Milestone One Comprehensive Site Enablement Support*

	Activity	Milestone One	Investigator
	Overall responsibility for study conduct		✓
	Provides administrative and operational support for study activities at the site under Investigator supervision and delegation	✓	
Strategic Enablement			
Site Promotion	Promote institution, investigators and site capabilities to sponsors and CROs	✓	
Trial Identification Support	Identify relevant study opportunities aligned with site capabilities and site population	✓	
Feasibility Support	Navigate feasibility and investigator selection process	✓	
Completion of the Feasibility Questionnaire	Provide realistic recruitment commitments, and accurate data on site capabilities and resources		✓
Study Start-Up and Regulatory Support			
CTA & Budget Coordination	Coordinate CTA, amendments, and related budget negotiations	✓	
Study Start-Up Readiness Support	Support completion of startup procedures, provide end-to-end coordination and site enablement to secure a smooth, timely, and compliant study launch	✓	
Clinical Oversight, Validation, & Signature Authorization	Review and sign final study documents (protocol, IB, budget, contracts), provide robust medical and scientific input to ensure the study is feasible and appropriate for the site		✓
Regulatory Documentation Preparation	Support preparation of regulatory submission package (local forms, CVs, site documents)	✓	
IRB / IEC Submission	Support preparation of ethics submission documents / taking responsibility for submissions in selected regions	✓	
Study Conduct Support			
Medical Assessment	Provide medical evaluation and clinical decisions for study participants, ensuring appropriateness of inclusion and treatment		✓
Safety Oversight	Responsible for patient safety, including timely AE/SAE assessment, reporting and implementation of safety measures		✓
Scientific & Operational Oversight	Exercises ongoing oversight of the study team and study conduct to ensure compliance with the protocol, GCP, ethical standards and institutional requirements		✓
Review, Approval, & Signatures	Reviews and signs all required study documents and key records during conduct (subject eligibility, medical decisions, safety assessments, key logs), formally confirming their accuracy and completeness		✓
Site Performance Oversight	Monitor recruitment, retention and protocol adherence to ensure site meets agreed performance and quality targets	✓	
Stakeholder Communication	Act as a central point of contact between Sponsor/CRO and site/PI, ensuring clear, timely communication and follow-up on study-related matters	✓	
Patient Recruitment & Retention Support	Support site in developing and adjusting recruitment and retention strategies based on site capabilities and performance	✓	
Patient Experience Enhancement	Promote practices that improve patient experience and adherence (clear instructions, visit reminders, pragmatic scheduling)	✓	
Patient Visit Scheduling & Coordination	Organize and optimize patient visit schedules and study procedures to minimize deviations and maximize patient convenience	✓	
EDC Data Entry	Support timely and accurate data entry, query resolution and source documentation, maintain high-quality clinical data	✓	
Investigator Site File & Study Logs Maintenance	Assist with maintenance of the ISF and related essential documents to keep them complete, current and inspection-ready. Maintain and regularly update study logs	✓	
Study Drug Accountability Support	Support study drug accountability and logistics, ensuring accurate accountability and continuous study drug availability at the site	✓	
Lab Samples Logistic Coordination	Support sampling, processing, and shipment facilitation. Monitor availability and proper handling of study materials, documents and non-IMP supplies needed for smooth study conduct.	✓	
Training for Site Staff	Monitor and coordinate initial and refresher training for investigators and site personnel	✓	
Support for Monitoring Activities	Coordinate with CRAs and site staff to facilitate monitoring visits, availability of staff, documents and source data for review	✓	
Vendor & Service Coordination	Coordinate third-party vendors (labs, imaging, couriers) to ensure services align with protocol requirements	✓	
Local Ongoing Regulatory Support	Coordinate submissions and notifications, management of local correspondence including safety reporting	✓	
Financial & Administrative Support			
Study Payment Processing Support	Assist in verification and processing of study-related payments	✓	
Patient Expense Reimbursement	Facilitate reimbursement processes	✓	
Audit / Inspection Coordination	Maintain ongoing readiness of sites for potential audits or inspections by supporting documentation, training and corrective actions as needed	✓	
Equipment Provision	Provide equipment on loan basis if required	✓	
Vendor Contracting support	Support in identifying, negotiating, and contracting project-required vendors	✓	
ISF Long-Term Storage Preparation	Support preparation of Investigator Site File for long term storage	✓	
Additional Agreed Upon Activities	Support other study-support activities agreed upon in writing	✓	

*All activities performed by Milestone One are conducted under Investigator delegation and supervision and documented as required.