are critical to quality (CtQ)—essentially critical processes and data that matter most to quality, clinical study outcomes, ensuring reliability of study results and participant protection and safety.

SIP enables early alignment between sponsors and sites on critical-to-quality factors by:

- Providing centralized access to study protocols and training materials
- Supporting structured feedback loops during study start-up
- Enabling version-controlled documentation to ensure protocol adherence

Application of CtQ factors, as part of quality by design, can eliminate nonessential activities and data collection from the study—thereby allowing sponsors to focus on what matters. This ensures that quality is embedded from the outset, aligning with ICH E6(R3)'s QbD philosophy.

**4. Supporting risk-based quality management**

SIP integrates seamlessly with RBQM strategies by:

- Enabling real-time data sharing and remote monitoring
- Allowing sponsors to track site performance metrics
- Facilitating early detection of risks through centralized dashboards

Transparency and real-time monitoring facilitate true oversight by sponsors and investigators throughout the trial and eventually reduce delays and enhance trial efficiency—a core tenet of ICH E6(R3).

**5. Empowering site readiness and training**

SIP enhances site preparedness by:

- Maintaining up-to-date digital CVs for principal investigators and delegated team members, along with individual training records. Automated reminders ensure the latest CVs and training certificates are always available on the platform.
- Enabling investigators to monitor site staff training and related documentation in a validated system by leveraging built-in, out-of-the-box (OOTB) reports of SIP which provide real-time oversight and simplify compliance tracking. With ICH GCP E6(R3) placing greater responsibility on investigators for training oversight, investigators who rely on manual tracking are at increased risk of regulatory findings.
- Providing centralized training modules aligned with ICH E6(R3) principles to ensure consistency and compliance
- Offering role-based access to study-specific SOPs and guidance, ensuring that staff only see what's relevant to their responsibilities

This comprehensive approach ensures that site staff are well prepared to meet evolving regulatory expectations with confidence and efficiency.

**6. Enhancing sponsor-site collaboration**

ICH E6(R3) emphasizes transparency and shared accountability between sponsors and research sites. SIP supports this collaborative approach by:

- Enabling secure messaging and document exchange to ensure sensitive communications are protected and traceable
- Facilitating joint review meetings and milestone tracking to promote alignment and timely decision-making across stakeholders
- Providing a single source of truth for all stakeholders, centralizing all relevant data and documentation for consistent access and oversight

This collaborative model strengthens operational transparency and aligns with the intent of the updated GCP guidelines.

**7. Enabling direct access for inspectors**

ICH E6(R3) requires that inspectors have direct access to all requested trial-related records. To meet this requirement sponsors must ensure their clinical oversight systems are readily accessible for inspections.

- SIP's robust role-based access control (RBAC) framework allows sponsors to grant tailored, time-bound access to external inspectors. This includes audit-ready visibility into key activities such as the distribution of safety notifications to research sites and the corresponding acknowledgements.

This approach supports compliance with inspection-readiness standards while maintaining data security and control.

## Conclusion: SIP as a strategic enabler of ICH E6(R3)

Cognizant Shared Investigator Platform is more than a document repository—it is a strategic enabler of modern clinical trial conduct. By aligning with the core principles of ICH E6(R3), SIP empowers sites and sponsors to:

- Enhance participant safety
- Improve data quality
- Streamline operations
- Ensure regulatory compliance

As the industry embraces ICH E6(R3), platforms like SIP will be essential in driving readiness, resilience and research excellence.

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