

# Strategic Modernization of Public Health and Environmental Laboratory's LIMS: A Case Study of NJDOH-ECLS's Transition from ELEMENT® to Clinisys®



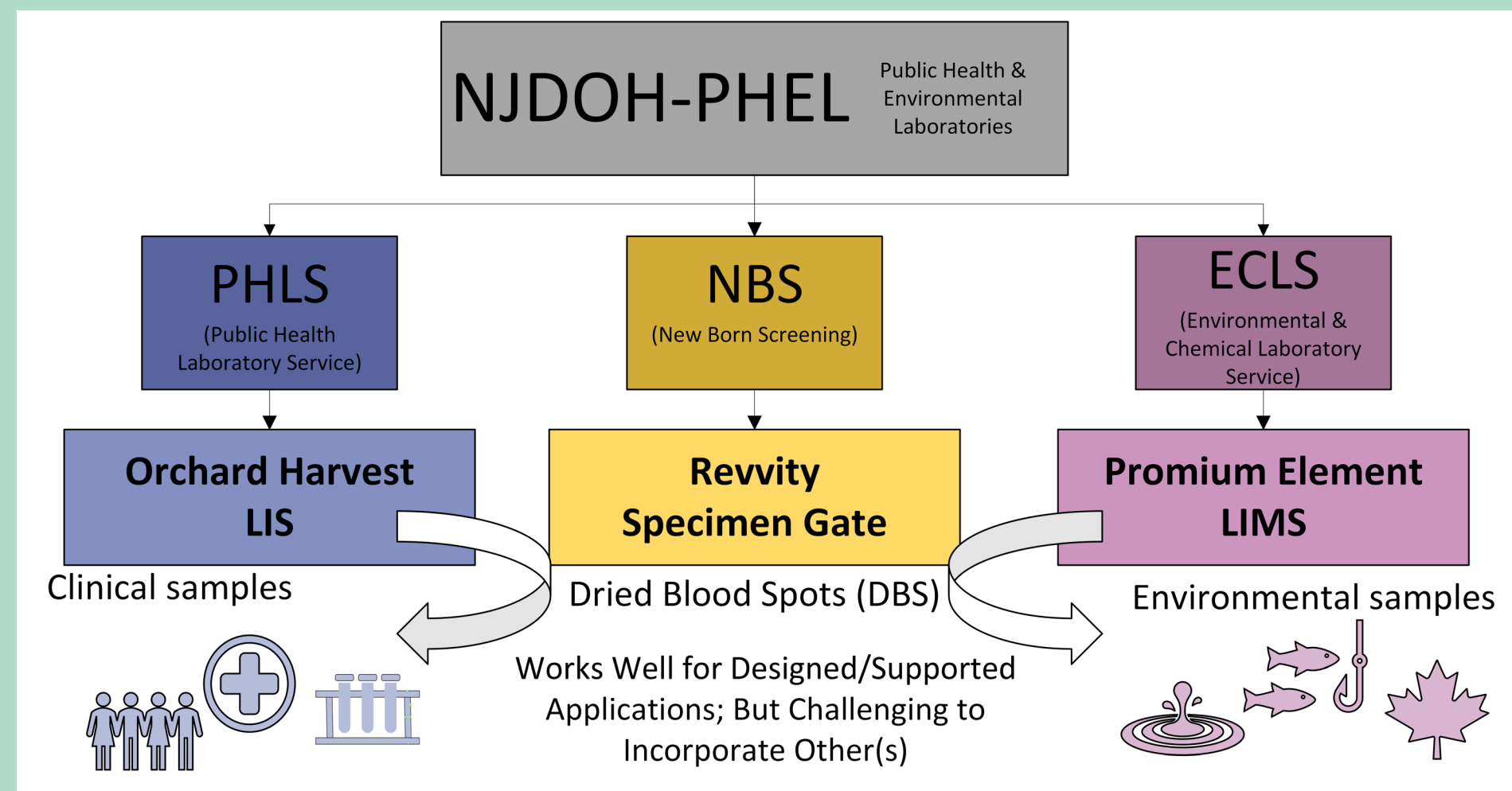
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## Background

**LIMS (Laboratory Information Management System)** and **LIS (Laboratory Information System)** are software solutions designed to manage and streamline laboratory workflows. While they have overlapping functions, they serve different primary purposes: LIMS is primarily **sample-focused**, optimizing sample tracking and data management, whereas LIS is **patient-focused**, handling clinical test results and integration with electronic health records.

Evolving needs and advancements call for a new LIMS for ECLS

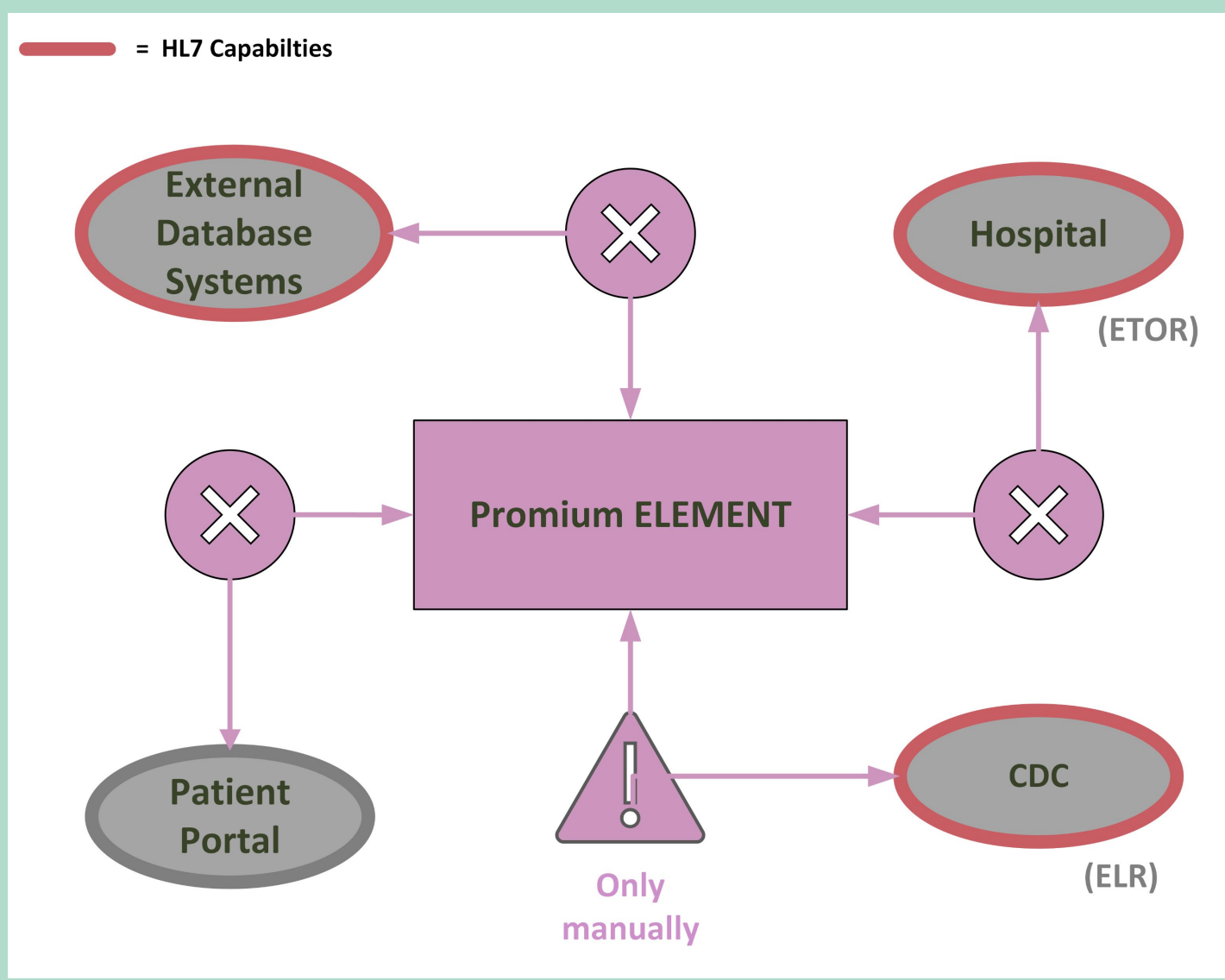


- **Premium ELEMENT:** sample login, batching, analysis, results reporting
- **Orchard Harvest:** specimen tracking, test ordering, analysis, results reporting
- **Revvity Specimen Gate:** specifically for Newborn Screening (NBS) processes

- In 2009, Premium ELEMENT® LIMS was adopted by ECLS Initially/primarily handled environmental samples
- Environmental Protection Agency (EPA)
  - New Jersey Department of Environmental Protection (NJDEP)
- 2010 expanded for human food matrices
- FERN (Food Emergency Response Network) project
  - U.S. Food and Drug Administration (FDA): Food and safety initiatives (2020-2025)
- 2012 expanded for medical marijuana
- 2014 expanded for clinical samples:
- Centers for Disease Control and Prevention (CDC): State biomonitoring grants 2014-2024

Complying with Regulatory Agencies

### ECLS LIMS Challenges



#### Key Limitations:

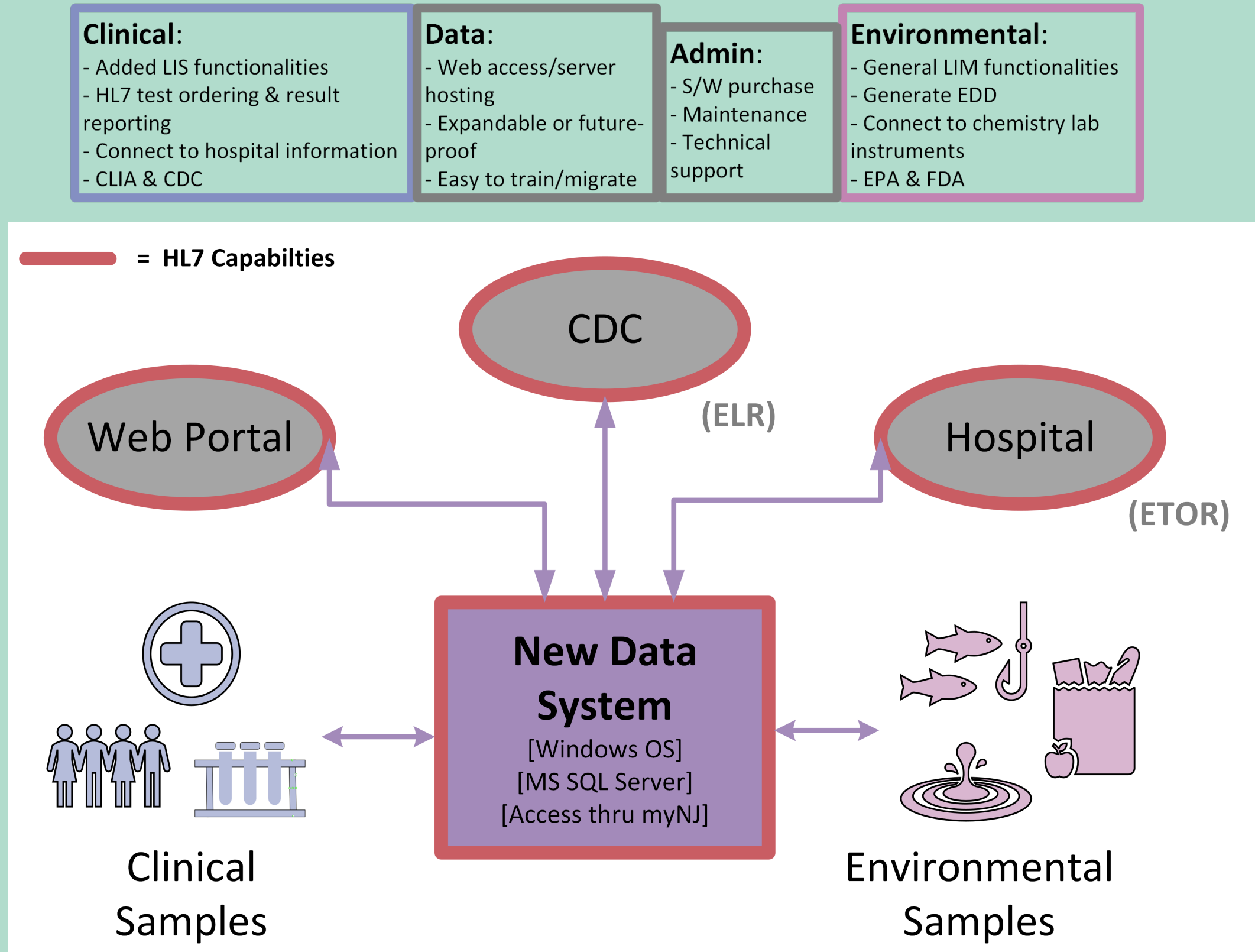
- ❖ **Lacks Health Level 7 (HL7)**, a data exchange standard that enhances interoperability
- ❖ **Limited/inefficient data sharing with external partners**, due to lack of system capabilities
- ❖ **Not integrated** to fully support Electronic Test Orders and Results (ETOR) and Electronic Laboratory Reporting (ELR) systems, resulting in inefficient data exchange

#### Single Solution

Necessitate/  
Prioritize  
**combined  
Clinical +  
Environmental  
capabilities**

## Methodology

### Envisioned LIMS Data Exchange Capabilities



### General LIMS vendor considerations

#### Technical Capabilities

Key Limitations\*  
(see Background)

Adaptation capabilities – support for automation, scalability, future needs

#### Ease of Migration from ELEMENT®

Compatibility with existing LIMS and data structures and departmental workflows for efficient integration

#### Support Services

Knowledgeable and responsive staff available throughout the entire LIMS lifecycle – implementation to end-user training

#### Organizational Requirements

CDC requires application of Clinical Laboratory Improvements Amendments (CLIA) guidelines

EPA/FDA pushing for tighter controls on data exchange and sharing  
NJStar Government Procurement

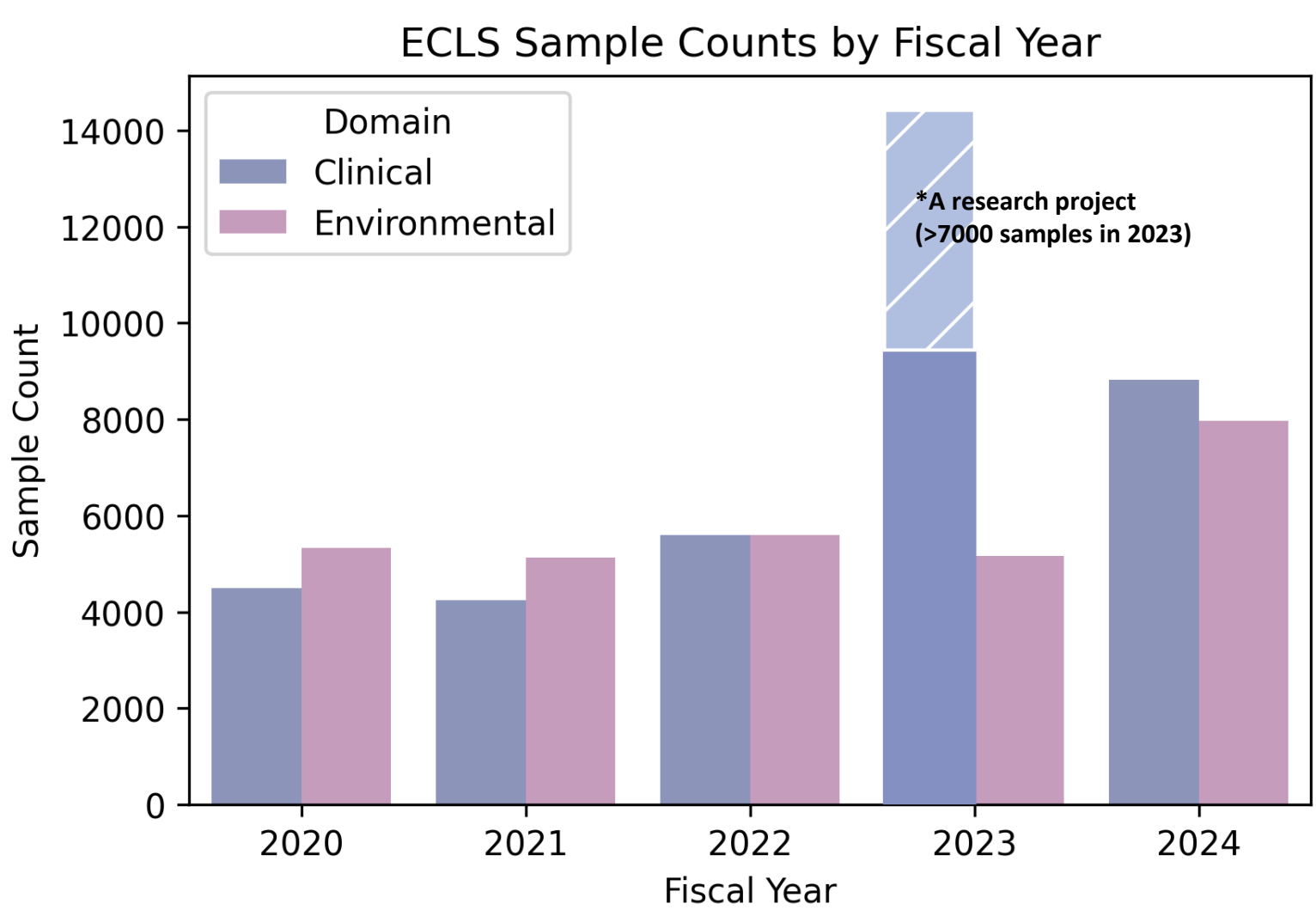
Send to potential vendors to assess support capabilities

## Vendor Evaluation

### Vendor selection prioritized having combined Clinical + Environment capabilities to:

Handle large volumes of clinical samples while complying with CLIA guidelines

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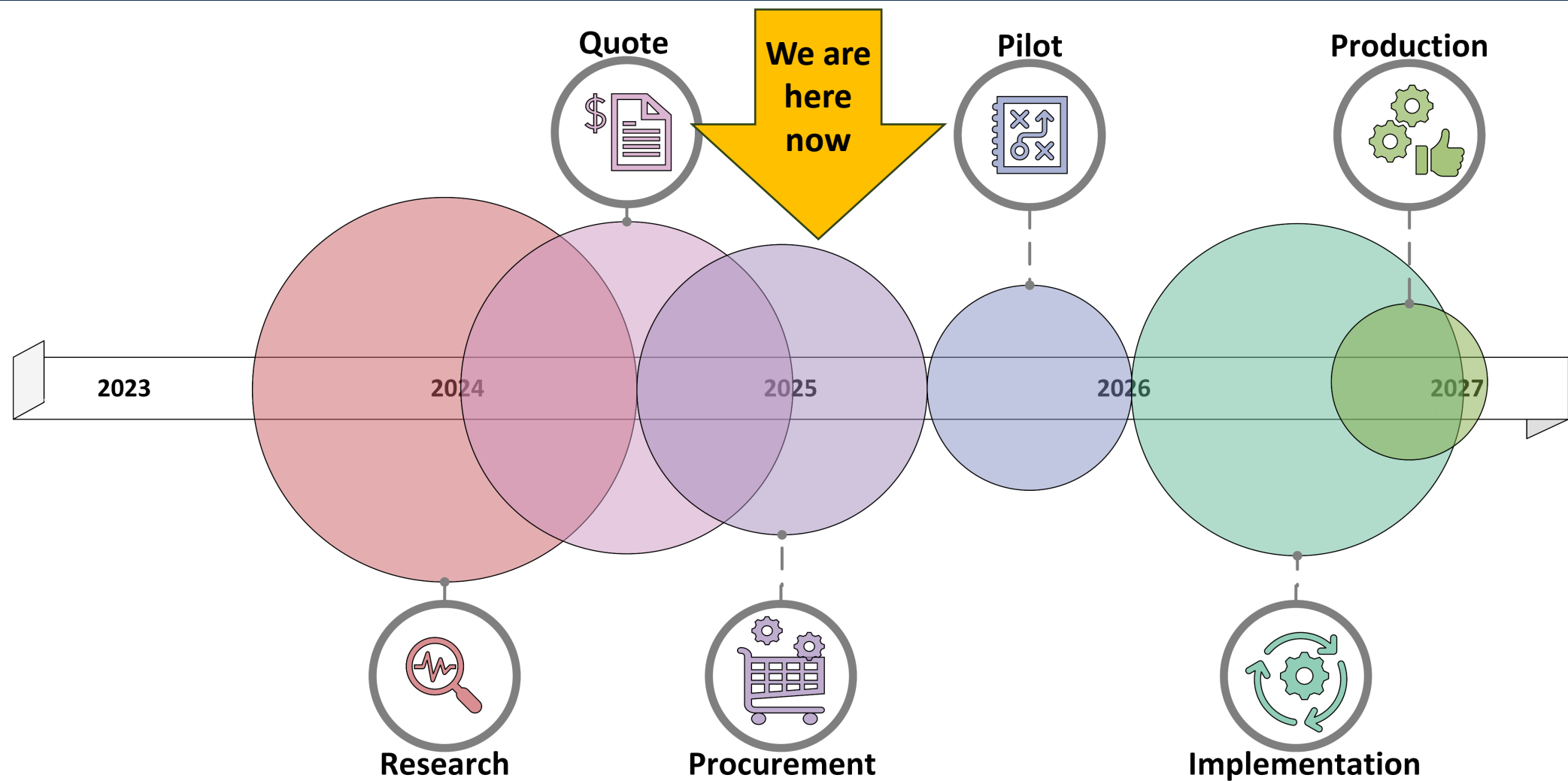
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### Step 1 screened two possible vendors:

Functions & Characteristics	STARLIMS	Clinisys
Clinical + Environment	+	+
Future proof (connect to databases and web portal)	+	+
Structure / Service	0	0
State Government Procurement	-	+
Ease of Migration from ELEMENT®	-	++
Support Services	-	++

Based on functions and characteristics encompassing the methodology considerations (see the two steps above), **Clinisys** is the chosen LIMS vendor

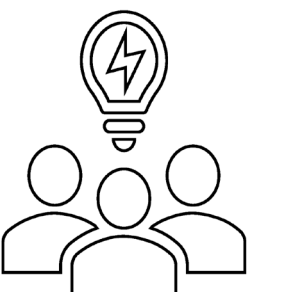
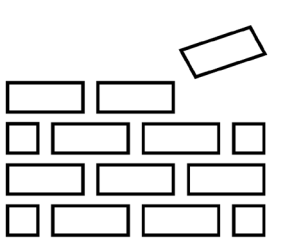
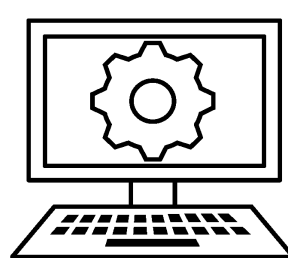
## Project Timeline



## Key Insights

### Expected Capabilities Gained LIMS Upgrade:

- **Modernize** data infrastructure
- **Build** foundational capabilities
- **Strengthen** workforce



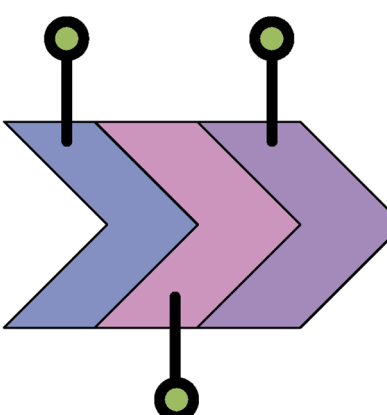
### Remaining challenges/critical conditions

- ✓ Data Migration Strategy
- ✓ System Validation Protocols
- ✓ Regulatory Compliance Documentation
- ✓ Comprehensive Staff Training Requirements
- ✓ Prepare for Emerging Cloud Environment
- ✓ Adopt new technologies (e.g., AI, ML,... etc.)

## Framework

### For State Labs Looking to Update Their LIMS:

- **Research First**
  - Current Laboratory Data System Limitations
  - Requirements from External Organization
  - Vendor Support
  - Migration Ease from Old System
- **Secure Funding Source**
- **Plan Thoroughly**
  - Research, Quote, Procurement, Pilot, Implementation, Production
- **Execute!**
  - Oscillate between Plan and Execute to adjust as needed



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