CASE STUDY

From Data to Decision: Streamlined Safety Committee Meetings in Phase 1 Dose Escalation Trials

Speed, precision, and readiness—REV Clinical accelerates trials when it matters most.

Study Details

- Phase: Phase 1/2 Study
- Indication: Solid Tumor
- Patients: Up to 30 dosed (up to 100 screened)
- No of Sites: 8 sites
- Country of Execution: USA

The Challenge

Following timeline delays and operational inefficiencies experienced in previous dose-escalation studies, the sponsor sought a partner with proven expertise in streamlined Safety Review Committee (SRC) management to accelerate decision-making, optimize cohort progression timelines, and reduce operational burden in a Phase 1 oncology trial.

Strategic Approach & Execution

- Defined SRC Governance: Established a clear SRC charter with aligned expectations on data requirements, review criteria, and decision timelines
- Real-Time Trial Tracking: Maintained a centralized tracker for screening, slotting, enrollment, dosing, and AEs; dynamically aligned SMC timelines with dosing cadence
- Proactive Dose Escalation Planning: Pre-scheduled next cohort dosing windows immediately upon SMC date confirmation to eliminate lag
- Cross-Functional Data Alignment: Enabled pre-SMC integrated review across DM, Biostatistics, Medical, Clinical Ops, and Sponsor covering AEs, SAEs, DLTs, lab trends, and clinical assessments
- Decision-Focused Meeting Preparation: Delivered concise, insight-driven materials (patient summaries, cohort status, escalation recommendations, risk assessment) to enable fast, confident decisions

Outcome & Impact

- ≤3 Days: SMC Decision Turnaround
- ≥95% Timeline Adherence
- Zero Data Gaps at Review
- ≤14 Days: SMC to Next Cohort Dosing
- Zero Repeat Meetings
- 100% On-Time SMC material for review