

Managing Your Info Flow with LIMS

Sam Singh at ACM-Pivotal explores the evolution of laboratory information management systems (LIMS) from the point of view of a global clinical trials organisation

Providing the backbone of a clinical trials organisation, a laboratory information management system (LIMS) impacts on all departments, machinery and personnel. In today's market, no clinical laboratory or CRO could operate without the support of a well-integrated LIMS package. And as the technology gets even more sophisticated, so do the opportunities for the pharmaceutical industry.

LIMS exist to track clinical trial collection kits, manage and track specimens, manage laboratory testing workflows and quality performance, create laboratory reports and manage study-specific databases.

PHARMA FINDS A ROLE FOR LIMS

Exclusive to hospitals in the early 1980s, LIMS were originally used to manage patient samples and data on site. The systems 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. A number of IT providers recognised the business opportunities available and began to mould the existing systems to suit the needs of clients working throughout the pharmaceutical sector.

By the 1990s, most clinical laboratories had installed some form of LIMS system and, in 1998, the FDA put into place 21 CFR part 11 to keep a tight grip on quality throughout the trials process. The regulation governs the scope and application of electronic records and signatures within the industry, with reference to validation, audit trails, record retention and record copying.

As the regulations changed, so did the users' need for more functionality – mainly driven by the pharmaceutical

companies. Within a clinical trials organisation, laboratory staff wanted the LIMS to incorporate quality control and trends emerging from the studies with significant changes from pre-study samples and tools were created to perform these tasks.

Project managers also recognised the benefits of integration into the LIMS package. As client demands increased, project management functionality developed to provide the capability to interrogate the data once it was captured. To this end, the search engines evolved, front-end reports were added, and the overall user interface began to change by developing monitoring and reporting systems.

The globalisation of the clinical trials industry has played a big part in the development of LIMS. The increase in multi-site studies has forced the need for a centralised database of patient and product data, which is fully compliant, secure and accessible.

The 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 different users varying levels of access depending on the need. For example, data may be blinded to a doctor carrying out the dosing on a diabetes study where 50

per cent of the patients are on the placebo. More sophisticated LIMS should also provide you with the capability to deliver the report in a number of ways – from hard copies, single or cumulative reports to remote data access systems.

RECENT DEVELOPMENT

One of the more recent developments in LIMS is the traceability of samples throughout the clinical trials process from despatch by the investigator, arrival at the lab, through the testing procedure, right 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.

Whilst a LIMS database cancels out the need for manual data input, it does not take away the need for trained personnel to manage the processes of distribution, sample storage and other manual laboratory work. However, it does provide you with the capability to process more samples, forecast the timings of studies, monitor patient safety and work more effectively throughout the lab procedures.

The system 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. The LIMS database will also record trends and help forecast the type of work in the months ahead,

predicting seasonal studies on winter viral infections for example. Once the scope of the study has been set up on the LIMS, accurate projections of workload can be calculated, subject to timely patient recruitment.

There are relatively few IT companies that offer LIMS packages across the UK and Europe. Those that do have often worked closely with their clients over the past decade to evolve their system and deliver the ever increasing list of functions and benefits. Other clinical trials companies and CROs have chosen to develop their own systems on site, responding directly and exclusively to the requests made by their sponsors and in-house team. The majority of service providers have released multiple versions of their LIMS package, improved, updated and in-line with any new regulations.

GETTING THE RIGHT PACKAGE

For a clinical trials organisation looking for a good LIMS package, the essential requirements are as follows:

- Compliance with regulations – an obvious one perhaps, but with the FDA regulations constantly evolving, a LIMS provider must be wholly up to date on the changes and additions to regulation 21 CFR Part 11
- Easy to use – the best LIMS packages are those that are web-based, offering flexibility to work from laptops at different workstations around the laboratory. Your personnel are trained as scientists, not IT experts, therefore the time it takes to train the staff on the system should be minimal
- Flexibility – a package that can be easily adapted, both by the IT provider and the user, allows an organisation to respond to its clients needs more effectively and add functionality as the business grows
- Security – a system's advanced security, data integrity and audit trail capabilities should meet the stringent requirements of pharmaceutical clients. LIMS must also provide a robust back up system to support a laboratory's disaster recovery strategy

- Compatibility – the system must integrate with a lab's different analysers

For a pharmaceutical company working with a clinical trial organisation, the most important elements of LIMS are as follows:

- Compliance with regulations
- Flexibility – the capability to see your study in any format you require
- Timely – to have real-time results, which allow you to review/amend the study as needed
- Integrity – for the LIMS to provide you with accurate and secure data, which can be monitored and shared globally
- A critical monitor of patient safety data
- Adaptability – the willingness of the clinical trials organisation to work with its LIMS provider to adapt the system to suit your requirements

FUTURE DIRECTIONS

So, where can the technology take the industry in the future? It is likely to be a case of evolution, not revolution, and developments will come in line with any amendment of the FDA regulations.

As technology improves, so will the functionality of LIMS and their ability to integrate with other systems. Already we are seeing an advancement in doctors' case reporting, with the majority now using electronic CRFs. Clinical trials organisations are now required to send their patient report for inclusion in these CRFs, creating a much more conclusive reporting system.

The improvements to LIMS will also be led by sponsors' needs. As the end-user, pharmaceutical companies are likely to 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

About the author

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monitor progress. Another request raised by a number of sponsors is the ability to link the storage information to the end data, including the freezer temperature and disposal requirements.

With the ever increasing use of electronic capture systems (EDC) within the clinical trials industry, all LIMS databases should be upgraded to provide functionality to directly communicate with these systems.

Away from the laboratory, improvements will need to be made to the invoicing procedures using LIMS. Integration of financial information is already being developed to include project management fees, analytical costs, courier services, sample storage and electronic data transfer – all of which require ongoing investment.

CONCLUSION

As a business and management tool, LIMS is integral to any clinical trials organisation and the investment required is fairly minimal compared to the obvious benefits it provides. The efficient running of a commercial laboratory has become dependent on LIMS technology and, with an emphasis on responding to clients needs, the opportunities for the future are endless.