

QUALITY ASSURANCE



Outlined below are the key responsibilities of Quality Assurance team:

Phase	Activities Performed
Start up	<p>Establish the Quality Management System (QMS): Ensure written SOPs are in place for all clinical trial activities, including data collection, monitoring, and reporting</p> <p>Vendor and supplier audits: Audit third-party vendors are audited to confirm their systems and processes meet Good Clinical Practice and trial requirements</p> <p>Audit Plan: Create an Audit Plan detailing scope, objectives, schedule and procedures for trial audits</p> <p>Training: Train site staff on Good Clinical Practice and quality standards during Investigator Meeting or Site Initiation Visit</p>
During Study	<p>Audits: Conduct site, vendor and system audits to ensure compliance with Good Clinical Practice, protocol and regulations; document findings, assess impact and review Corrective and Preventive Actions</p>

	(CAPA) responses for adequacy Inspection readiness: Verify documentation, identify gaps and confirm regulatory compliance; lead and support inspections if within scope
Study Closure	Audit Findings and Documentation: Ensure all audit findings are thoroughly addressed with appropriate Corrective and Preventive Actions (CAPA) and fully documented for future inspections Continuous Improvement: QA may conduct post-trial debriefings to identify process improvements for future studies

Thus, Quality Assurance department ensures the trial follows Good Clinical Practice, regulations and protocol to protect participants and ensure reliable data

Primary Technology / Tools used by Quality Assurance:

- **Electronic QMS (eQMS):** Robust validated platform designed to automate critical quality processes including document control, training management, audit tracking, Corrective and Preventive Actions (CAPA), supplier qualification and comprehensive risk management
- **Audit management software** to plan, conduct and track audits and inspections