CASE STUDY

Speed and Precision under $4M-Constrained Phase 1 Oncology Trial

Where Speed Meets Cost Efficiency

Study Details

- Phase: Phase 1/2 Study
- Indication: Solid Tumor /Advanced Melanoma
- Patients: 20 (Phase 1a – Dose Escalation)
- Dose levels: 5 Doses + 1 Food effect extension
- Study Design: BOIN
- No of Sites: 6 sites
- Country of Execution: USA

The Challenge

Sponsor needed to execute a capital-efficient Phase 1 oncology trial within a constrained (<$4M) budget while strategically preserving resources across multiple early-phase assets and achieving rapid development milestones.

Strategic Approach & Execution

- Balanced Site Mix: Deployed an optimal blend of community and academic oncology centers to maximize reach and quality.
- High-Performing Community Sites: Prioritized Phase 1–experienced community centers to drive faster enrollment and operational efficiency.
- Smart Enrollment Design: Implemented efficient slot allocation and SEC planning to accelerate recruitment while maintaining healthy site competitiveness.
- Cost-Optimized Digital Stack: Leveraged a fit-for-purpose, cost-efficient clinical technology ecosystem (EDC, eTMF, CTMS) to deliver compliance without enterprise-level cost burden.

Outcome & Impact

- <100 Days to FPFV
- 40–60% Faster Startup
- 5 Cohorts Enrolled in 9 Months
- Delivered Under $4M in the U.S.