Indian Society for Clinical Research

ISCR

Enhancing patient outcomes through clinical research

Indian Society for Clinical Research

Aug 2026 Edition

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Investigator Council presents: INSIGHTS

This Edition Contains

- ICTD Events Summary
- ICH GCP E6(R3): Investigators Checklist for Clinical Trials in India

Preface

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

PATIENT INTERACTION SESSION AT IQVIA BANGALORE OFFICE- HEARING PATIENT VOICES

1. ICTD Event at Bhaktivedanta Hospital, Mumbai

ISCR and Bhaktivedanta Hospital had planned a full day ICTD event on May 23rd on occasion of International Clinical Trias Day. One of highlights of the event was the panel Discussion from industry members. The core themes and summary of the Panel discussion

- Patient Safety & Data Integrity as Non-Negotiables
  From RBQM to traceability, the message was clear — every data point represents a patient journey, demanding accuracy, transparency, and real-time account-ability.

- Decentralized Trials = Expanding Patient Access
  Hybrid and decentralized models are breaking barriers — reducing travel, time burden, and improving accessibility by bringing clinical research closer to patients.

- Continuous Inspection Readiness = Compliance
  A strong shift from "inspection-week readiness" to a continuous quality culture ensures patient safety and compliance at all times.

- Digital Innovation with Responsibility
  As trials embrace eSource and eConsent, cybersecurity, governance, and ethical data handling remain critical to protecting patient information.

- Diversity & Inclusion = Better Science, Better Care
  Improving representation and reducing participation barriers are key to more inclusive trials and better patient outcomes. Taking Trials to Patients

- **Key Takeaway**

- Clinical excellence is no longer just about compliance - it is about building trust, enabling access, and ensuring every decision is patient-centric.

- **Closing Thought**
  The discussion ended with a closing thought
  "Remember every data point tells a patient's story. It is our responsibility to ensure that this story is shaped with integrity, quality, and accountability at every step. Let's not keep "Patient First" just as a guiding principle in our work but carry in our mind and most importantly in our heart.

The panelist covered diverse councils of ISCR.

- Dr Vaibhav Salvi- Chair- Investigator Council
- Ms. Swapnali Raut- Chair- Training, Quality nd Compliance Council
- Ms. Tanuka Ganguly- Ethics Council
- Dr Vijaykumar Gawali- CRC Workstream
- Mr. Sarang Vinze- Co-Chair- Investigator Council (Session moderator)
- The event was planned in collaboration with the ISCR West Chapter


CLASS ROOM - 1
Indian Society for Clinical Research
In collaboration with
Bhaktivedanta Hospital & Research Institute, Mumbai
India as a Global Trial Powerhouse: Ethics, Digital Innovation & Inspection-Ready Excellence at Site Level
Venue: 8th Floor Auditorium, Bhaktivedanta Hospital & Research Institute
Date - 23rd May 2026
Time - 08:00 am

SUMMARY OF INTERNATIONAL CLINICAL TRIALS DAY EVENTS

To celebrate International Clinical Trial Day and advancing patient-centricity across clinical development, IQVIA hosted Celebrating Our Patients session at IQVIA Bangalore office on June 03, 2026. Hearing directly from individuals who have experienced clinical trials firsthand brought deeply human perspective to the session. Their stories powerfully highlighted the real-world impact of clinical research and served a meaningful reminder that behind every protocol, milestone, and data point are real people, real emotions, and lives profoundly touched by clinical research.

ICH- GCP E6 (R3): INVESTIGATORS CHECKLIST FOR CLINICAL TRIALS IN INDIA (ICH GCP E6(R3) + NDCTR 2019 + ICMR ETHICS)

MS. RAJANI I MENON
Director,
Global Project Management
Syneos Health

A. Regulatory & Ethics Readiness (India-Specific)

- Trial approval obtained from ***CDSCO (DCGI)*** where applicable, before initiation
- Approval obtained from a ***CDSCO-registered Ethics Committee,*** valid for the trial duration
- Trial registered in ***Clinical Trials Registry–India (CTRI)*** before first subject enrolment
- I understand my ***legal responsibilities under NDCTR 2019***, including medical management and safety reporting

B. Investigator Oversight & Quality by Design

- I have identified ***Critical-to-Quality (CtQ) factors*** relevant to my site (eligibility, SAE handling, primary endpoint data)
- Site ***procedures are proportionate and fit-for-purpose,*** based on trial risk, as expected under ICH E6(R3)
- Delegation of duties is documented, but ***overall accountability remains with me*** as Investigator

C. Informed Consent (India-Critical Requirement)

- Written informed consent is obtained in a ***language understandable to the participant***
- ***Audio-Visual (AV) recording of the informed consent process*** is conducted, as required in India, while maintaining confidentiality
- Impartial witness present if participant/LAR is illiterate, with proper documentation
- Informed consent is treated as an ***ongoing process,*** including re-consent when required

D. Participant Safety & SAE Management

- ***Free medical management*** is provided to trial participants for trial-related injury, as required in India
- All ***Serious Adverse Events (SAEs)*** are reported to Sponsor, Ethics Committee, and CDSCO within 24 hours of knowledge
- Detailed SAE analysis and follow-up reports are submitted within Indian regulatory timelines
- I participate in and support ***causality assessment and compensation procedures*** under NDCTR 2019

E. Data Integrity & Technology Oversight

- All site data comply with ***ALCOA+ principles*** and Indian data confidentiality norms
- Electronic systems (EDC, eSource, wearable data) are ***fit-for-purpose*** and securely used
- Confidentiality of AV consent recordings and subject data is ensured and auditable

F. Documentation & Regulatory Readiness

- Essential documents are maintained according to ***NDCTR 2019*** and ICH E6(R3) expectations
- Key decisions impacting participant safety or data reliability are ***documented with rationale***
- I am inspection-ready for ***CDSCO, EC, and sponsor audits*** at all times

✦ **India-Specific Investigator Reminder**

In India, investigators have ***both ethical and legal accountability.***
Participant safety, informed consent (including AV recording), and timely SAE reporting are the most scrutinized areas during CDSCO inspections.