Central laboratory in clinical trials

Whether it's about assessing eligibility criteria, safety monitoring, determining baseline or demonstrating efficacy of the drug under investigation, laboratory testing of multiple clinical, immunological and in certain studies genetic biomarkers is an integral part of clinical trials.

Earlier, most clinical trial laboratory testing was done by local laboratory which was organized by individual principle investigator. Collecting data from multiple local laboratories that used different testing methodologies, reference ranges and standard operating procedures (SOPs) was associated with data errors resulting in consequent delays and increased cost for sponsors. Mislabelled kits, missing samples and incorrect tests were common. The laboratory data received at the end of a clinical trial had a very high error rate. This scenario became much more complex as the trial became globalised. Analysis of data with such inaccuracies leads to months of work cleaning the data in order to make it analysable.

The central laboratory concept was first implemented in the mid 80's driven by the need to deliver consistency in collection and uniform standards of reporting as well as consolidation of test results and data from different sites. A central laboratory is an institution that is exclusively responsible for laboratory assessments and provides services ranging from conducting laboratory assessments and compiling lab test reports, to contracting courier services for delivering lab kits and biosamples from/to medical institutions where diagnostics and treatment of patients is performed.

The value that central labs add as compared to a high volume diagnostic lab is due to consistency in all aspects of the laboratory functionality starting from uniform specimen collection kits to standard analytical method platform following customary SOPs, equipment, reagents and standards. Non standardisation of these parameters leads to variability and inconsistency in results. E.g. standardization of a lab collection kit enhances ease of use for those who do the actual collection of samples. Central labs train the site staff for proper collection, packaging and labelling requirements, thereby reducing human errors which can lead to miss identification and reporting of samples. Central laboratories standardise selection of proper method for analysis and equipment that indicate suitable blood volume to be collected, and also standardise the final report formats.

Central laboratories have professional logistics teams who understand sponsor's requirements and establish relationship with courier agencies. The logistics arrangement gives due consideration to requirements such as dry ice and ensure that the shipments take place under desired condition. They have customised tracking systems which provide visibility of specimen while in transit. Central labs have uniform SOPs in place, IT platforms and QA standards and are able to provide data in a single file format using set reference ranges and units as required by the sponsor. The central laboratories are familiar with regulatory requirements, diversified by different geographies and try to be well informed with the changing regulatory environment.

Central labs deliver globally harmonised, statistically meaningful data providing consistency over time, while diagnostic labs provide individual snapshots of lab results. Diagnostic Laboratories cannot provide solutions for global clinical trials, have limited scalability and need to adjust to the diagnostic laboratory needs where decisions are driven by cost effectiveness of diagnostic testing rather than maintaining the consistency needed for pharmaceutical grade testing.

These compelling observations seal the place of a central lab in clinical trials.