

FROM START-UP TO CLOSE-OUT.

DELIVER QUALITY CLINICAL INVESTIGATION.

End-to-end clinical operations from study start-up, strategic project management and site management to risk-based monitoring and close-out.

Deliver clinical investigation with consistent oversight, participant protection and quality management aligned with ICH E6(R3) GCP & ISO 14155:2020.

YOUR CHALLENGES



STUDY START-UP COMPLEXITY How to coordinate feasibility, site activation and regulatory submissions across multiple stakeholders and sites?



RISK-BASED TRIAL OVERSIGHT How to focus monitoring and oversight on the risks that matter most to participant safety and reliable study results?



OPERATIONAL CONTROL & TRACEABILITY How to keep sites, vendors, study documentation and critical activities controlled throughout trial execution?

OUR APPROACH

01 ASSESS

- Project feasibility evaluation and investigator site screening across target regions
- Regulatory submissions preparation and management (Ethics Committees, Competent Authorities, CNOM, CNIL)
- Risk analysis, study risk-based management planning aligned to ICH E6(R3), & financial agreement formalization



02 IMPLEMENT

- Study conduct coordination, team scheduling, and Trial Master File (TMF) maintenance
- Risk-based monitoring and full site oversight: qualification (SQV), initiation (SIV), routine (IMV), and close-out visits (SCOV)
- Vendor selection, DSMB and endpoint review committee management, and ongoing safety/vigilance tracking



03 ASSURE

- Dedicated data reconciliation, clinical quality checks, and structured site closure activities
- Rigorous TMF completion, data finalization, formal regulatory close-out & archiving
- Specialized team training and flexible delivery models (full-service, task-based, or functional service provider)
- Inspection and audit readiness support

YOUR BENEFITS



CONTROLLED STUDY START-UP

Structured feasibility, site activation and regulatory coordination establishing a solid foundation for study execution.



PROPORTIONATE, QUALITY-FOCUSED OVERSIGHT

Risk-based monitoring and site oversight focused on participant protection, protocol compliance and reliable trial results.



END-TO-END OPERATIONAL OVERSIGHT

Clear control of sites, vendors and study documentation from initiation through close-out.

READY TO STRENGTHEN YOUR TRIAL OVERSIGHT?

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