WHITE PAPER

IMPROVING EFFICIENCY IN DELIVERING CLINICAL LABORATORY RESULTS USING A CLOUD-BASED LIMS

A cloud based LIMS improves clinical laboratory efficiency

CloudLIMS
Empowering Labs

427 N Tatnall St #42818 Wilmington DE 19801-2230 USA
www.cloudlims.com | support@cloudlims.com | +1-302-789-0447

INTRODUCTION

The move from strictly paper-based processes in the clinical research laboratory to processes that are more automated and paperless has been ongoing for several decades. Driving this change has been the promise of greater laboratory efficiency and more time for laboratorians to focus on other aspects of the lab. This move from paper to electronic information management has required a solid in-house information technology (IT) foundation that includes investment in hardware, data management software like a laboratory information management system (LIMS), middleware, and IT personnel to manage it all.

However, clinical research and testing laboratories have seen a fundamental shift in analytical tools and knowledge, which in turn has increased the variety, velocity, and volume of data being created. High-throughput sequencing and more federated methods of integrating real-world data sources create new "big data" challenges for these laboratories. Whole gene sequencing has become easier and more cost-effective to implement in the laboratory thanks to advances in technology and greater competition. Patients participating in clinical trials today may now wear mobile, network-connected health devices that can be monitored over the cloud, adding even further to the data deluge. This requires an improved, more holistic approach to data management, one that draws both from the sample-based approach typically associated with a LIMS and the patient-based focus of a laboratory information system (LIS). Additionally, as the software-as-a-service (SaaS) model has matured, a cloud-based clinical LIMS that is scalable, portable, and cost-effective, while further improving laboratory efficiency, has becomes more realistic and appealing.

CLINICAL DATA MANAGEMENT CHALLENGES

Many data management challenges await the intrepid clinical researcher today, and how they are addressed may shape the future overall success of how service is rendered. In 2014, Jones et al. made clear that despite laboratory computing driving innovation in how health outcomes are improved and laboratories are managed, clinical data management is at risk of falling behind due to rapidly changing demands in healthcare. They addressed the following types of clinical data management challenges for researchers[1]:

1) More frequent high-throughput data streams in clinical research and testing.
2) New methods of service delivery, such as point-of-care testing.
3) A greater push for more evidence-based medicine.

4) An increasingly vital integration of data and services at all levels of the clinical sphere.

Today, those challenges remain and are even more acute in some cases. In particular, integrating research laboratory and business workflows, patient and customer data, and test results with patient outcomes creates greater value to not only the laboratory but also the patients they ultimately affect. When pairing the need for this integration with the wealth of analytical data from high-throughput sequencing and other sources, it becomes clear that clinical research laboratories need solutions to better improve laboratory efficiency and save personnel time.

What other needs do these laboratories have that demand intelligent data management solutions? First, clinical and pre-clinical data management needs to be easy for researchers and laboratorians to learn and use, while providing core functionality that helps researchers make new discoveries and improve patient outcomes. A clinical data management solution that is cluttered and unintuitive, requiring too many steps to complete tasks, slows down workflows and increases the time it takes for patients to receive results. Second, a modern solution for clinical and pre-clinical research needs to flexibly handle structured and unstructured data securely and without error. Error-free tracking and traceability of specimens across multiple locations is necessary for a variety of research and testing labs, all while maintaining patient confidentiality and allowing for secure organizational and third-party data sharing — even in real time — as necessary.

Additionally, researchers increasingly need a system that can integrate with other informatics systems such as customer relationship management (CRM) and electronic quality management systems (eQMS), whether they be local or also in the cloud. Finally, given shrinking budgets and globalization of services, a data management solution needs to be cost-effective and agile. A system that is globally accessible and has standardized architecture, all with a relatively low total cost of ownership in the long term (taking into account software maintenance, licensing costs, and internal IT costs) is more necessary than ever before.

CLOUD LIMS FOR CLINICAL DATA MANAGEMENT

A paper-based methodology combined with a smattering of data management tools has historically been the route most frequently used to combat the critical challenges of a clinical research laboratory. However, with new data management challenges and needs arriving at researchers' front door, a more robust clinical LIMS paired with a reliable and secure service-based distribution model offers greater efficiencies and reduced task time to clinical researching and testing laboratories.

Undoubtedly, any clinical data management solution that streamlines workflows and automates manual tasks can create a more efficient lab and save laboratory personnel time. Dr. Nicole Tolan, the Associate Director of Clinical Chemistry at Beth Israel Deaconess Medical Center and the Director of Scientific and Medical Affairs at SCIEX, notes that "taking even the smallest steps to simply replace the current manual processes with autoverification generates efficiency and, ultimately, the time needed to develop more sophisticated rules" that flag specimens requiring exceptional handling.[2]

Yet a modern LIMS for clinical data management can do more than test result autoverification to make workflows more efficient. The testing phase of specimens and related aliquots requires rigorous tracking of their status, while maintaining a clear chain-of-custody and current storage location, down to the rack slot position or storage box number. If specimens need to be shipped elsewhere, flexible business logic that can handle shipment tracking is also required. Additionally, a LIMS for clinical research will need to address specific design needs for qualitative and quantitative analyses as well as study management. After test results have been autoverified (or handled as exceptions), they need to be reported and authenticated. Reports should be customizable to a lab's needs and support HL7, electronic signatures, and visualization of data. The LIMS should also provide enterprise system integration, which allows for a more focused end-to-end flow of data across the entire clinical workflow. A well-designed clinical LIMS can handle all these requirements and more, while readily meeting the challenges of today's data-heavy, competitive clinical research and testing labs.

Then there is the matter of the cloud and its benefits. In particular, a cloud-based LIMS has the potential to meet today's challenges and adapt to tomorrow's. A LIMS hosted in the cloud offers flexibility, allowing for different hardware and operating system configurations based on the lab's needs and providing wider, more global system availability. Customizable workflows and variable data sources and intake (the problem of data volume, variety, and velocity, as found in high-throughput sequencing and biobanking) are also readily handled in a cloud-based LIMS.[3, 4] A cloud LIMS should be scalable, able to have its background resources dynamically adjusted to take advantage of business expansion and changing business requirements. And of course, cloud hosting has the potential to reduce the total cost of ownership (TCO) of a LIMS. A 2015 analysis by Beroe, Inc. suggested a cloud-based LIMS could produce significant cost benefits over 10 years when taking into consideration reduced IT infrastructure costs and reduced upfront investment.[5]

CLINICAL DATA SECURITY AND OTHER CONSIDERATIONS

Despite the myriad benefits a cloud LIMS has in managing both clinical and pre-clinical data and workflows, laboratory managers shouldn't implement the first option they discover. Not all SaaS-based LIMS offerings are alike in their features and service packages. Special considerations concerning data management, data security, regulatory compliance, and service level agreements should be made in the context of a laboratory's specific needs.

First and foremost, whether upgrading an existing LIMS or implementing a new LIMS for the first time, a master data management (MDM) strategy should be created to better guide the purchase decision. The MDM should largely be driven by management's business vision. In the case of clinical research and testing labs, that vision may be centered upon providing accurate results and meaningful research, ultimately improving patient outcomes. The MDM may also work hand-in-hand with the lab's quality management system (QMS), with a focus on providing and linking accurate data and metadata across multiple IT systems that are standardized, searchable, and, in some cases, mineable. For the small independent clinical laboratory, this may not be so critical; however, even the smallest labs can benefit from having at minimum an extensible data management plan that takes future growth into account.

Just as important are the security and regulatory requirements needed of a cloud-based LIMS. Is the service staff of the hosting company trained in the requirements associated with Title 21 CFR Part 11 and the Health Insurance Portability and Accountability Act (HIPAA)? How easy and secure is it to integrate other clinical applications (locally and hosted in the cloud) such as clinical trial management, interactive voice/web response, and drug safety systems with the cloud LIMS? What sort of built-in disaster recovery options are available? Are the unique regulatory requirements of speciality labs such as biobanking facilities addressed? All these questions and more should be asked of the service provider.

Finally, having a solid service level agreement that covers all important considerations and delineates who is responsible for what proves invaluable. While there are definitely benefits to moving from an in-house to a managed services model, the change shouldn't be taken lightly and questions should be asked. Does the communication between the cloud LIMS and local instruments occur directly, and if not, what safeguards have been put into place to ensure the indirect communication hasn't been tampered with? Where are the servers holding your data located? What does the vendor mean by a "prevalidated" system? What are the details

on the audit trail file and what advanced options are available for logging specific information?[6]

CONCLUSION

Clinical research and testing laboratories, like many others, have unique needs when it comes to data management. For many of them, the standard LIMS is not enough; data streams have become more varied at increasing velocity and in increasing volume, inevitably becoming siloed and difficult to work with. These laboratories require a more robust, flexible solution that can integrate and standardize data from top to bottom of the business chain, allowing for greater insights, increased rapidity, and more efficient processes. The cloud-based clinical LIMS, when properly implemented and serviced, gives clinical research and testing labs an edge and allows them to serve their customers and patients better in less time and for a lower total cost of ownership.

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