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Investigator Council presents: INSIGHTS NEWSLETTER

This Edition Contains

- ICH GCP E6(R3): What's New for Investigators & Required Actions
- Investigator Column- Walk the Talk with Dr. Rajiv Mehta, Senior Gastroenterologist & Clinical Research Specialist, SIDS Hospital & Research Centre, Surat

Preface

Welcome to our April 2026 edition of the Investigator Council Newsletter.

ICH- GCP E6 (R3): WHAT'S NEW FOR INVESTIGATORS AND REQUIRED ACTIONS

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ICH GCP E6(R3): What's New for Investigators & Required Actions

Key Takeaways for Investigators

- Think "critical to quality," not "more paperwork"
- Be able to explain why your site's approach protects participants and data
- Oversight is active and continuous—even in decentralized or digital trials
- Your accountability remains, even when work is delegated

Key Aspects	What's New in E6(R3)	What Investigators Need to Do (Actions Required)
Principles-based GCP	Shift from prescriptive requirements to **explicit GCP principles.** Emphasis on critical thinking rather than checklist compliance.	• Understand and apply GCP **principles,** not just • Be prepared to justify decisions based on participant safety and data reliability, not just SOP adherence
Quality by Design (QbD)	QbD is now a **core concept,** requiring proactive identification of **Critical-to-Quality (CtQ) factors** that affect participant safety and data reliability	• Actively participate in identifying CtQ factors at site level • Focus effort on activities critical to safety and primary endpoints • Document rationale for prioritization of key processes
Proportionality & Fitness-for-Purpose	Proportionality is a **formal GCP principle.** Not all data or processes need the same level of control if scientific conclusions remain valid.	• Avoid unnecessary procedures or documentation • Ensure site processes are scaled to trial risk and complexity • Be ready to explain why certain controls are sufficient
Investigator Oversight	Stronger emphasis on **documented investigator oversight,** even when tasks are delegated or activities are decentralized.	• Clearly document delegation and supervision • Demonstrate ongoing oversight of staff, vendors, and remote activities • Review key data and safety information personally
Delegation & Vendor Use	Greater clarity that investigators remain accountable, even if activities are supported by partners (e.g. labs, telemedicine providers).	• Ensure third-party vendors are qualified and fit-for-purpose • Maintain oversight records (training, performance, issues) • Confirm clarity of roles and responsibilities
Data Governance (NEW section)	Introduction of explicit **data governance responsibilities** for investigators, covering data integrity, reliability, privacy, and traceability across systems.	• Understand data flow for all site data (eSource, wearables, labs) • Ensure ALCOA+ principles are applied • Verify data protection and confidentiality safeguards

Key Aspects	What's New in E6(R3)	What Investigators Need to Do (Actions Required)
Use of Technology & eSystems	Guideline is **media-neutral** and supports eSource, eConsent, remote visits, and digital tools. Focus is on reliability, not paper.	• Ensure validation/fitness of electronic systems used at site • Train staff on correct use of digital tools • Maintain secure access and audit trails
Decentralised & Non-Traditional Trials	Annex 2 (forthcoming) supports decentralized elements; Annex 1 already expects investigators to manage associated risks.	• Maintain oversight of participants outside the site • Ensure participant safety, protocol compliance, and data quality are not compromised by remote activities
Safety Reporting	Removal of the blanket requirement for all SUSARs to be expedited to investigators; encourages **fit-for-purpose safety communication.**	• Follow protocol-defined safety communication plans • Focus on safety information relevant to participant wellbeing and trial conduct
Informed Consent	Stronger emphasis on **ongoing informed consent,** including adaptability for electronic or remote consent processes.	• Ensure consent is an ongoing process, not a one-time event • Confirm participants understand trial changes and risks • Document consent processes appropriately
Essential Records	Essential records are now clearly linked to **fitness-for-purpose** rather than volume of documentation.	• Maintain records that support participant safety and data credibility • Avoid redundant documentation • Ensure records are accessible and inspectable
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Investigator Column – Walk the Talk with

DR. RAJIV MEHTA,
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Senior Gastroenterologist &
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Sids Hospital & Research Centre,
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As we continue our walk the talk series with renowned Investigators, we have a snapshot of the interview conducted with Dr. Rajiv Mehta, Senior Gastroenterologist & Clinical Research Specialist, SIDS Hospital & Research Centre, Surat

Dr. Rajiv Mehta is a senior gastroenterologist and experienced Principal Investigator with over two decades of involvement in global clinical trials across gastroenterology, hepatology, and pancreatology. He has led multiple Phase II–IV studies, including industry-sponsored trials in inflammatory bowel disease.

He is the Co-Founder of SIDS Hospital & Research Centre, where he leads a large clinical research program and actively works on translational research, drug repurposing, and AI integration in healthcare.

Q1. What are the biggest challenges sites face in running clinical trials?

The biggest challenge remains patient recruitment, particularly in countries like India where protocol criteria often do not align with real-world disease epidemiology. A key example is the exclusion of latent tuberculosis (LTB) in IBD trials, which significantly limits eligible patient pools. In addition, patient awareness, trust in research, and protocol complexity pose practical challenges. There is often a gap between protocol design and ground realities, which impacts feasibility and timelines.

Q2. How do you maintain quality when recruitment rates are high?

We follow a strict principle of "quality over quantity." Only truly eligible and committed patients are enrolled after thorough screening. Close team-based monitoring, real-time tracking, and patient education are critical. Ensuring that patients understand the trial and remain engaged significantly improves adherence and overall data quality.

Q3. How crucial is the study coordinator's role in trials?

The study coordinator is the backbone of trial execution. They manage patient coordination, documentation, regulatory requirements, and communication between all stakeholders. In many cases, they are the primary point of contact for patients, and their efficiency directly impacts recruitment, retention, and data quality. A strong coordinator is essential for a high-performing site.

Q4. What monitoring issues do you commonly encounter?

Monitoring challenges today are largely driven by increasing trial complexity and digitization. A key issue is inconsistent patient compliance with e-diary entries, especially in long-term studies. Delays in central lab reports can also lead to overshooting protocol timelines despite best efforts.

Protocol deviations remain difficult to eliminate, particularly in longer trials with multiple visits and assessments. The involvement of multiple vendors adds coordination challenges and communication gaps. Additionally, EDC-related workload, frequent queries, and system variability increase the operational burden on sites. Overall, better integration, streamlined processes, and more patient-friendly tools are needed to improve efficiency and data quality.

Q5. How do you ensure best practices are maintained across studies?

We maintain consistency through a system-driven approach, including standardized trackers, checklists, and regular team reviews. Continuous training, internal audits, and clear communication ensure adherence to protocols. Most importantly, fostering a culture of accountability and patient-centric care helps maintain high standards across all studies.

Q6. How ready are you to embrace new tools and technologies in clinical research?

We are highly open to adopting new technologies that improve efficiency, accuracy, and patient experience. However, tools must be adapted to local realities, where a hybrid model of digital and manual systems often works best. Looking ahead, technologies like AI, remote monitoring, and integrated platforms will play a key role, provided they enhance—not complicate—clinical research workflows.