LIMS Get Agile

With little margin for error when running a clinical trial, Ed Krasovec of STARLIMS highlights how agile and well-integrated clinical trial LIMS enhance the ability to meet a 'right the first time' agenda

The clinical trial process – which produces the scientific data used to determine the safety and efficacy of a new drug, treatment or medical device – has become increasingly complex, time-consuming and costly. Laboratories play an important role in most trials, producing a significant percentage of the data generated during the clinical study.

Despite the significant effort that is expended in collecting and managing the data generated by the laboratory, it is often difficult to extract the information needed to identify and address problems and make informed decisions. A modern comprehensive Laboratory Information Management System (LIMS) solution that integrates study management and biorepository management functionality can dramatically improve operational visibility. This means reducing cycle times related to identifying and resolving issues, implementing critical business process changes, implementing changes to study protocols, and exchanging data with other organisations and information systems.

QUERY IDENTIFICATION AND RESOLUTION

The challenge presented by a clinical trial is to produce, in a timely manner, high quality data, while adhering to the precise requirements specified in the clinical protocol. In order to give the operations personnel a fighting chance of managing the clinical trial successfully, they need to be immediately aware of any potential issue that could have an impact on data quality or compliance with the protocol. The ability to act and react in a timely manner is crucial. Every potential query (issue) that may have an effect on the validity, availability or quality of the data generated through the laboratory must be identified, investigated and resolved as a matter of extreme urgency. The longer a query remains outstanding, the smaller the chance of a successful resolution. For example, the sooner a call is placed to the clinical site, the greater the likelihood that the clinical site will be able to locate a missing sample and ship it before the sample stability period expires. Efforts to address inconsistent or missing data are much more likely to be successful if the follow-up effort is initiated immediately after the original data collection and recording. As time passes, the chances increase that the relevant clinical site personnel will be unavailable, or unable to remember important information. Furthermore, prompt feedback to the clinical sites regarding recurring patterns of issues can be an effective tool for driving continuous improvement in order to eliminate queries at their root cause.

A LIMS that effectively integrates sample management (accessioning, specimen testing, routing and storage) with a detailed definition of the clinical study enables early detection and prompt resolution of issues or queries. As the specimens undergo different steps in the lifecycle (such as ship, receipt, test, report, store and passing through the collection, shipping, and laboratory workflows), the LIMS can find deviations between the requirements specified in the LIMS clinical study manager and actual conditions. Furthermore, the LIMS should include a query management tool so that items can be tracked, managed and assigned, until each is resolved. A clinical trial LIMS that is well-integrated with biorepository and specimen storage management features will also allow personnel to manage the logistics related to shipping and receiving the specimen, query the status of specimens that are in transit, and find alternative specimens for a given subject in the event of a lost or damaged specimen.

STUDY AMENDMENTS AND ADAPTIVE TRIAL DESIGN

A clinical trial LIMS must provide flexibility to implement study changes quickly and effectively. These changes can be either amendments to a traditional trial or modifications that are part of an adaptive clinical trial design. As clinical development increases in complexity and cost, interest in the use of adaptive clinical trials design will continue to grow. The LIMS should provide:

◆ Immediate access to reliable data produced by the current version of the protocol, facilitating effective decisions about how the protocol should be adapted
◆ Tools that streamline modifications to protocols, including validation and implementation

Protocol amendments must be implemented and validated in the clinical trial LIMS. Any modification that changes the testing, kit requirements, accessioning, specimen handling, reporting workflow or business rules must be appropriately reflected in the LIMS. Following a data-driven, configuration approach offers great advantages over any method that requires changes to the software's underlying code. In particular, a data-driven approach greatly streamlines the effort and turnaround time associated with implementing and validating the protocol changes within the LIMS. LIMS today can provide a high degree of configurability, with a multi-tier architecture separating configuration tools and application modules from underlying technology and core software codes. This approach enables workflow and business logic changes to be implemented via data-driven user configuration. This can be carried out either by using configuration wizards within the various application modules or via system configuration tools.
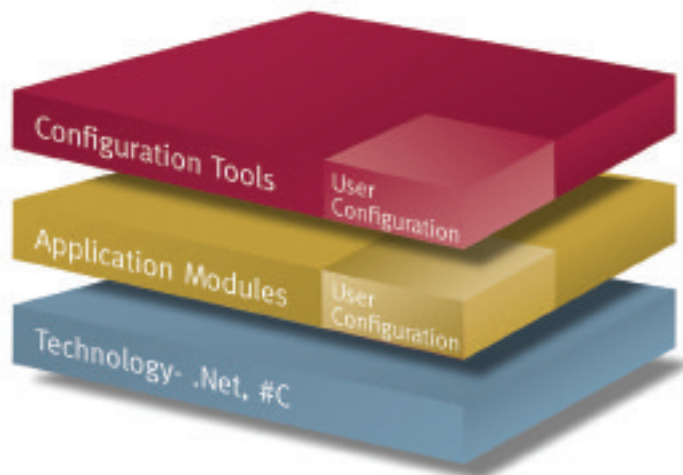
Figure 1: System configuration tool Image: STARLIMS

DATA EXPORT AND INTEROPERABILITY TOOLS

Since scientific data is the most valuable product produced in a clinical trial, the LIMS must provide data export capabilities and interoperability tools for the exchange of data with other systems, both internal and external to the CRO or sponsor organisation. Data exports from the LIMS should be accomplished easily and without the need for complicated coding. One option is to use a data export utility that utilises a user configurable template to build a query to extract the desired data from the LIMS database. The utility automates the data extraction and includes configuration options to transform the data (for example to change date format and concatenate data elements), format the file of extracted data, schedule regular extraction events, and route the extracted file to an appropriate ftp address or other location.

Furthermore, the LIMS interoperability tool set should include support for web services/XML, HL7, direct database connectivity, and file handling and manipulation (csv, ASCII and so on). These interoperability options provide the flexibility to integrate LIMS with a wide variety of information systems. A clinical trial LIMS that includes an integrated scientific data management system (SDMS) can enable automated data acquisition, as well as data integration and consolidation from other systems in or outside the laboratory – and especially those creating or managing unstructured data in the form of files and documents. To date,

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this information has been seen as too difficult or too expensive to integrate.

One particular example of a unified SDMS/LIMS combination in action is the automatic acquisition of electronic test results from external laboratories. Clinical trial customers can use an integrated SDMS to parse unstructured reports (in .pdf, MS Word or other formats) produced by external laboratories, store the test results and related information into the LIMS database, and make the key data available across the organisation from within the SDMS itself. SDMS has lowered the barriers to implement these interfaces by including artificial intelligence capabilities that greatly simplify and streamline the effort involved with parsing an external laboratory's report file. Electronic acquisition of this external lab data into the LIMS provides more immediate visibility and value to all stakeholders in the clinical trial.

BUSINESS PROCESS CHANGES

Clinical trial operations personnel are faced with a dynamic, demanding and competitive environment that changes unexpectedly. New regulations, new cost structures and unplanned disruptions to operations provide great operational challenges. However, opportunities exist for an organisation that has agility and flexibility to adapt. The clinical trial LIMS can be an effective tool that can ensure the implementation of business process change quickly, as illustrated by the following examples:

◆ A web-based LIMS can be easily deployed to a new facility when increased shipping costs or regulatory restrictions make it desirable to start up a new laboratory or sample handling facility
◆ A user-configurable clinical trial LIMS enables specimens to be easily redirected to a back-up laboratory (including third-party outsourcing laboratories) in the event of a laboratory or instrument breakdown
◆ By closely tracking inventory levels of kits and other supplies, the LIMS can allow operations personnel to: optimise the use of existing inventory; transfer specimen collection supplies; or provide suitable handling alternatives to avoid the multitude of issues that can arise from samples being collected and shipped using the wrong containers and materials

CONCLUSION

The exacting nature of clinical trials leaves little margin for error; specimen handling, testing and reporting should be executed 'right the first time'. An agile and well-integrated clinical trial LIMS greatly enhances the ability to meet these requirements. The rich set of clinical trial tools offered by a comprehensive web-based clinical trials laboratory informatics platform can unleash organisational agility, leading to significant time savings for study setup and modification, query identification and resolution, rapid implementation of business process changes, and data exchange with other information systems.