



A central laboratory in a clinical trial is one specialized facility that analyzes samples from all study sites, ensuring consistent, accurate and traceable results. This approach helps reduce bias by standardizing testing across sites, providing a single

point for sample management, specialized testing and data reporting and thereby avoiding differences between local laboratories.

**Outlined below are the key responsibilities of Central Laboratory team:**

| Phase               | Activities Phase Performed   |
|---------------------|--|
| <b>Start up</b>     | <p><b>Protocol Review:</b> Identify required tests based on the clinical trial protocol</p> <p><b>Analytical Plan:</b> Define laboratory tests, sample handling and reporting per protocol</p> <p><b>Laboratory Manual Creation:</b> Outline collection, storage procedures, kits and logistics for trial sites</p> <p><b>Kit Design and Laboratory Requisition Forms:</b> Create sample collection kits and requisition forms for accurate test ordering</p> <p><b>Logistics:</b> Plan sample transport and management from sites to central laboratory</p> <p><b>Database Setup:</b> Establish secure database for clinical trial data management</p> <p><b>Training:</b> Train sites on sample handling and shipment procedures</p> |
| <b>During Study</b> | <p><b>Specimen Management:</b> Handle sample receipt, registration, processing and testing</p> <p><b>Quality Control:</b> Verify sample integrity, transport and documentation upon receipt</p> <p><b>Reporting Results:</b> Share laboratory results with trial sites for timely reporting</p>  |

|                      |   |
|----------------------|---|
|                      | <b>Sample Storage:</b> Store leftover samples securely per protocol-defined conditions  |
| <b>During Study</b>  | <b>Critical Result Communication:</b> Notify Investigator and Sponsor of critical results promptly<br><b>Periodic Reports:</b> Submit scheduled reports to Sponsor as per agreed timelines  |
| <b>Study Closure</b> | <b>Final Specimen Testing and Reporting:</b> Complete protocol required testing and provide final result summaries<br><b>Final Reconciliation:</b> Confirm specimen data is complete and aligned for reconciliation and database lock<br><b>Specimen Storage, Retention and Disposal:</b> Manage storage and disposal per protocol requirements<br><b>Archival:</b> Store laboratory data and documents securely per regulatory standards |

Thus, The central laboratory team supports clinical trials by developing analytical plans, designing sample kits, ensuring accurate sample testing, analyzing data, maintaining quality and supporting reliable trial results from start to finish

#### **Primary Technology / Tools used by Central Laboratory:**

- **Laboratory Information Management System (LIMS):** Focuses on managing samples, workflows and laboratory operations—ideal for research, clinical trials and industrial laboratories
- **Laboratory Information Systems (LIS):** Designed for diagnostic laboratories, tracks patient specific tests, results and integrates with hospital systems
- Central laboratories design their own **web-based portals** that allow investigators and study teams to access laboratory results, track specimens, order kits and supplies, receive alerts and download documents such as manuals, training materials