

Positioning Your Biobank for Success



FROM THE EXPERTS

According to Michael Shanler, Analyst, Gartner, “If the situation presents itself, take the opportunity to reduce the footprint of legacy ELN and LIMS systems, consolidate them into one system that is more suitable for expansion with the enterprise, and extend it to collaborators and supply chain partners.”¹

– Gartner

WHY A PURPOSE-BUILT LIMS?

The Data Management Challenge

A successful lab is more than a scientific hub. In today’s age, it’s a digital data enterprise. An oil and gas lab managing hundreds of concurrent tests, a food and beverage lab tracking incubation in real time, a biobanking lab with a vast and complex inventory of samples – it’s all data. And it grows exponentially day by day, week by week, creating an urgent need for an integrated informatics platform where that data can be securely and efficiently stored, retrieved, and analyzed.

But should that platform be one-size-fits-all across industries? A pharma lab needs regulatory documentation, while a diagnostics lab requires advanced tracking of biospecimens. Traditionally, each would begin with the same basic building blocks: a Laboratory Information Management System (LIMS) with standalone point solutions such as an Electronic Laboratory Notebook (ELN) or a Laboratory Execution System (LES) daisy-chained together to approximate an end-to-end solution. Then, through a complex à-la-carte development and validation process, each of these labs would customize their platform in response to their divergent needs. Repeated for every organization, across every industry, this bulky deployment process represents an enormous amount of cost and effort, and a considerable degree of risk.

Until now.

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The Case for a Pre-Configured, Fully Integrated Solution

A purpose-built LIMS, with the option to embed ELN, LES, and other modules, leapfrogs the lengthy customization process. Because your industry’s best-established workflows and operating procedures determine its functionality, your platform is configured to meet your needs before you’ve even begun. The advantages of this accelerated start are numerous and notable.

1. Save Time

A pre-configured LIMS can deploy up to 75% faster than a more typical LIMS system. Its purposeful functionality reinforces a consistent, industry-standard workflow to help your lab achieve greater efficiency and productivity.

2. Save Money

Faster deployment and improved functional efficiencies translate to significant cost savings. Abandoning stand-alone ELN and LES products and other point solutions in favor of pre-packaged, fully embedded modular capabilities in one streamlined platform will help you maximize your return over time.

3. Reduce Risk

A purpose-built LIMS reflects industry best practices and the latest regulatory and compliance developments within your industry. As a result, it eliminates the need for custom code and reduces the overall configuration effort, thereby lowering the risk inherent with other LIMS projects.

4. Stay Focused

Lab managers can conceal or disable non-essential functionality in the purpose-built LIMS. The result is a user experience that's responsive not just to your industry, but also to the specific needs and use cases of your front-line staff. That means less training time, greater productivity, and better quality overall.

5. Future-Proof Your Business

Industry regulations and conditions change over time, and your lab will likely change too – you may add new service areas, new tests, or new users as you grow. A modular, purpose-built LIMS that makes use of industry-standard web technology can expand with you, from startup labs through global operations, without the prohibitive time, cost, and compliance issues of specialized coding.

Built Better for the Biobanking Industry

Biobanks, registries, and biorepositories need to enable advanced biomedical research while protecting data integrity and confidentiality. To do that, they need a data management solution designed for richly annotated biospecimens and compliant with regulatory requirements, patient privacy, and ethics policies.

For most of these facilities, success is determined by the answer to two important questions:

1. Can the facility connect the right people to the right biospecimens quickly and securely?
2. Is the facility compliant with the latest regulations and best practices?

The first question is about how biobanks support research interests while addressing issues of patient privacy, as stipulated in the Health Insurance Portability and Accountability Act (HIPAA).

A single specimen may move between internal and external researchers; it may be engaged in clinical or academic protocol; it may be divided into aliquots or pooled into a composite sample. At each twist and turn in this chain of custody, the potential for error multiplies. Biobanks using manual-intensive systems are especially vulnerable; the integrity of medical and epidemiological data often depends on a user's ability to accurately copy and paste a column of data from one spreadsheet to another. One wrong click and patients' consents may be lost, or clinical data may be scrambled. Catastrophe awaits.

**JUST LIKE YOUR BIOBANK,
THIS PURPOSE-BUILT LIMS
NEVER STANDS STILL.**

Our product team is constantly working on your behalf to update the platform's features and functionalities in response to shifts in the biobanking industry.

When ISBER introduced v4 of their Best Practices, we refined LabVantage Biobanking to ensure compliance. When customers with a global footprint began using the system, we added multi-national functionality to dynamically shift between languages and time zones. The updates are continuous, and because the product is 100% web-based, they're easy to integrate and accessible for every qualified user — no local installations required.

To safeguard against such errors while facilitating streamlined research and collaboration, biobanks need an alternative to data silos and manually built datasets. They need a centralized and automated solution that can:

- Track and confirm specimen details, including precise location and genealogy.
- Manage internal and external requests and uphold donor privacy.

In answer to question two, biobanks, like labs in most industries, must comply with the data integrity regulations enforced by the U.S. FDA's 21 CFR Part 11 or the EU's Annex 11. But biobanks are also under pressure to uphold a range of industry-standard best practices proposed by organizations like the International Society for Biological and Environmental Biorepositories (ISBER).

To help biobanks understand, apply, and maintain these best practices, the College of American Pathologists (CAP) in 2012 introduced the Biorepository Accreditation Program (BAP). CAP BAP is an elective program that has engaged 66 biorepositories as of early 2018; it's just one example of the many influences affecting biobanks as they navigate an increasingly complex regulatory landscape.

Such complexity would be much simpler with the right information management system. A system robust enough to maintain a high security threshold, agile enough to adapt alongside changing regulations, and intuitive enough to support global collaboration efforts between researchers.

LabVantage Biobanking is that system. It provides advanced functionality based on over 15 years' experience working with biobanks. The result is a platform that enables customers to:

Quickly Locate Specimens Using Expanded Search Criteria

Users can run searches based on subject or sample. This means researchers can more easily search the specimen collections and related clinical data.

Find Samples and Investigate Genealogy With Advanced Inventory Management Tools

Track specimens and know with precision who's involved at every point along the chain of custody. Plus, easily uncover the genealogy of aliquots, derivatives, and pooled samples.

Save Money by Optimizing Storage Space

The platform includes a visualization tool that provides a hierarchical view of specimen flow, actually showing the freezers and the boxes and plates within them. This allows users to closely track inventory and uncover opportunities to better manage freezer capacity, lowering energy costs and improving overall efficiencies.

Improve Data Integrity With Controlled Vocabulary

Through pre-established specimen accessioning, the platform compels all users to apply standardized terminology. There are few "free text" forms; instead, users select category labels from drop-down menus, which helps to reduce confusion and establish a single consistent language.

Protect Donor Privacy With PHI Masking

The platform offers enhanced privacy control with the user-driven Protected Health Information (PHI) masking function. It allows managers to selectively anonymize information related to a specimen, ensuring data integrity in compliance with HIPAA.

The Accelerated Implementation Experience

Choosing a purpose-built LIMS is like strapping a rocket booster to the implementation process. It means much of the background work is complete before you even begin, giving you a head start without sacrificing consistency, compliance, or performance.

Here's how the LabVantage implementation process compares to a typical implementation experience.

| A Typical LIMS Implementation | LabVantage LIMS Implementation |
|--|--|
| <i>Minimum 12 months to deploy</i> | <i>Deploys in as few as three months</i> |
| <p>A massive up-front investment drives this deployment process, which begins with a detailed discovery and documentation of user needs and progresses through multiple design iterations and testing phases. Heavily customized and configured systems introduce risk and its corresponding compliance requirements, necessitating a significant investment in validation and test planning.</p> <p>Once fully customized and compliant, the system is ready for use – but only after a significant investment in training for all users and administrators. Training timelines are contingent on the complexity of customization and are often a significant factor in typical deployment costs. When updates are required after deployment, the vendor must be involved for specialized customization and/or installation, further adding to the costs and time required to maintain performance.</p> | <p>Because this system is already configured for your industry using established industry best practices, the implementation process is much more efficient. Data templates are integrated and the products and functions most commonly relied upon by industry-specific users are engaged and ready. If further configuration is required, the system's modular design is easily adaptable without code; ongoing updates and enhancements require no specialized skill or outside management.</p> |

Run Your Digital Enterprise with LabVantage

Across industries, every successful laboratory functions at the nexus of talent and technology: the right people using the best, most streamlined tools. And as the market's leader in modern and efficient LIMS solutions, LabVantage is essential to that winning formula. Here's why.

The Best and Most Secure Technology in the Industry

Our feature-rich LIMS is completely web-hosted, giving networked users access to the same information from one secure, easy-to-use system – whether they are in the same lab or across the world. Hosted on-premise or in the cloud, the system also connects labs with third-party contributors outside of their firewall, like manufacturing partners or research organizations, allowing for harmonized data input through a single platform.

A System That Adapts to Your Needs – Without Code

Our purpose-built LIMS features a modular design that invites further configuration and adaptation without specialized coding skills. Users can configure their platform themselves or rely on our global professional services team to do it; both scenarios reduce the cost, effort, and complexity of additional testing and compliance.

A Fully Interoperable Experience From Start to Finish

No more siloed informatics systems for individual use cases within a product life cycle. Our system interconnects your processes within a single, central hub, meaning that documentation generated during early R&D explorations is consistent throughout manufacturing and final quality assurance testing. The result is a more efficient lab with fewer opportunities for risk, leading to a stronger business performance overall.

A Professional Support Team in Lockstep With Your Needs

From deployment through validation and ongoing monitoring, our global professional services team of solution engineers, business analysts, and project managers offer consistent and top-rated support services. We seek to become more *partner* than *vendor* through our managed services offering; for example, our team will regularly monitor, optimize, administrate, and enhance your system, giving you greater confidence and more control over your IT and labor costs.

Conclusion

LabVantage Biobanking helps biobanks, registries, and biorepositories store and distribute high-quality specimens while ensuring donor privacy and regulatory compliance.

Enhance your biobank with the full-featured, entirely web-based informatics platform designed specifically for success in your industry.

TAKE ADVANTAGE of LabVantage Biobanking at [LabVantage.com/biobanking](https://www.labvantage.com/biobanking)

REFERENCES

¹ Gartner, "Hype Cycle for Life Sciences, 2018", Published 25 July 2018, Analyst(s): Stephen Davies, Michael Shanler, Jeff Smith



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ABOUT LABVANTAGE SOLUTIONS

LabVantage is the recognized leader of enterprise laboratory software solutions with over 35 years of experience. We deliver an integrated laboratory informatics platform including laboratory information management systems (LIMS), electronic laboratory notebooks (ELN), and laboratory execution systems (LES). We support more than 1500 customer sites in the life science, pharmaceutical, medical device, biobank, food & beverage, consumer packaged goods, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, N.J., LabVantage offers a comprehensive portfolio of products and services that enable companies to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements. The LabVantage integrated LIMS/ELN/LES platform is highly configurable, purpose-built, and 100% web browser-based to support hundreds of concurrent users and seamlessly interface with instruments and other enterprise systems.

For more information, visit www.labvantage.com.