WhitePaper

Clinical Laboratory Information System Implementation Brief:

What You Need to Know About LIS Installations, Conversions, and Interface Projects

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Introduction

A June 2019 laboratory information system (LIS) market report shows demand for a modern LIS driven by the acceleration of laboratory automation and need for better lab efficiency; advances in integrated functionality; the need to comply with regulatory requirements; and the rising prevalence of chronic disease.

However, if evidence showed that health information technology projects exceed budget, drag past their target date for going live, or are abandoned or cancelled, would laboratory information system projects show similar results? The answer is 'yes'—without a project map, team buy-in, setting expectations, and effective project management.

Numerous reasons now compel hospitals and independent laboratories to invest capital and mindshare in a major laboratory information system implementation, including:

- Lack of current vendor support,
- Slow system functionality,
- Expanding testing, including molecular testing,
- Need for increased data storage,
- Compliance,
- Business strategy alignment,
- Introduction of new laboratory equipment, and
- Partnership development.

Urgent needs revolve around changes in regulations, compliance issues, growth in test menus and test menu requirements, reimbursement, and overall mounting tension over slow and inadequate laboratory information systems. All laboratories are being asked to do more with less.

Laboratory directors, medical technologists, physicians, clinicians, and most importantly, patients need an LIS that works like a sail rather than an anchor. An estimated 60-70% of all decisions regarding a patient's diagnosis, treatment, hospital admission, and discharge are based on the results of tests that medical laboratory scientists perform. **A modern LIS is key to quality operations.**

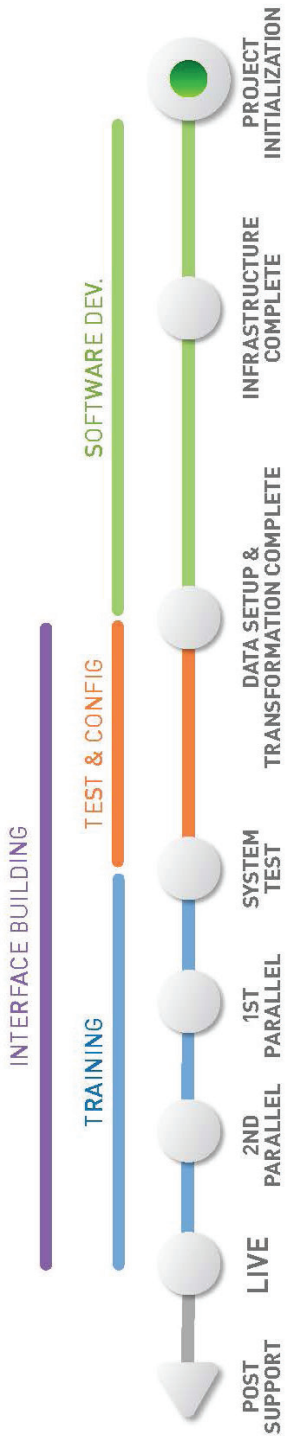
When I started my career in the healthcare industry in the mid-1980s, one of my initial projects was to design and build a laboratory information system for National Health Labs. It took us six months to design a system and another year to build the software that was to go into 16 different locations.

From initial conversations to total implementation, the whole process took five years—yes, five years. That project got especially complicated because, just as we were finishing, the company merged and became LabCorp. We ended up carving up that system, and I believe to this day they still use part of it as a worksheeting system. It's one of the few things I did during the 1980s that is still relevant—unlike those Flock of Seagulls cassettes.

Installing, converting, and interfacing a laboratory information system is an enormous project that is often fraught with challenges. But I've seen it bring laboratory teams together toward the common goals of expanding the lab's capabilities, ensuring efficient operations, and producing quality improvement.

The years and projects have shown me a clear project map to LIS implementation. That is the focus of this white paper, and I have written this guide to help lab directors know what to expect through each of the four phases of an LIS change.

—Bryan Firestone, Founder, U.S. HealthTek



Part 1:

Major Components of a Clinical Laboratory Information System Implementation

An LIS implementation project usually follows a six- to nine-month timeline and consists of four major components: 1) infrastructure; 2) data; 3) software; and 4) training/testing.

While each of the four components has its own unique needs and complexities, the overall project requires early care and attention to existing workflows, processes, and especially, the lab culture. Operational workflow must change, which is a huge obstacle for those entrenched in the habits of manual, laborious workarounds.

Along with the four major components of an LIS project, **installations and conversions take place in four phases.** One long lead-time step that is necessary to troubleshoot earlier rather than later is external interfaces.

As many labs are moving toward 100% electronic, paperless requisitions and reports, interfaces that are built in the legacy LIS must be rebuilt into the new LIS. And labs must have their test/result code and client file database built or at least specified to accomplish this. Without planning, laboratories usually find themselves at the mercy of their electronic medical record (EMR) vendor, hospital, or reference lab, as each has a large working queue where the lab's tasks will be placed.

The contracted project manager (PM) typically represents the lab client when the lab does not have the resources or personnel to dedicate its own LIS implementation project manager.

Phase 1:

Project Initiation, LIS Preparation, Gap Analysis, and New Software

An LIS implementation project is like a symphony, and the project manager is the conductor. A conductor knows the music that is being played throughout the piece, knows how the different instruments and movements fit together, and can lead the orchestra in perfect harmony. An experienced, qualified project manager understands and can anticipate all the moving parts that are required to successfully install a laboratory information system. ***Preparing for the LIS project*:**

Communication: Setting the expectations at the beginning is crucial. Timing of events affects the outcome of the product. Knowing what is required of the lab staff—and when—helps lab management plan for both the interruptions and the additional spend of overtime (OT). **A PM will set a cadence of communication that will keep all informed on what is happening and what to expect next.**

Gap Analysis: It is important to compare the functionality of the old system to the functionality of the new system, as well as identify things that may not be able to be handled by the new LIS software. These types of exceptions are usually proprietary techniques, testing, or customized software, that make the lab unique, and they require special accommodations within the LIS. Specifically, reporting is usually the differentiator. A lab will produce a special report format or capability that highlights its testing. Sometimes this is done with a web portal. Whatever it is, it must be accounted for (i.e., spec out software to be written and tested) and built into the project plan.

New specialized software is a long lead-time aspect of an LIS implementation and needs to be identified at the beginning of the project.

Infrastructure: This is the foundation of the LIS. **The biggest mistake you can make is to build a house on a foundation that is too small or weak.** Doing so would require future repairs or even a rebuild, which you want to avoid if possible. Infrastructure is your hardware, network, and peripherals. It is important to have a robust, flexible, and stable foundation to support the needs of the software. Don't do it "on the cheap." You will pay for it eventually, and not with funds. Labs that scrimp by, purchasing equipment from Walmart, Amazon, and eBay, tend to suffer from outages and nagging, unexplained faults.

Security is the most prevalent subject in managing information today. Health information security requires continual assessment of risks to electronic and all health information. Seek out experts who have experience in this area.

Two Key Questions to Ask/Answer

1. ***Do you want or need to house your laboratory information system on premises (on prem) or in the cloud?*** Today, we are seeing a shift to putting as much as possible into the cloud, typically with one of the three major providers (AWS—Amazon, Azure—Microsoft, Google).

2. ***Does the vendor's LIS work in a hosted environment?*** If the vendor's LIS does not work in a hosted environment, it probably means that it is a legacy developed application and isn't current technology. Obviously, this is a complex topic and cannot be covered and given the space it deserves in this paper. Seek out the experts who have experience in this area for their advice.

Phase 2:

Installing the LIS, Configuration, Data, Interfaces

Installation of the software is usually a straightforward event. Most vendors package their LIS software so that it has an auto-installation loader. Once the software is installed, the PM will work with the departments in the lab to determine the best configuration of the software that will provide the highest level of efficiency and the least amount of impact to the workflow. ***Key elements:***

Configuration: Flexibility is key here. **Do not have the vendor rebuild the software to match your workflow** (unless your testing cannot be accommodated by the existing functionality of the system). The underlying system architecture of the LIS is usually designed and programmed to follow a single workflow. Deviating from this design introduces workarounds that lessen efficiency, often introducing quirks, bugs, and annoying time wasters. **It is generally better to configure your workflow to match that of the LIS.**

Data: This consists of all the static files (client and test code files) and volatile files (patient and log files) that the lab will use to operate the LIS. If you are moving from an existing LIS to a new one, conversions are in order. Conversions are more common, but some startup labs launch with a blank slate. Putting some thought behind your test code and client file naming/numbering approach can add visibility and additional organization to your files. An experienced PM can help guide the lab through the multitude of naming/numbering schemes, along with the pros and cons of each.

Important: Testing and interface building cannot really begin until the database is built. The database files are required to test all aspects

of the system functionality. One approach is to build test code, message code, and result code files by department, so the lab can test earlier. If the database is being converted from an existing LIS, now is the time to clean it up. Test code and client files get junky with time. Instrument interfaces require lab resources and instrument time. This can be disruptive and cause stress on your lab staff. (Pizza is always a favorite way of saying thanks!)

External Interfaces: Another long lead-time step in the conversion of a laboratory information system is interfaces. Interfacing to a hospital's LIS, a commercial lab's LIS, a physician office's EMR, or an electronic health record (EHR) system involves many variables that affect configuration, and consequently, that influence the capability of data sharing from system to system.

Interfaces that are built in the legacy LIS must be rebuilt into the new LIS. This means that processes and workflows must be considered and accounted for. However, if you planned ahead in your legacy LIS architecture and implemented an interface engine, this transition will be much easier.

- INFRASTRUCTURE
- DATA SETUP & TRANSFORMATION
- SYSTEM TEST
- TEST AGAIN!
- GO LIVE

Part 2:

Critical LIS Testing and Parallels: Can We Achieve a 'Non-Event' at LIVE?

Effective LIS project management can help the lab's implementation team feel successful. However, by the latter half of the project, the additional stress of the implementation running parallel with daily lab operations may become evident.

The obstacles inherent in an LIS implementation are rooted in its complexity, as well as each lab's unique requirements, forward planning, risk, and cost. Technical issues and trade-offs, performance specifications, and project scheduling also are important considerations.

When harmony seems like a pipe dream, an experienced LIS implementation project manager can keep the lab's objectives on track. Keep in mind, though, that the work of leading the LIS implementation project is not for the designated project manager alone.

It is important to identify project champions early, as well as a point person for assessing early warnings that may hinder the project's goals. Senior laboratory leadership must also take time to listen, understand, and communicate during the project, at go-live, and beyond.

By the end of Phases 1 and 2, data setup and transformation should be complete. All attention will be toward preparing for system testing, training, go-live, and support.

Phase 3:

Laboratory Information System Testing and Training

In Phase 3, the LIS is tested. Expect and prepare to address gaps.

Testing will likely reveal gaps that need to be addressed. Expect them. Lab systems and the labs they serve are complex, and the complexity is multidimensional.

Testing usually follows a process of functional or unit testing, module testing, system testing, and parallel testing. In functional/unit testing, the user tests a step or function, such as data entry or worksheet build. Module testing includes testing all functions used within a group, department, or functional area, such as management reports or resulting/releasing of results.

Arranged in advance of and during module testing, **training** is usually conducted using train-the-trainer methodology, in which superusers are trained and become responsible for training the lab staff. **All training conducted is documented for each lab staff member.**

Frequently Asked Question—*Where can we expect to spend the most time testing?*

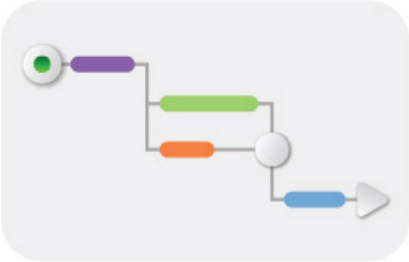
Answer: The most time-consuming testing is system tests and parallels, when the entire system is exercised from front to back. Usually a system test is performed by the vendor, IT, or a small group of superusers. Functionality of the system is tested here. Factors such as system speed, hardware stability, configuration completeness, missing or incorrect data, and successful development of any new software are determined.

Without a satisfactory grade of the testing, a lab should not proceed to parallel testing.

Documentation of all testing is required for most regulatory agencies, and all documentation should be kept in a book, as well as online in the company's electronic repository. **Note:** During testing, turn off all client-facing output.

Parallel testing is basically a system test. However, it is performed by the laboratory, where a small sample of real requisitions that are production tested on the legacy system, is tested on the new system, and the reports are compared side by side. The use of the real specimen is optimum, but not required. Normal and abnormal results are needed to test flagging and messaging. The results will not be perfect.

It usually takes at least two parallels to get to an acceptable position. Test until lab personnel are comfortable with both the results and the system.



Phase 4:

Laboratory Information System LIVE and Support

Going LIVE with an LIS is both exhilarating and nerve-racking. If the PM and the lab have built a great plan, followed the proven methodology, not cut corners, and tested and retested, LIVE should be a non-event. Even with "non-event" in mind, there is still much to do.

What to expect:

A LIVE event is usually scheduled on a Friday, Saturday, or Sunday (depending on which day/evening works best for the operation). This allows for recovery. Also, it takes time to convert interfaces. There are some novel approaches to this, which is another topic altogether.

Frequently Asked Question—*How do we know we are ready to go LIVE with the new LIS?*

Answer: Management will know how comfortable the lab staff is with operating the new lab system. Time and motion studies produce good estimates on efficiency. Management should sign off on the readiness of the lab, and that sign-off should be documented in the project book. A general practice is to hold all output until this sign-off has occurred. Also, management should determine whether they will notify their customers of the LIS change. Sales and customer services should be trained on what to say to clients who are inquiring regarding results or notable changes. Additionally, at LIVE, the legacy LIS is usually left running to continue to process pending orders and for inquiries. The system is eventually sunset. Typically, the legacy system's accession and history are not converted to the new system.

You will continue to tune and modify a lab system post go-live.

Key Takeaways

When it comes to LIS installations, conversions, and interface projects, there are a multitude of issues to consider. These issues will be covered in the planning documents, as they are too numerous to cover here. ***However, as you contemplate an LIS implementation, remember:***

1. Find the right project manager who will mesh well with the laboratory—a PM who represents your lab and business, not the vendor's. An experienced project manager will build a detailed project plan, engage the laboratory through effective communication, and follow through with adequate testing. This will make your LIS installation or conversion a success!

2. Eliminate as many variables, non-essential tasks, and complicated workflows as possible. These issues lengthen the timeline and add complexity without providing any value. You will continue to tune and modify your new LIS post go-live to get it just right.

3. Build budgets that are realistic. Adding a plug or a miscellaneous line item for the unknown is smart. It is not unrealistic to add 20-50% additional spend just for surprises. Get your project manager to help you build the budget as he/she will have insight into considerations not directly related to the implementation (e.g., instrument concentrators, bar code readers/printers, etc.).

4. Build delays into your schedule. Plan for personnel outages and holidays.

Enjoy the ride! Going through an LIS implementation can be exhilarating. Expect some highs and lows. In the end, though, you will see and experience the fruits of your labor. Making your lab work like a well-oiled machine not only improves morale, but strengthens your relationships with your clients and investors.

About the Author

Bryan Firestone founded his first consulting company in 2003, which was rebranded as U.S. HealthTek in 2013. He has more than 30 years of experience in the clinical and environmental laboratory space, holding the position of Chief Information Officer for major laboratory companies. He has held senior management positions at National Health Laboratories, LabCorp, American Medical Laboratory, Quest Diagnostics, Clinical Pathology Laboratories, TestAmerica Laboratories, Solstas Lab Partners, and U.S. HealthTek. In addition, he has several years of experience managing and automating a semi-conductor reliability testing lab for United Technologies. For more information about LIS implementation, Firestone can be reached at *bryan@ushealthtek.com*.

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