

DESIGN ROBUST TRIALS. GENERATE RELIABLE EVIDENCE.

End-to-end clinical operations, biometry, and regulatory execution aligned with ICH E6(R3) GCP & ISO 14155:2020.

Bring clinical strategy, operational excellence and robust biometry together to generate reliable evidence.

YOUR CHALLENGES



STUDY DESIGN COMPLEXITY How to build a scientifically robust, operationally feasible study aligned with regulatory and GCP expectations?



SITE MONITORING & RECRUITMENT How to manage multi-center investigator sites and CRA monitoring without timeline slippage?



DATA INTEGRITY & BIOMETRY How to ensure clinical data, statistical analyses and reporting generate reliable, traceable evidence?

OUR APPROACH

01 ASSESS

- Study design, methodology, and risk-based monitoring strategy
- Sample size calculation and statistical justification
- Drafting of essential study documents (synopsis, protocol, ICF, CRF)



02 IMPLEMENT

- Site identification, qualification, recruitment, and contract negotiations
- Regulatory filings to Ethics Committees and Competent Authorities
- Trial Master File (TMF) management and on-site / remote risk-based monitoring



03 ASSURE

- Data management (plan, validation document, eCRF, clean database)
- Statistical analysis plans (SAP), SAS programming, and CDISC deliverables
- Site closing, final Clinical Study Report (CSR), and scientific data valorization

YOUR BENEFITS



ROBUST STUDY DESIGN

Fit-for-purpose protocols and study strategies built around scientific validity, feasibility and regulatory expectations.



COMPREHENSIVE TRIAL GOVERNANCE

Consistent oversight of sites, CRA monitoring and trial activities to protect participants and study quality.



RELIABLE CLINICAL EVIDENCE

High-quality, traceable data and statistical outputs supporting robust clinical conclusions and regulatory submissions.

**READY TO STRENGTHEN
YOUR CLINICAL STUDY?**

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