

# LIMS & Bioinformatics



We connect your lab data, systems, and teams—so you can get answers faster. From automation to integration, we help you streamline complex workflows, scale efficiently, and stay focused on what matters most: results.

## Always Integrated. Always Compliant.



SOLUTION  
PLANNING & PROJECT  
MANAGEMENT



SOLUTION  
BUSINESS  
ANALYSIS



COMP SYSTEM  
VALIDATION & DATA  
MIGRATION



SYSTEM  
IMPLEMENTATION &  
INTEGRATION



SYSTEM  
ONBOARDING/TRAINING  
& RUN SUPPORT



CUSTOM  
DASHBOARDS &  
REPORTING



### Continual Improvement

We drive continual improvement by strengthening safety, security, and risk systems—helping organizations modernize processes and evolve with confidence.



### LIMS Expertise

We streamline operations by mapping business processes, selecting the right systems, and managing setup and integration. From data transfer to user training, we ensure a smooth transition and lasting adoption.



### Integration

LIMS connects with your ERP to give users easier access to reference data, improving efficiency in the lab and across departments. This integration supports smoother operations in Supply Chain, Logistics, Accounting, HR, and Manufacturing.

#### Vendor Selection & RFPs

- Project & product scale (Waterfall & agile approach)
- Scope for possible projects
- Asset & resource planning
- Project execution reports
- Finalizing & closing

#### Project Management Services

- Local & enterprise assessments
- Initial RFI & vendor evaluations
- Case development & demonstration scoring
- RFP development budgeting & financial evaluations
- Project decision tools

#### Digital Transformation Strategy Program

- Assess current-state technology and operations
- Form change momentum across teams
- Provide transformation coaching
- Evaluate emerging technologies and align to industry needs

#### Lab Instruments, Sensor Data & Integrated Systems

- ERP & ELN
- Registration & inventory
- Integration of LIMS & layer tech
- Lab instruments & robotics
- Project planning & lab audit tools
- Instrument data standards
- Tech blueprints

#### Business Analysis & Consulting Services

- Requirements gathering
- Lab & Instrument audits
- Data maturity evaluations & analysis
- FRS development
- FAIR dashboarding
- Mapping application & data landscapes

#### Custom Software Development & Consulting Company

- Custom arch & development
- Design & construction
- Testing, including web & cloud solutions
- Visualizations
- Automated tests
- Microservices architecture

#### Change Management Consulting & Services

- Local & enterprise assessments
- Engagement of stakeholders & end users
- Capture needs & vision
- Assess change readiness & reach decisions
- Organize communication
- Track program effectiveness

#### Don't See What You're Looking For?

**Let's talk.** Reach out to explore LEAP's services and how we can help you move forward with clarity and confidence. Contact us at +1(212)257-1801 or [starthere@leapcg.com](mailto:starthere@leapcg.com).

# Digital Health & Clinical Diagnostics



With deep roots in digital healthcare, LEAP drives transformation at the pace of change—helping organizations adapt, integrate, and scale with speed and confidence.



TECHNOLOGY  
ORG & PROCESS  
DESIGN



OPERATIONAL  
EXCELLENCE



DATA  
STRATEGY



ENTERPRISE TECH &  
DIGITAL STRATEGY  
DEVELOPMENT



ENTERPRISE SOFTWARE  
& SYSTEMS  
INTEGRATION



STRATEGIC HARDWARE,  
SOFTWARE, APP  
DEVELOPMENT

## Standards and Regulations

### ✓ Standards, securely in the cloud

Our experience adapting regulated industry published standards in practical applications is extensive.

- HL7 / FHIR / CodeX
- DICOM / CDISC
- BAM / FASTQ / VCF
- ANSI ASC EDI X.12
- MT940 / BAI / BAI2
- Bank lock-box files tied to remittances
- AWS
- GCP
- Azure
- Salesforce

## Community Members

ASCO®

HL7  
International

Health  
IT  
gov™

ADLM

NCCN

National Comprehensive  
Cancer Network®

AMP  
ASSOCIATION  
FOR MOLECULAR  
PATHOLOGY

ASHG

## Compliance is in our DNA

Every discussion includes considerations for the validation, certification, and quality management regulations to ensure we achieve objectives and compliance.

- HIPAA
- SOX
- PCI DSS
- CLIA and CAP
- ISO 27001 and ISO 9001
- FDA 21 CFR Part 11 CSV
- GLP and GMP

## Members of the Community

Participating in industry associations, LEAP helps to define and deliver best-in-class patient care and research outcomes. We are proud members of:

- HL7 and CodeX
- ACHE
- ASCO
- ADLM
- ASHG
- AMP

## Focus Areas

From strategic plans and roadmaps to build/buy decisions and integration. LEAP advises and implements what your organization needs.

- IT Org & Process
- Enterprise IT Platform
- Lab IT & Bioinformatics
- Patient Experience
- Clinical Research & Data Monetization
- New Test Design
- Revenue Cycle



# Corporate Digital Transformation



Digital transformation isn't one-size-fits-all. LEAP partners with you to assess needs, chart the right path, and build future-proof systems that keep your organization moving forward—with speed and confidence.



NEEDS ASSESSMENT,  
VENDOR SELECTION &  
ROLLOUT STRATEGY



TESTING & TRAINING  
STRATEGY & DELIVERY



IMPLEMENTATION  
SERVICES



ONE TIME &  
RECURRING  
COST ESTIMATES



PROJECT  
PLANNING  
& EXECUTION



WAVE 2 &  
CONTINUOUS  
IMPROVEMENT

## Key Corporate Digital Transformation Components

- 1 Needs Assessment & Vendor Selection**  
Capturing your needs and identifying potential solutions, with guidance to select the most appropriate solution for your organization.
- 2 Project Planning**  
Identifying the appropriate implementation methodology and developing an implementation plan in alignment with the methodology.
- 3 Implementation & Testing**  
Providing implementation solutions across CRM, ERP & boundary applications, including managing testing phases and cut-over.
- 4 Training & Continuous Improvement**  
Enhancing skills and knowledge through structured learning programs to empower and drive organizational performance and growth.

### DIGITAL CXO ADVISORY SERVICES

SUPPLY	DEMAND	CONNECTIVITY	PLATFORMS	ARCHITECTURES	INFO SEC & COMP	GOVERNANCE	M & A
<ul style="list-style-type: none"><li>Functional Groups</li><li>Leaders</li><li>Skillsets &amp; Teams</li><li>Staff Aug &amp; Vendors</li><li>On Shore/Off-Shore</li></ul>	<ul style="list-style-type: none"><li>Clients &amp; Sponsors</li><li>Sources of Demand</li><li>Demand Planning</li><li>Track Commitments</li></ul>	<ul style="list-style-type: none"><li>Voice &amp; Data Telco</li><li>LAN/WAN/VAN</li><li>Client &amp; Vendor EDI</li><li>Remote Work &amp; CTI</li></ul>	<ul style="list-style-type: none"><li>Colo vs. Cloud</li><li>IaaS vs. PaaS</li><li>Custom vs. COTS</li><li>Infra &amp; Cloud Ops</li></ul>	<ul style="list-style-type: none"><li>Biz &amp; Data Arch.</li><li>Enterprise Arch.</li><li>System Arch.</li><li>Event &amp; Data Maps</li></ul>	<ul style="list-style-type: none"><li>Perimeter Security</li><li>Identities &amp; Access</li><li>Apps &amp; Storage</li><li>Audit &amp; Docs</li></ul>	<ul style="list-style-type: none"><li>Strategic Goals</li><li>Roadmaps Release</li><li>Plans Mgmt</li><li>Reporting</li></ul>	<ul style="list-style-type: none"><li>Diligence</li><li>Plan</li><li>Integrate</li></ul>

### TURNKEY TECHNOLOGY DELIVERY SERVICES

Needs Assessment	Requirements	Sourcing & RFPs	Program Management	Prototyping PoCs	Hardware Build	Mobile Native Apps
Incubation Ideation	Tech Design	Consumer Web	Vendor Management	Release Planning	Enterprise S/W	Org. Change Mgmt & Go-to-Market

# We Get You There Faster.

Accelerating progress in your laboratory system’s transformation. Your trusted partner to get you there faster—with precision, compliance, and confidence.

Since 2010, LEAP Consulting Group has helped organizations in regulated industries modernize, connect, and scale with confidence. Our team brings together deep operational know-how, system integration expertise, and a relentless focus on compliance to solve challenges from sample to system.

- ✓ CLIA/CAP/FDA Specimen journey, bench process, instrument interfacing, and automation
- ✓ Practice focus on LIMS, lab automation, dry and report related lab workflows
- ✓ Practices focused on customer digital, lab master-data, EMR interfacing, preanalytical, logistics, client-service, genetic counseling, RCM, ERP, and more

LEAP your lab from master data to provider experience to lab workflow to report writing, RCM, and everything else...

Test Launches	EMR Setup & Physician Ordering	EMR EDI	Specimen Collection & Logistics	Accessioning and Preanalytical	Bench Processes & Automation	RA, GC, and Pathology Workflows	Report Automation, HL7, RWD Readiness	RCN	Client Svcs	
Client Onboarding										
Business Model Variations (eg. [R-]TCPC)					Instruments & Technologies by Modality by Lab Facility					
Compendium & Medical Specialty Targeted Reqs (Onc/Path/GI/Uro/etc)					Codified Results & Unstructured Result Artifacts					
Exception Workflows - Adds/Deletes/TNPs					Sendouts, Reflexes, Stat/Rush					
CLIA LDTs vs. FDA Kits   CAP Testing vs. CFR 21 PART 11					Patient Workflows - Results, Genetic Counseling, etc					
RCM @ Ordering - Medical Necessity, Eligibility, Prior Auth					Specimen Tracking, Retention, and Return of Client Specimen					
Enterprise-wide Data Assets - Operational Reporting, Quality Management, RWD Revenue-lines, Internal R&D and Publishing										
Customer Lifecycle Reporting					Master Patient Indexing					
CRM	Portals		LIS		LIMS & Bioinformatics		Modalities		RCM	
EMPI	Test Master		Data Lakes		QMS		ERP/HRIS		ITSM & DevOps Stack	