

The Evolving Role of LIMS Database in Global Clinical Trials Testing

Current LIMS database packages are used to track clinical trial collection kits/supplies, manage and track specimens, manage laboratory testing work flows and record quality performance, create laboratory reports and manage study-specific documents. Originally used by hospitals in the 1980's to manage patient samples and data on site, the system's began to evolve and were identified by clinical trials organisations as an effective way of managing the processes in commercial laboratories dedicated to drug development studies.

Since then these packages have developed to meet the user's need for more client focussed functionality and therefore brought in the need to integrate it with other departments within a clinical trials organisation. Laboratory staff needed LIMS to incorporate quality control, trends emerging from the studies along with significant changes from pre-study samples, so tools were created to perform these tasks. Project managers also recognised the benefits of integration into the LIMS package, as functionality developed to provide the capability to interrogate the data once it was captured.

The globalisation of the clinical trials industry has played a big part in the development of LIMS, to the extent that it is now essential to the effective running of any clinical trial. Some centrally held LIMS packages are now actually controlling laboratory analysers around the world and storing the results in a fully harmonised central database. The increase of multi-site studies has forced the need for a centralised database of patient and product data which is fully compliant, secure and accessible.

LIMS reports need to be available to all relevant personnel, sometimes on a global scale, including all the internal clinicians and project managers and externally to the doctors, monitors and sponsors. This is usually delivered through a front-end system, which allows varying levels of access depending on the need. More sophisticated LIMS can provide you with the capability to deliver reports in a number of ways – from hard copies, single or cumulative reports to remote data access systems.

LIMS also provides traceability and storage conditions of samples throughout the clinical trial process from despatch by the investigator, arrival at the lab, through the testing procedure, right through to freezer storage and disposal. Client requirements have to be met for full sample auditable history reports for every sample received in the laboratory listing, such as sample freeze/thaw cycles or storage temperatures, for example.

The system provides you with capability to process more samples, forecast the timings of studies, monitor patient safety and work more effectively throughout the lab procedures. It also allows you to measure the output capabilities of the laboratory, project the workload and any backlog, and forecast the number of personnel needed to perform the work. Furthermore, the LIMS database will record trends and help forecast the type of work in the months ahead, predicting seasonal studies on winter viral infections, for example.

As technology improves, so will the functionality of LIMS and their ability to integrate with other systems. Improvements will be sponsor lead, as they request more sophisticated reporting systems which provide quicker and more accessible results, particularly with regard to patient safety. In the future, interim reporting is likely to become more mainstream, giving the sponsor the opportunity to review the study at any stage in order to amend the dosage, recruit more patients or simply monitor progress.

With the ever increasing use of electronic data capture (EDC) systems within the clinical trials industry, all LIMS databases should be upgraded to provide functionality to directly communicate with these systems. Other upgrades could include allowing couriers to access LIMS via the internet to improve the efficiencies of their role and providing more integration with laboratory information such as SOP's.

As technology improves, so do the opportunities to further develop and enhance the fundamental role that LIMS systems play in the management and interpretation of clinical laboratory data to the ultimate benefit of patients and sponsor companies.