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Clinical Research & Diagnostics Tutorial

LIMS Streamlines Translational Science

Lab Information Management Systems Help Researchers Make the Most of Collaborations

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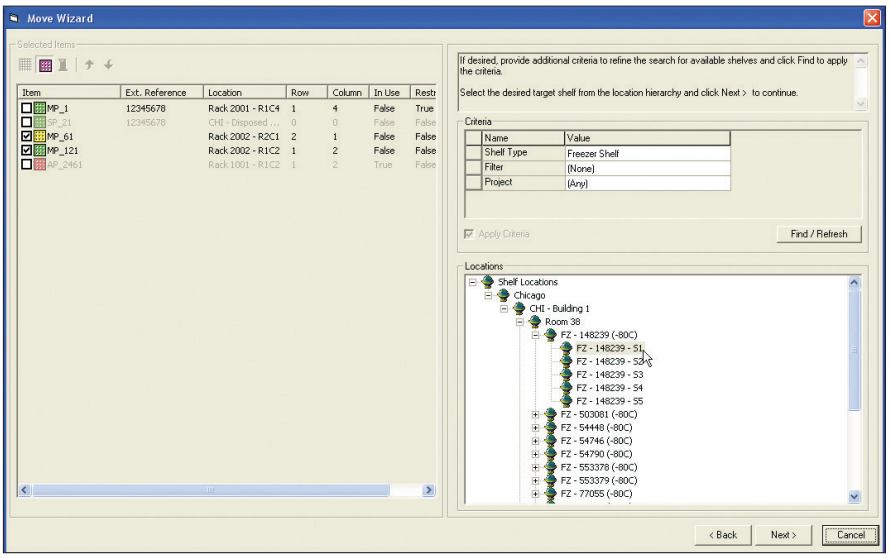
Through the American Recovery and Reinvestment Act of 2009, the Obama administration has set aside $8.2 billion in additional funding for scientific research in the hopes of stimulating the U.S. economy. As part of this funding, the NIH has created Challenge Grants in Health and Human Research for scientific disciplines, and one of the 15 areas identified for these Challenge Grants is translational science. This focus by the NIH is not new. In 2006, the NIH initiated the Clinical and Translational Science Awards Consortium to create a collaborative environment that spans across all facets of medical research.

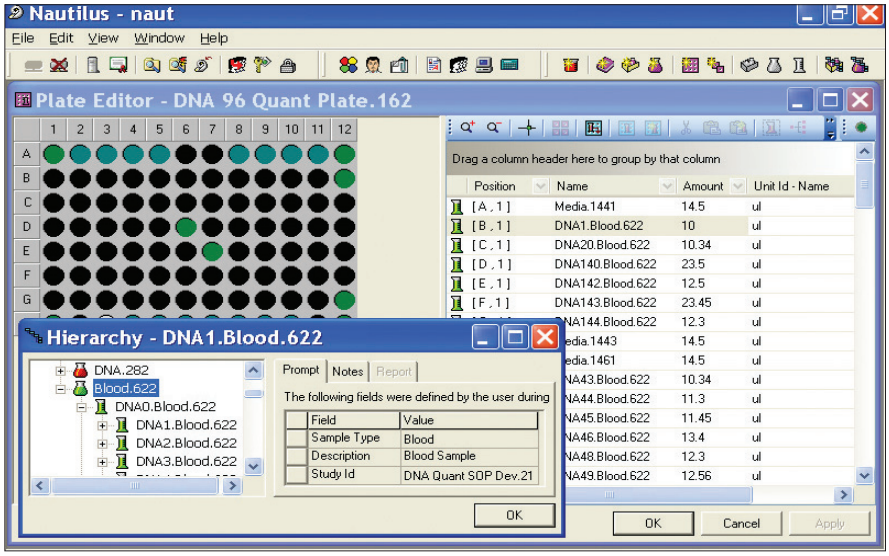
Translational science, also referred to as translational medicine or research, is at its core a relatively simple concept. By taking a focused point of view, the biomedical community is able to translate what it has learned in the laboratory into the diagnosis and clinical treatment of patients.

While this bench-to-bedside approach holds the promise of tomorrow's innovative and personalized medical treatments, it presents some real challenges today. To translate information from the clinic to the laboratory and back requires that researchers and clinicians integrate and collaborate on information from pharmaceutical and biotechnology companies, hospitals, and academia. Furthermore, the growing amounts of data associated with this research has posed enormous challenges for laboratory information management. Research labs now need flexible and robust systems to integrate and manage donors, biospecimens, workflows, sample derivatives, experiments, protocols, instruments, reagents, lab personnel, collaborators, and reporting.

To meet these needs, organizations are utilizing laboratory information



Samples often move between the hospital and the pharmaceutical company during the study. Thermo Scientific Nautilus LIMS tracks samples from the building, to the freezer shelf, down to the individual well position of the plate.



Users perform a variety of actions on plates, like pooling, cherry picking, or splitting. Thermo Scientific Nautilus LIMS allows users to graphically move or split aliquots directly through the plate interface.

management systems (LIMS) to facilitate information exchange without compromising the day-to-day operations of the hospital. This article discusses these developments and describes how a novel and flexible LIMS framework can facilitate collaboration and manage experimental results of clinical outcomes.

Key Challenges

Unlike most disciplines, translational research is being done in multiple locations by organizations with entirely different roles in improving human health. Research hospitals and academia are balancing their desire to move medicine forward through sponsor- or grant-funded research studies without compromising their paramount goal of improving the health of their patients.

On the other hand, drug manufacturers need to demonstrate real results from their research. Despite their differences, these organizations share a common goal to move medical treatments forward. In order to do this, close collaboration among a variety of constituents from different disciplines, inside and outside of an organization, is an absolute requirement. Nevertheless, it can be difficult to manage all of the data and people involved in this collaboration so that the proper results are communicated to the right audiences at the right time.

Flexibility and adaptability are key components in this effort, and the ability to attack new therapeutic areas and design new studies is crucial. Organizations also need to ensure that information is available in real-time to provide a clear view of the study's progression and to enable researchers to make the right decisions.

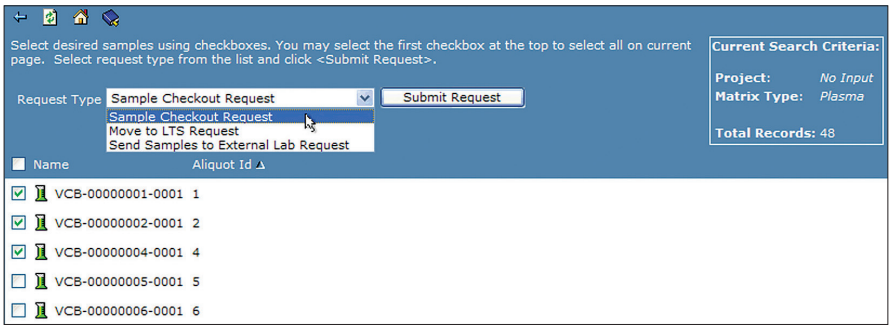
If a biomarker is showing a positive response to a drug, researchers may add an additional draw to the study to gather more data or add an additional test. If it takes them two weeks to gather these results, they may miss the opportunity to enhance the study and increase its value for both the sponsor and the hospital. A LIMS is crucial for a laboratory to provide research scientists with the information they need while managing the day-to-day responsibilities of tracking, storing, and testing physical samples.

The Role of LIMS

A LIMS solution can help to address all of the above challenges and help support translational science, whether it is deployed at a single organization or as a collaborative LIMS solution across a consortium. Systems like the Thermo Scientific Nautilus LIMS™ from **Thermo Fisher Scientific** (www.thermo.com) provide scientists with all of the information they need to track their experiments and view the progress of patients in a clinical trial. Nautilus LIMS serves as a single interface where scientists enter study data that is immediately available to principal investigators and laboratory managers. Any data trends are easily seen in common reports generated by the LIMS, providing complete visibility into all aspects of an ongoing study.

The LIMS facilitates visual filtering and reporting on data to show the progress of a study at any time, demonstrating to sponsors that operations are running efficiently and yielding the best possible return from their grant money. It also prioritizes laboratory and clinical work so that resources can be managed effectively.

The ability to manage laboratory and patient data in a secure and auditable manner is critical. A LIMS enables laboratories to segregate study data, simplifying the user experience while providing security and traceability. Each group is allowed to interact with the system in a way that is intuitive and makes sense to them. A LIMS like Nautilus allows users to view patients and draws, which is intuitive for doctors and nurses, or as samples, plates, and aliquots by laboratory personnel.



Users external to the laboratory can submit sample requests through a web interface. This facilitates the sample hand-over between the clinic and the laboratory.

Once collected, data must be referenced at each level in the hierarchy to enable laboratories to track draws and aliquots, and ensure that all of that information is available at the study level. Nautilus tracks and displays the location of all samples, and monitors their parent-and-child relationships from the freezer to the individual plate well. A LIMS also provides useful information about the availability of instruments, supplies, and personnel prior to any testing request, which enhances the decision making process in the lab.

In addition, web accessibility simplifies maintenance and deployment of the system in a low-cost manner. LIMS users across multiple sites, laboratories, and hospitals can access the data at any time, so disparate groups that comprise a research environment can work and share information in an optimal way. Laboratories gain the efficiency and oversight they need without sacrificing productivity.

Conclusion

As a relatively new and evolving science, one of the key challenges in translational medicine is how to balance the need to provide the best possible patient care with the need to further science in clinical research. For these seemingly divergent objectives, a LIMS is a critical tool for managing and optimizing laboratory operations, but is far more than that.

The LIMS monitors what equipment and personnel are available in the laboratory, helping scientists prioritize work. It facilitates the visibility of information across the study and allows for real-time trending of study results for sponsors and principle investigators locally or from remote locations. It enables nurses and doctors to see the draws they need to perform and input those results in an intuitive manner. The LIMS ensures that samples are tracked from the patient to the laboratory for in-house and sponsored studies.

In the collaborative environment of translational science, a LIMS provides a single solution for study design and execution, making it possible for scientists to translate data into real medical advancements. GEN