WHITE PAPER

ENHANCING LABORATORY EFFICIENCY USING COST EFFECTIVE LIMS FOR BIOBANKS AND TESTING LABORATORIES

CloudLIMS
Empowering Labs

4023 Kennett Pike #50373 Wilmington DE 19807 USA
www.cloudlims.com | support@cloudlims.com | +1-302-789-0447

Modern day labs are under constant pressure to reduce expenses, improvise lab efficiency and constantly enhance the quality of results. To begin with, it is important to understand what lab efficiency exactly means. In simple terms, lab efficiency is all about how a lab effectively manages time and available resources to improvise data quality, eliminate manual errors, improve laboratory results turnaround time, and streamline lab operations. Many labs are interested in improvising their lab efficiency; however, and are not keen investing in cost-intensive Laboratory Information Management System (LIMS) to manage their laboratory data. Labs continue to use paper based systems, spreadsheets, customized in-house developed data management tools, or a combination of these to manage their data. Such labs do not realize the adverse effects of using these outdated data management practices on their lab efficiency. This white paper underlines the challenges faced by biobanks, clinical research, and diagnostic labs and how switching to a cost-effective cloud based LIMS can help to improve lab efficiency by automating various lab processes.

Some major challenges of modern day labs and how LIMS can effectively address those challenges to enhance laboratory efficiency.

1) Big Data Management: A biobank is a repository or storehouse which collects and stores biological specimen such as blood, serum, tissue, DNA, etc. and keeps a record of sample origin, medical history and demographic information of patients or representatives of the human population. Today, Biobanks play an increasingly important role in healthcare industry and clinical research as they become more patient-centered and medicines become more personalized. Biobanks prove to be an important resource to researchers by providing diverse specimens, thereby facilitating complex studies to understand the underlying mechanisms of various diseases such as cancer. Biobanks and clinical research laboratories usually receive hundreds of thousands of samples per day. Sample tracking and managing a huge number of samples including associated patient data manually, and using paper based systems or spreadsheets, can be a daunting and time consuming task. This challenge can be overcome by using a LIMS. A LIMS can improve efficiency of biobanks and clinical research laboratories through sample accessioning and facilitating seamless sample tracking through the use of barcodes. A LIMS can store patient data, sort and quickly retrieve it, and can generate comprehensive reports in a desired format in a few clicks.

2) Ensuring Patient Privacy: Safeguarding sensitive patient information from unauthorized access is of paramount importance to biobanks and clinical labs. This ensures donors' rights are

not violated under any circumstances. A LIMS can play a crucial role in safeguarding patient information by ensuring that it follows the guidelines laid under the HIPAA (Health Insurance Portability and Accountability) Act of 1996 to adopt national standards for electronic healthcare data transactions. Per the HIPAA Privacy Rule, all data management systems such as LIMS that oversee health information must secure data with passwords, data encryption and other technical safeguards.

3) Real-time Collaboration Between Clinical Laboratories, Physicians and Patients: Clinical laboratories across the globe are facing tough international competition to reduce cost, and provide faster high quality results. Many times, specific clinical tests are outsourced to distant clinical laboratories having multi-specialized facilities so that tests can be performed with utmost accuracy and in minimal time. It is important that physicians should be able collaborate in real time with clinical laboratories to quickly order testing of samples. As soon as sample testing is complete, the physician should be able to instantly access the test report so that they can analyze it and recommend personalized medicine for their patients on time. A cloud based LIMS can be a powerful resource that bridges the gap between clinical laboratories, physicians, and patients and pave the way for superior healthcare. A cloud based LIMS will enable physicians to place online orders for clinical tests, track progress of their ordered tests, instantly access test reports, and recommend personalized medicine besides ensuring secure electronic transmission of test reports to patients.

4) Meeting Regulatory Requirements: A large number of testing laboratories worldwide need to meet one or more regulatory requirements such as GLP (Good Laboratory Practices), ISO/IEC 17025-2005 etc. The GLPs are designed to protect integrity of scientific data. ISO/IEC 17025-2005 specifies the general requirements for the competence of testing and calibration laboratories and is applicable to all laboratories performing tests and/or calibration. A LIMS can be instrumental in helping labs to meet the necessary regulatory requirements. A LIMS can help labs establish protocols, processes related to laboratory test results, and documentation methods that meet ISO/IEC 17025-2005 guidelines. For meeting GLP regulations, a LIMS can help labs to maintain a record of resources (facilities, equipment, etc.) employed to perform the test, details about the test item and test system (plant, animal, etc.), protocol used to conduct the test, besides saving results (raw data, final report, and archives).

5 Data Security: Confidentiality of laboratory data is of paramount importance for laboratories worldwide. In the case of cloud based LIMS, the actual LIMS software resides on a highly secure

cloud server. It is the responsibility of the cloud provider to ensure the security of users' data. They employ a dozen compliance programs in their infrastructure that ensure data protection, prevent IP address spoofing, shut down port scanning, etc. Additionally, they use industry standard encryption technology to secure data transmission across the web. Breaching all these security measures is practically impossible. Hence, users do not need to worry about the security of their data when they are managing their data using a cloud based LIMS.

6) Managing Sample Requests by External Researchers: Many biobanks usually receive a large number of requests for different sample types on a daily basis. Managing such requests manually or by using spreadsheets is error-prone and time consuming. A LIMS can automate the registration of samples and external users, besides enabling them to directly place their requests for new specimens. All new specimen requests should be registered in the LIMS to ascertain that they are not lost and approved by the lab manager on time for further processing. Besides, a LIMS can quickly search the database based on sample type and other demographic factors to check if the requested sample is in stock or not. For example, an external researcher is interested in conducting blood cancer study among caucasian patients of age 30-40. To accomplish this objective, the researcher places a request for 5000 blood samples from different patients in the age range 30-40, each sample constituting of 1 ml blood. Here, a LIMS can play a pivotal role in improving turnaround time by enabling a biobank to quickly search their blood sample database and determine if they have sufficient volumes of the requested samples. This functionality in turn helps the lab manager or lab director to quickly take the next step and notify the researcher whether his request can be fulfilled or not.

7) Maintaining Sample-Based Chain of Custody: In many testing laboratories, a sample may be used in multiple processes and locations by different laboratory personnel and at different times. Maintaining a chain of custody, from the time a sample is received by a lab until the time it is disposed of, helps keep track of the original custodian of the test and all subsequent custodians. Additionally, the date and time of transfer of custodian for each sample is also recorded. This helps laboratory managers identify the owner of a sample at any point of time. Illegible and incomplete chain of custody is one of the main concerns of labs across the globe. This can lead to loss of samples at times. A LIMS can automate this process by electronically maintaining a chain of custody for each sample along with date and time stamp.

8) Maintaining a Record of Permanently Disposed Samples: If a sample is contaminated, no longer required, or if at any time consent is

withdrawn by the donor, it is the responsibility of the laboratory to permanently dispose of that sample. Managing information of disposed samples manually or using spreadsheets can be detrimental to the efficiency of the concerned lab. A LIMS system can help lab administrators to seamlessly keep track of disposed samples along with the protocol followed for sample disposal.

9) Making Informed Decisions to Replenish Depleting Samples or Lab Inventory Stock: It is imperative for a laboratory to maintain a record of the total and current volume of samples so that replenishment decisions can be taken on time. Manually alerting lab managers or concerned personnel regarding the depleting sample volumes for thousands of samples is not feasible. Here, a LIMS can come to the rescue of lab managers by alerting them via emails regarding the critically low volume of samples. This improves the turnaround time and efficiency of any lab by avoiding any delay in fulfilling sample requests, and also helps lab managers make informed decisions a lot faster.

10) Storing and Organizing Information of Aliquots and Derivatives: In many labs, a large number of aliquots or derivatives is created from a large number of parent samples everyday. A LIMS can enhance the efficiency of such labs by keeping track of aliquots/derivatives created and their genealogy along with their storage locations.

11) Real-time Integration with Automated Analytical Instruments: The integration of analytical instruments with LIMS will maximize automation in data transfer, both uni-directional and bi-directional. A LIMS can interface with analytical instruments through an Application Programming Interface (API) that enables one-way and two-way communication, thereby seamlessly facilitating data transfer between LIMS and the instrument. This will escalate lab efficiency by enhancing the accuracy of reported data, reducing the expenses incurred in manual data reporting and by transferring sample results into LIMS faster, thereby improving sample turnaround time.

12) Laboratory Inventory Management: Many laboratories manage supplies such as glassware, kits, plasticware, reagents with nothing more than sheets of paper in a binder or entries in an Excel spreadsheet. Manual entry of lab supplies may lead to erroneous entry of number of lab supplies available in stock, reduce lab productivity, increase expenses, besides causing an unexpected delay in placing orders to replenish the existing stock. A LIMS can effectively manage not only lab inventories but also inventory orders. By registering different laboratory inventories in a LIMS, lab users can set expiration alerts, for e.g., reagent expiration date alert. These alerts will help lab managers to

timely place orders for the lab inventory that is either going to expire or whose availability is critically low in the lab.

13) Managing Billing and Invoicing Process: Proper management of lab finances is crucial for financial and operational efficiency of a lab. Many labs still handle finances manually as a discreet business process. However, this can be a time consuming task, thereby compromising lab efficiency. A good LIMS solution can automate this process by taking care of the financial documentation of all sorts. A centralized automated billing and invoice management using a LIMS will help to keep track of all orders placed, expenses incurred, pro forma invoice/price quotes generated, workload tracking in case of billable man hours etc.

14) Managing Incoming and Outgoing Packages and Shipment: The receiving department usually receives a large number of samples per day for testing or storage. Additionally, many samples are shipped to external researchers or collaborating laboratories. Hence, it is imperative to keep track of all incoming and outgoing packages. Tracing them manually is error prone and may lead to loss of packages at times. A LIMS can significantly reinforce lab efficiency by automating the tracking mechanism. A LIMS facilitates lab managers and authorized personnel to register all incoming and outgoing packages. A unique system generated packaging ID is assigned to each incoming and outgoing package for better tracking. Besides, it keeps a record of package origin and destination, packaging date, sender or recipient information, tracking ID and carrier etc. Many LIMS systems also enable labs to assign unique barcodes to each and every incoming and outgoing package for effectively managing shipment.

15) Audit Trail: Most labs, specifically regulated laboratories, need to keep a documentary evidence of sequence of activities performed by all users along with the corresponding date and time of each activity. Manual documentation is almost impossible. A LIMS can enhance lab efficiency by maintaining an electronic audit trail along with date and time stamp. Based on user-specific login, a LIMS can maintain an electronic record of all activities performed by different lab members in real time. Since the audit trail is now taken care of by the LIMS, researchers can devote more time on their core research.

16) Managing Tests and Test Results: Modern day labs conduct several tests, both quantitative and qualitative, everyday. Efficient management of tests and test results can decrease turnaround time by providing faster results to clinicians, researchers and testing labs etc. It is essential for labs to keep a record of the samples used in the test, manage multiple test runs, calculate an

average based on the observed value of multiple test runs, flagging test results if they are critically low or high for taking informed decisions. A LIMS can help labs not only to effectively manage various tests and their results under one niche, but also can facilitate labs to generate customized portable reports of test results in desired layouts in a few clicks. Besides, it also facilitates recording of analysis comments or remarks where manual interpretation of test results is required.

WHAT IS A COST EFFECTIVE LIMS?

A LIMS solution that maximizes investment returns, decreases total cost of ownership, and offers benefits over other products in terms of functionality, services and support can be termed as a cost effective LIMS.

On-premise LIMS is expensive and difficult to manage without the aid of trained IT personnel. In case of on-premise LIMS, the client and the server need to be configured in the same network area. Besides, any configuration made to the LIMS server should be replicated at the client level as well to reflect the customized modifications. On-premise LIMS has some major disadvantages such as requirement to purchase expensive hardware, license and upgrades; need for trained IT personnel and IT maintenance budget allocation; fear of data loss in case of natural calamities, in addition to costly customization, training and support services. Amongst the different types of LIMS architecture available until date, cloud based LIMS is the most economical solution to manage lab data and automate lab workflows.

CLOUD BASED LIMS OFFERED AS SAAS (SOFTWARE AS A SERVICE)

A cloud based LIMS is the most cost-effective LIMS solution available until date and is a boon for laboratories that cannot afford to purchase an expensive on-premise LIMS solution to manage their laboratory data. In the case of cloud based LIMS, the actual LIMS software resides on a highly secure cloud server and authorized users can access it using a web browser on any internet-ready device. Cloud based LIMS imparts zero footprint on the users' computer, thereby eliminating any pre-installation requisites on the client computer. All necessary upgrades are done by the service provider who hosts the LIMS application. Hence, users no longer need to bear the additional charges for receiving upgrades.

SOME ADDITIONAL ADVANTAGES OF CLOUD BASED LIMS ARE:

1) Users no longer need to be wary of data loss due to natural calamities since the data is hosted on mirror servers located at different geographical locations and regular data back-ups are performed to maximize data recovery.

2) The use of cloud computing helps researchers and labs to share their data in real time with their external peers located at different geographical locations.

3) Cloud based LIMS is highly scalable making it a preferred choice to cope with the ever changing laboratory data management needs.

4) Users do not need to invest in IT infrastructure or hire IT personnel, thereby reducing expenses.

SaaS is the present day software delivery model for cloud based LIMS. SaaS model leverages a popular payment model, Pay As You Go (PAYG) model. This model facilitates users to pay only for the services available to them and only for the duration they use the software. The SaaS model now enables labs to subscribe to the LIMS software, usually on a monthly basis, rather than purchasing full licenses at a skyrocketing price. Additionally, some vendor offering cloud based LIMS as SaaS offer users to purchase the LIMS software in modules. This means that they can purchase only those modules that they require for their data management.

CONCLUSION

Lab managers across the globe put relentless efforts to accelerate lab efficiency, reduce lab expenses, without compromising the quality of results. Manual data management practices using traditional paper based systems and spreadsheets cannot help labs to efficiently manage massive volume of data generated per day. Furthermore, many labs, specifically clinical labs, need to operate under stringent regulatory guidelines as well. It is time to embrace new data management solutions to stay afloat in the highly competitive environment. A cloud based LIMS, employing PAYG payment model, is the most economical lab data management solution known unto date. A cloud based LIMS can geographically disperse labs to collaborate and securely share their data in real time, improve turnaround time of lab tests, quickly generate reports with minimal manual intervention, effectively manage lab inventory, orders, bills and invoices, etc. Additionally, a cloud based LIMS is highly scalable, thereby making it capable to meet the ever growing lab needs of today and tomorrow.

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