

Bench to Bedside

Trish Meek at Thermo Fisher Scientific and Dennis Fallen at Fisher BioServices look at creating a next-generation research information network to advance medicinal breakthroughs

Translational science is an emerging area of medical practice, integrating research inputs from the basic sciences, social sciences and political sciences to optimise patient care. This process, often described as 'bench-to-bedside', 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 learnt 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 personalised medical treatments, it presents some real challenges today. The sheer volume of data from these organisations poses an enormous obstacle, which is why informatics tools are an essential component of the translational science process, ensuring that all organisations are connected and have access to critical information, data and reports. 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.

A novel and flexible laboratory information management system (LIMS) can address the challenges faced by researchers in their day to day operations and facilitate collaboration across all

organisations by creating a unified global research information network.

DATA MANAGEMENT NEEDS

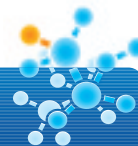
Translational research is being done in multiple locations by organisations with entirely different roles in improving human health. Research hospitals and academia are balancing their desire to move medicine forward through sponsor- or grant-funded research studies without compromising their paramount 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 organisations 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 organisation, 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. Organisations 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. All of these organisations have research laboratories that need to track, store and test physical samples, which is why they rely on a LIMS to help drive the scientific process.

PHARMACEUTICAL & BIOTECHNOLOGY REQUIREMENTS

Drug manufacturers need to demonstrate the efficacy and safety of their compounds as early as possible, and they employ translational medicine to learn more about their compounds and how they interact with the human body. To do this, cross-disciplinary collaboration with peers inside and outside of the organisation is a key requirement. Extensive amounts of data, results and reports need to be collated from a variety of partner and contract research organisations (CROs). The timely and accurate flow of information and samples is essential, and pharmaceutical companies can extend the use of their LIMS by making it the central point to manage information from partner organisations as well. This is not a trivial task since the information is in different formats and is not easily translated. A LIMS' sophisticated integration capabilities greatly simplify this process and connect organisations with partners to form a research information network.

CLINICAL REQUIREMENTS

While research hospitals and academia conduct research studies with a primary goal of improving the health of their patients, it is also important to keep the study results separate from the patient records to ensure that the patient's privacy is maintained under HIPAA regulations and that the science is unbiased. It is important to keep the study results separate from the patient records to ensure that the patient's privacy is maintained under HIPAA regulations and that the science is unbiased. Managing this information and samples in a secure manner requires a comprehensive LIMS to gather, store, sort and retrieve data. Researchers can query patient demographic and sample type information and request the correct



samples without violating the patient's privacy. LIMS also provide:

- Equipment and personnel availability to help scientists prioritise work
- Visibility to information across the study for real-time trending of results, locally or from remote locations
- An intuitive interface so nurses and doctors can see the tests they need to perform and input without interrupting patient care
- Chain of custody records to ensure that samples are tracked from the patient to the laboratory for in-house and sponsored studies

CRO INDUSTRY REQUIREMENTS

CROs also play a key role in this process. They deliver value to customers by delivering highly skilled analysts to supplement in-house capabilities in a cost-effective way. To do this, they must be incredibly efficient and provide advanced sample, result and report management services to their customers. A LIMS not only drives operational objectives and information exchange with sponsors, it also ensures that regulatory and quality procedures are followed. This is crucial for pharmaceutical customers who need to ensure that all of the data used in their regulatory submissions is in compliance. A LIMS enhances a CRO's ability to service their clients better and be viewed as a strategic partner by facilitating faster, more informed decisions about a study's progress.

THE ROLE OF LIMS

The 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

A turn-key role for global biorepositories

Translational medicine connects the research laboratory to the patient (bench-to-bedside) to help drive potential drug candidates through the drug development lifecycle. This increased focus on epidemiology and translational science has led to a surge in the number of samples generated for research and analysis. As a result, biospecimen management has become a key component of drug development research and clinical trial activities. In addition, a significant increase and focus on high quality sample yields and how they are accurately and efficiently managed is a key issue for researchers who are charged with managing enormous volumes of samples and their relevant data.

Biobanks play a critical role in the research information network and require an advanced LIMS to manage biospecimen locations, online requests, chain of custody and patient demographics. The benefits of properly managed data can be significant and reduce the time to develop a lifesaving drug or diagnostic by providing the critical samples and information in a timely and accurate manner. By optimising logistical and operational support for researchers, a LIMS ensures that samples are available when and where needed.

In addition, with the enormous amount of detailed operations and regulatory compliance required of biobanks, it is

becoming more important than ever that these services be consolidated and offered in a turn-key fashion so that multiple parts of the translational science process can be managed by a global organisation focused entirely on these distinct processes and deliverables. A turn-key approach provides a full complement of offerings for biobanks, from biospecimen collection, processing, testing and storage to sample and data management. Companies in search of this type of turn-key biobanking solution will also want their provider to offer a complete end-to-end portfolio, including everything from centrifuges, concentrators, freezers, robotics, two-dimensional barcodes, microplate readers, to mass spectrometers and comprehensive services, as well as software (LIMS), lab equipment and sample storage. Large global providers specifically focused on biological specimen management supporting life science and clinical research industries can offer capabilities that span the spectrum from collection to repository, including transportation, inventory, biorepository services, and biological lab processing, and bring greater efficiencies to the process of translational science. Outsourcing some of these processes allows organisations involved in translational science to make faster, more informed decisions about advancing science and developing drugs that save and improve the quality of lives.

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 prioritises 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. Organisations can establish user protocols within the LIMS so collaborating groups can view only the data that relates to a particular study. Each group is allowed to interact with the system in a way that is intuitive and makes sense to them. A LIMS allows users to view patients and draws, which is intuitive for doctors and nurses, or view samples, plates, and aliquots by laboratory personnel. 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. The LIMS tracks and displays the location of all samples, and monitors their parent-and-child relationships from the freezer to the individual plate well. The LIMS also provides useful information such as instrument, supplies and personnel availability prior to making a 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

A LIMS solution can help to address all of the above challenges and enable collaboration and sharing to support translational science, whether it is deployed at a single organisation or as a collaborative LIMS solution across a consortium. A LIMS can provide scientists with all of the information they need to track their experiments and view the progress of patients in a clinical trial. A LIMS is a critical tool for managing and optimising laboratory operations and allows users to know what equipment and personnel are available in the laboratory, helping scientists prioritise work. A LIMS 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. A 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.

About the authors



Trish Meek joined Informatics when Thermo Fisher acquired Thru-Put Systems, Inc in June 1999. She is the Director of Product Strategy, Life Sciences, and is responsible for determining the strategy of Thermo Fisher's current portfolio while identifying new market opportunities within the Life Sciences. She has worked for Thermo Fisher for the past nine years in the development, sale, support, and marketing of laboratory software. A graduate of Loyola University with a BSc in Chemistry, Trish began her career doing environmental analysis and chemical vapour deposition research. [Email: trish.meek@thermofisher.com](mailto:trish.meek@thermofisher.com)



Dennis K. Fallen is Vice President and General Manager of Fisher Bioservices, having joined in July 2007. He has more than 25 years' experience in the healthcare industry – prior to joining Fisher Bioservices he led the development of a new business for a specialty stem cell processing company, and prior to that was founder and CEO of a company providing unique management services to hospitals and medical device corporations in the transfusion medicine market. He previously served as President of Business Development in Baxter Healthcare's Biotech Group (now Bioscience Division). Dennis is a graduate of DePaul University in Chicago, IL and has an MBA from the Charles H. Kellstadt School of Business. [Email: dennis.fallen@thermofisher.com](mailto:dennis.fallen@thermofisher.com)

MORE PATIENTS. RIGHT LOCATIONS.

Rapid Recruitment, 58 Countries Worldwide.

PharmaNet's global footprint, rapid patient recruitment, and therapeutic expertise ensure your clinical trials are conducted efficiently and effectively. Our global teams conduct streamlined multinational studies or smaller regional studies with the knowledge of local culture, practices, and regulatory requirements. **PharmaNet works for you** on trials of any size, anywhere around the world.

609 951 6800 www.pharmanet.com

 **PharmaNet**
Works For You

Phase I-IV

Bioanalytical

Bioequivalence

Consulting

Staffing