

Outlined below are the key responsibilities of Clinical Operations team:

Phase	Activities Performed	
	Project Management	Operational
Start up	<p>Roles and Responsibilities: Define and assign tasks to ensure smooth workflow</p> <p>Project Timelines: Develop a task schedule with deadlines to align teams and meet timelines</p> <p>Core Study Documents: Draft, review and finalize key documents like protocol, consent forms and Case Report Form</p> <p>Study File Set-Up: Organize physical/electronic study files for easy access and tracking</p> <p>Plans, Logs and Forms: Set communication plans, manage risks, monitor compliance and tailor logs/forms to study needs</p> <p>Team Training: Train study team on roles, procedures, regulations and data collection</p>	<p>Site Feasibility and Selection: Evaluate and select sites based on experience, resources, patient pool and protocol compliance</p> <p>Ethics Committee Submission: Prepare and submit required documents for ethics approval</p> <p>Essential Documents</p> <p>Compilation and Filing: Compile and file study documents for compliance and reference</p> <p>Budget Negotiation and Agreement</p> <p>Execution with Sites: Finalize site budgets and contracts</p> <p>Investigator Meeting / Site Initiation Visit: Conduct Investigator Meeting and site initiation visits to align, train teams and confirm site readiness</p>
During Study	<p>Timelines and Milestones Management: Track schedule, address delays and meet key milestones like recruitment</p> <p>Budget Oversight: Monitor actual spending versus approved budget and process vendor invoices on time</p> <p>Project Meetings: Hold regular project team meetings to</p>	<p>Ongoing Monitoring: Continuously monitor trial data and site activities-on-site, remotely or via centralized systems to detect trends early and ensure compliance and participant safety</p> <p>Investigational Product Management: Oversee supply, storage and accountability of</p>

	<p>share updates and resolve issues</p> <p>Risk Management: Identify, assess and mitigate risks having impact on study execution, safety and data quality</p> <p>Change Management: Manage study changes by assessing impact on the project to avoid disruptions</p> <p>Audits: Conduct internal audits to ensure compliance with Standard Operating Procedures and protocol</p> <p>Vendor Management: Oversee vendors for protocol, timeline and quality adherence</p>	<p>investigational product at sites</p> <p>Safety Management: Track, document and report adverse events to protect participant well-being</p> <p>Protocol Deviation Management: Identify, record and resolve deviations from the approved protocol</p> <p>Essential Documents Review: Review trial documents to ensure completeness, accuracy and protocol compliance</p>
Study Closure	<p>Final Timelines Review: Confirm all trial activities are complete and deviations are documented</p> <p>Budget Reconciliation: Match actual costs to budget, resolve payments and close accounts</p> <p>Vendor Closure: Verify vendor deliverables and formally close contracts</p> <p>Shared Learnings: Conduct team review to capture successes and improvement areas</p> <p>Archival: Store completed study files (physical / electronic) securely per regulatory requirements for future access</p>	<p>Site Close-Out Visits: Conduct final site visits to confirm all procedures are completed and documented per protocol and regulations</p> <p>Investigational Product(s)/Supply Accountability: Reconcile investigational product(s) and supplies; ensure proper return or destruction</p> <p>Specimen Disposition: Verify samples are analyzed, stored or destroyed as per protocol</p> <p>Essential Document Reconciliation: Ensure all regulatory and trial documents are complete, signed and correctly filed at site and sponsor level</p>

Thus, the Clinical Operations team manages and coordinates all operational and project management activities throughout the trial, ensuring timelines, resources,

site readiness, monitoring, risk management, documentation, training and communication are effectively handled to enable a smooth and successful clinical study from start to finish

Primary Technology / Tools used by Clinical Operations:

- **Clinical Trial Management System (CTMS):** Centralizes and streamlines the planning, tracking and management of all operational aspects of a clinical trial from startup to closeout, enhancing efficiency, compliance and real time study oversight
- **IWRS (Interactive Web Response System):** It is a web-based platform that automates key processes like patient screening and enrollment, randomized treatment assignment and management of drug supply and distribution
- **Electronic Trial Master File (eTMF):** It is a digital system used to organize, store, track and archive essential clinical trial documents, ensuring regulatory compliance and efficient trial management throughout the study lifecycle
- **Electronic Consent (eConsent):** eConsent is the process of obtaining informed consent from clinical trial participants electronically using digital platforms, allowing participants to review study information, ask questions and sign consent forms remotely and securely
- **Electronic Patient-Reported Outcomes (ePRO) and Electronic Clinical Outcome Assessment (eCOA):** These digital tools let patients report their health and symptoms using devices like smartphones or tablets, improving data accuracy, patient engagement and realtime monitoring in clinical trials