CLINICAL EXCELLENCE CONSULTING

Types of Sponsor & CRO Visits in Clinical Trials

PSV/SSV/SQV • Site Initiation Visit • Interim Monitoring Visit • Close-Out Visit • Booster Visit • Audit Visit

Data Quality

Ensures accuracy and compliance of trial data throughout the study.

Regulatory Compliance

Facilitates adherence to GCP and regulatory requirements.

Site Support

Provides resources and guidance to site staff for efficiency.

Issue Identification

Early detection of issues enables timely corrective actions.

Pre-Site Visit (PSV / SSV / SQV)

Conducted before study start to evaluate if the site and investigator have the capability to conduct the trial.

- Evaluate site infrastructure, lab, storage, and patient examination areas.
- Assess PI qualifications, experience in therapeutic area, and ongoing trials.
- Review retrospective data and assess competitiveness of concurrent trials.
- Confirm feasibility of recruitment, enrollment goals, and study timelines.
- Outcome: site approved to proceed to SIV, or deficiencies addressed first.

Site Initiation Visit (SIV)

Conducted after PSV approval. Site is authorized to begin enrolling participants upon successful completion.

- Review study protocol, eligibility criteria, procedures, and assessments.
- Confirm all staff accesses, GCP training, and delegations are complete.
- Discuss regulatory/ethical requirements: IRB approval, informed consent, GCP.
- Review IP management, safety reporting (AEs/SAEs), and data collection.
- Establish monitoring visit schedule and key contacts between site and sponsor.
- SIV report generated — official record of discussions and action items.

Site Initiation Visit (SIV)

Proactive contingency visit when enrollment falls behind projections. Sites, sponsors, and CROs develop action plans.

- Review trial data, performance metrics, and recruitment progress.
- Develop collaborative strategies — recruitment materials, protocol amendments.
- Address retention challenges: LTFU, OOW visits, withdrawn consent, screen fail.
- Offer additional site training, resources, and adaptive trial design if needed.

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Interim Monitoring Visit (IMV)

Periodic visits to ensure the trial is conducted per protocol, GCP, and regulatory requirements. Frequency varies from monthly to quarterly.

- Source Data Verification (SDV) — verify CRF data against source documents.
- Confirm informed consent obtained, documented, and re-consenting completed.
- Assess regulatory compliance: IRB approval, protocol amendments, AE reporting.
- Verify IP accountability, storage, dispensing, and return procedures.
- Review data management, documentation, delegation logs, training certificates.
- CRA issues Monitoring Confirmation Letter, Editing Notes (MENs), and Follow-up Letter.
- Prepare workspace for monitor: quiet area, copy access, internet, CRFs ready.

Close-Out Visit (COV)

Systematic, independent examination of trial-related activities and documents to verify compliance with protocol, SOPs, and GCP.

SPONSOR AUDIT	Conducted by pharma/biotech sponsor — assesses site compliance and data integrity.
REGULATORY AUDIT	FDA or other authority — inspects trial conduct, source docs, consent, and IP accountability.
3RD PARTY AUDIT	Independent external auditors assessing overall trial quality.

- Process: Preparation → On-site visit → Findings report → CAPA → Follow-up.
- Key areas: informed consent, data management, AE reporting, protocol adherence.
- Most common finding: lack of reliable and adequate source documentation.
- Consequences: protocol amendments, data correction, training, or trial suspension.