



The LIMS Reboot: Design & Build Best-in-Class Lab Workflows That Scale

Case Study

Use your LIMS to build the perfect storm of speed, quality, and efficiency —A LEAP STORY

A leading national reference laboratory partnered with LEAP to build and launch high-complexity molecular workflows. The lab needed an approach that was both aggressive and predictable; one that enabled rapid assay launches and incremental improvements while ensuring each go-live was planned and achievable.

LEAP worked with R&D, automation, and lab operations teams to map workflows and dataflows, then translate them into Epics and Stories for Agile sprints. This encompassed LIMS functionality, work instructions, compliance tasks, instrument integrations, and related dependencies. The stepwise process brought visibility, prevented delays, and improved cross-functional efficiency. The outcome was a repeatable framework that strengthened efficiency, ensured traceability, and positioned the lab to scale with confidence.

CLIENT OBJECTIVES

Scaling Operations:

Expanding operations required workflows that could grow in step with demand.

Regulatory Readiness (FDA, CAP, CLIA):

Opportunity to elevate compliance and traceability standards to meet rigorous regulatory scrutiny.

Automation & Robotics:

Multiple instruments from different vendors required unified coordination with LIMS to avoid bottlenecks.

Modular Design:

Need for a design that would allow individual workflow steps to be updated or replaced without disrupting entire complex system.

OUR APPROACH



Deep engagement with client including site visits, and workshops with lab, R&D, and automation teams.



Translate information into visual workflow and dataflow diagrams ("swimlanes") for clarity, scalability, and end-to-end visibility.



Develop Requirements and build sprints of Epics & Stories.

Deliver LIMS implementation and instrument integrations using Agile methodology.



Work through acceptance testing of LEAP implemented changes and updates.

Support higher environment UAT and validations.



Partner with client's IT, bioinformatics, and lab operations teams to train the lab, prepare deployments, and support the lab post-release.



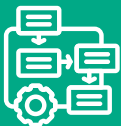
Site Visits, Discovery, and Leadership Alignment

- Lab operations experts, LIMS developers, and scientific analysts visit the lab to properly immerse themselves in lab workflow for LIMS specification.
- Includes leadership meetings, and delivery reviews to support adaptive, iterative design aligned with evolving client needs.



Capture Lab Workflow and Dataflow in Diagrams

- Create detailed workflow and dataflow diagrams ("swimlanes") to visualize operations, validate logic with the client, and support story development.
- Identify points of data transfer and interaction between sample files, manual processes, reagent logging, user interface, work instructions, and bench sheets.



LIS and LIMS Implementation, Customization, and Integration

- Design and configure a Laboratory Information Management System (LIMS) tailored to the client's workflows, developing an end-to-end implementation timeline and using Epics, Requirements, and User Stories for precise alignment.



Regulatory Alignment and Compliance

- Ensure LIMS implementation aligns with CLIA, CAP, and FDA requirements, including traceability of reagents and protocols.



Instrument Integration Optimization

- Orchestrate seamless connections between instruments from multiple vendors, enabling efficient sample handling and automated transitions across workflows.



Launch an MVP and Bolster Exception Flows

- Deliver a minimal viable product first, then expand functionality to handle exceptions, rare cases, and evolving laboratory needs.

SYSTEMS ENGINEERING APPROACH: COLLABORATIVE CLIENT ENGAGEMENT

LEAP brings deep expertise in LIMS implementation—as both a full-cycle LIMS developer and a partner of major LIMS platform providers. In collaboration with our client's laboratory team, LEAP translates operational workflows into precise technical requirements for developers using a leading off-the-shelf LIMS platform and a collaborative engagement model.

1 Site Visit & Strategic Discovery

Capture workflow strengths, limitations, and lab-specific nuances.

1A Automation Team Sessions	Identify integration points and bottlenecks.
1B Lab Manager Workshops	Explore day-to-day workflow intricacies.
1C R&D Alignment	Anticipate future workflow changes and corresponding LIMS updates.

Ongoing Activities

- **Client Engagement:**
Frequent meetings to ensure evolving requirements are integrated seamlessly
- **Management Updates:**
Regular check-ins to align progress and forecast milestones

2 Workflow & Dataflow Diagrams

Validate operational logic and align dataflow via cross-functional diagramming.

4 Implementation

Implement client-approved Stories, collaborate with client engineering teams when appropriate, and deliver system implementation changes and updates through client-approved change management processes.

3 User Stories & Specs

Document functional needs for current and scalable future use.

5 QA / UAT

Partner with client to work through acceptance testing of LEAP implemented changes and updates.

6 Go-Live Support

Partner with client to train the lab, prepare deployments, and support the lab post-release.

CROSS-FUNCTIONAL ENGAGEMENT MODEL

LEAP personnel are trained in real life conditions in various high profile laboratories, enabling them to combine their experience to the advantage of our client.

LEAP TEAM:

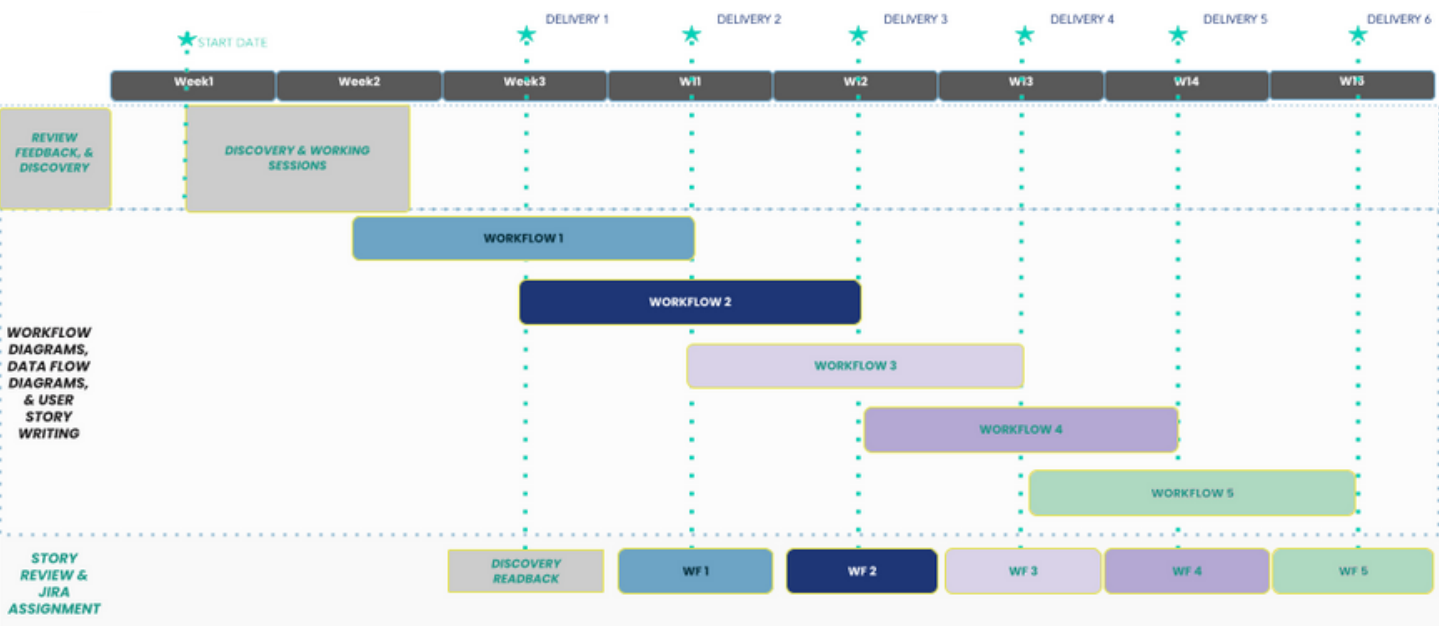
Practice Principal Drives LEAP's strategic value creation	Lab SME Expert Leads lab and systems workflow & dataflow	Scientific Analyst Develops detailed Epics and Stories while driving sprints	LIMS Developer Implements hands-on system
---	--	--	---

PROJECT ESTIMATION & DELIVERY

Drawing on past experience, LEAP forecasts labor, timelines, and complexity with precision—estimating the utilization of Agile Epics and User Stories while accounting for dependencies across workflows.

Once engaged, LEAP utilizes Agile methodologies to deliver and maintain a detailed project plan with clear milestones and dates. Regular client-driven check-ins ensure transparency, accountability, and on-time delivery.

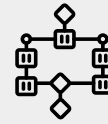
Project Timeline Planning Example



WORKFLOW MAPPING AND DIAGRAMMING

Laboratory operations are complex, with parallel processes that must stay precisely timed. For our clients, LEAP applies proprietary *workflow swimlanes* and *data diagrams* to bring clarity, align timing, and ensure every process contributes seamlessly to overall progress. This ensures:

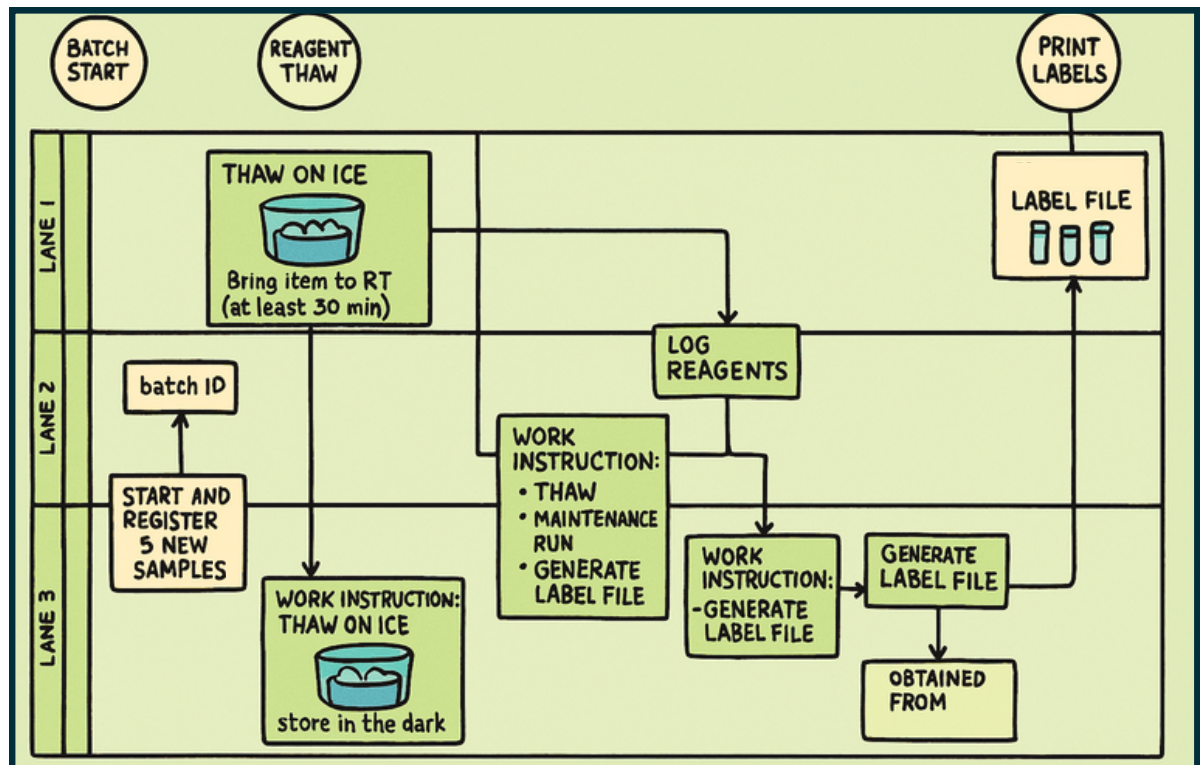
- ✓ **Cross-functional visibility** into process timing, instructions, and dependences.
- ✓ **Clear planning** for instrumentation triggers and manual interventions.
- ✓ **Effective storytelling** for LIMS configuration and stakeholder validation.



LEAP workflow diagrams provide the blueprint for building Epics and User Stories. By mapping events across interconnected swimlanes, we capture both logic and timelines in a way that mirrors real lab operations.

Through collaborative sessions with our clients, these diagrams validate the lab's processes and become the foundation for defining Requirements and User Stories with clarity and confidence.

Workflow Diagram Example: Library Prep

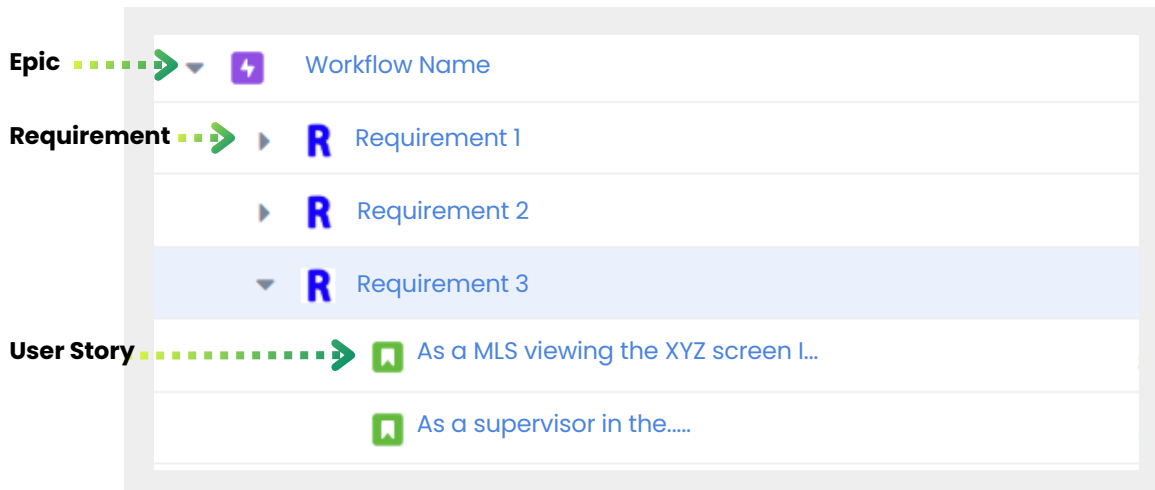


LIMS DEVELOPMENT METHODOLOGY

LEAP utilizes an Agile, story-driven approach to LIMS design while preserving requirements traceability for **regulatory validation** and audit trails. Each **User Story** captures a piece of workflow, grouped into **Requirements** and organized into **Epics** aligned to major lab processes. From accessioning to DNA quantification, this hierarchy ensures uninterrupted data and process continuity.

Loaded into JIRA, our design preserves connections across Stories, Requirements, and Epics—which gives our clients a transparent, traceable framework that mirrors real-world operations and is available for regulatory reference in validations and filings alike.

Agile Approach to LIMS Design Example:



Epics

Encompass entire workflow units, physical lab zones, or external integrations

Requirements

Bundle related stories to support complex lab tasks

User Stories

Define discrete workflow actions

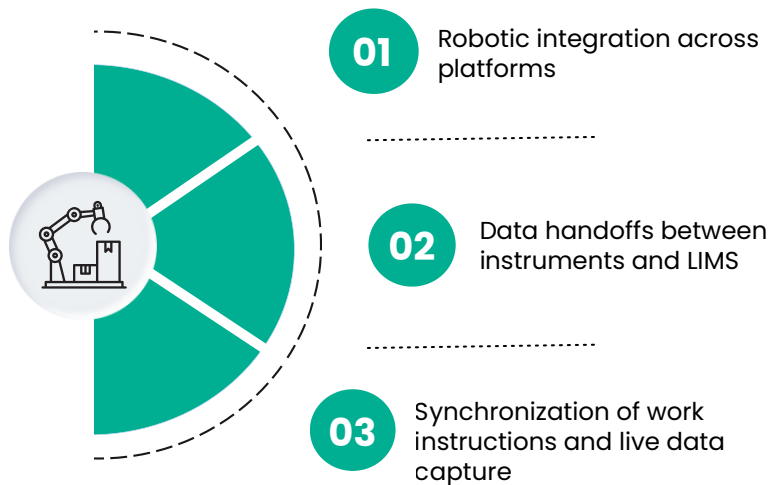
REGULATORY COMPLIANCE ALIGNMENT

In clinical diagnostics, precision and traceability are non-negotiable. Every sample, reagent, protocol, and instrument must be tracked with confidence—meeting CLIA, FDA, and CAP standards. For our clients, we apply deep compliance expertise to design protocols that are practical, defensible, and align with the principle: *say what you do, do what you say*.

- ✓ Implement **reagent and protocol traceability**
- ✓ Capture **audit trails** for personnel and instrument interaction
- ✓ Establish thorough **documentation** regimens

AUTOMATION & ROBOTICS INSTRUMENT INTEGRATION

Our client's labs frequently rely on advanced robotic platforms from multiple leading providers—each with specialized programming and unique integration demands. LEAP draws on extensive experience with diverse robotic systems to unify these instruments within the LIMS, ensuring seamless transitions across equipment modules and a fully connected workflow.



STEPWISE & MODULAR IMPLEMENTATION

LEAP implements a **modular design** within the LIMS, enabling individual workflow steps or instrument integrations to be updated or replaced without disrupting data continuity or overall system architecture. LEAP maps:

Complex workflows take time to design and embed in LIMS, and trying to deliver everything at once often leads to delays and endless revisions. LEAP avoids the “almost ready” trap with a **stepwise approach**, giving our clients a usable system (MVP) while additional functionality is introduced in successive stages.

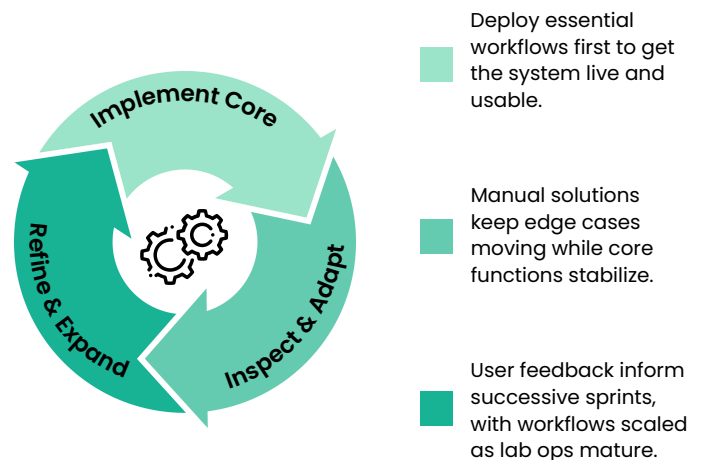
Workflow Modularity

Isolate sub-processes for independent variation



Scalable Data Aggregation

Ensure that all data funnels into centralized reporting for combined review



Why Leap?

Our team of industry veterans and subject-matter experts bring decades of hands-on experience to every partnership to accelerate growth and maximize impact.

Drawing on a deep understanding of operational complexities and market demands, we'll position you for success, whether you're scaling up from current momentum or just starting to break ground.

50+

Professionals, led by
industry & domain experts

8

Full-time
Practice Leads

25

Full-time
Engineering Professionals

Leadership



JOSH
Managing Partner



ANTONY
Head of Delivery



RAINA
Practice Lead



STEVEN
Practice Principal



HEATHER
Practice Principal



YUIRY
SME Consultant



SADE
Practice Principal



DEBRA
External Affairs

Our Expertise



Diagnostics &
Life Sciences



Telecom &
Mobile



Banking &
Insurance



SAAS &
Cloud ISV

LEAP in Genetics, Oncology, and Multiomics

- ✓ Combined cross-industry experience building, scaling, and digitizing clinical labs
- ✓ Specimen journey, bench process, instrument interfacing, and automation
- ✓ Practice focus on LIMS, lab automation, report related lab workflows
- ✓ From lab design, to workflow design, requirements gathering, through full implementation, training, launch, and post-launch refinements

GenPath[®] Oncology GeneDx

CARIS[®] Life Sciences

NEO[®] Genomics natera[®]

BROAD[®] Clinical Labs

BAYLOR[®] Genetics

BioReference[®]

Want To See How Fast You Can Move?

Let's talk about your roadmap.

Contact us at starthere@leapcg.com
or visit leapcg.com to schedule a
30-minute strategy session with
LEAP's transformation team.