

# Laboratory Data and Integrated Laboratory Information Systems

## Implementation Guidance



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# CONTENTS

- 1. Introduction..... 4**
  - 1.1 Symbol Glossary..... 4
  - 1.2 Acronyms ..... 4
  
- 2. Laboratory Information Systems ..... 5**
  - 2.1 LIS Functions ..... 5
  - 2.2 The Role of LIS for Patient Care and Public Health ..... 6
  - 2.3 LIS Structure: LIS Module vs. Dedicated LIS ..... 7
  - 2.4 LIS Architecture ..... 8
  
- 3. About Laboratory Systems Integration ..... 9**
  - 3.1 The Importance of an Integrated LIS ..... 9
  - 3.2 Interoperability: Getting the Tech to Talk..... 10
  - 3.3 Essential Concepts for LIS Integration ..... 10
  
- 4. Types of interoperability ..... 11**
  
- 5. Options for Systems Integration ..... 12**
  - 5.1 Web Services / Web APIs..... 12
  - 5.2 File Exchange ..... 12
  - 5.3 Direct Database Interactions ..... 12
  - 5.4 Extract, Transform and Load (ETL) ..... 12
  
- 6. Standards ..... 13**
  - 6.1 Data Standards for Messaging ..... 14
  - 6.2 Data Standards for Coding ..... 15
  
- 7. Integration Tools..... 16**
  
- 8. Preparing for Integration ..... 17**
  - 8.1 Examine the Workflow..... 17
  - 8.2 Integration Needs Analysis ..... 18
  - 8.3 Implementing Integration ..... 20
  
- 9. Systems Available for LIS Integration ..... 22**
  - 9.1 Submitting Systems..... 22
  - 9.2 In-laboratory Systems ..... 24
  - 9.3 Direct Data Capture from Output Ports ..... 24
  - 9.4 Direct to Centralized Data Repository or Central Data Exchange ..... 26
  - 9.5 Instrument to Manufacturer’s Central System ..... 26
  - 9.6 Equipment Inventory and Consumables ..... 26
  - 9.7 Freezer Management..... 27
  - 9.8 Quality Management, EQA ..... 27
  - 9.9 Personnel ..... 27
  - 9.10 Reporting/External Systems ..... 28

<b>10. Linking LIS to Surveillance Systems .....</b>	<b>30</b>
10.1 Tightly Coupled Data Flow .....	30
10.2 Loosely Coupled Data Flow .....	30
<b>11. To Integrate or Not To Integrate .....</b>	<b>32</b>
11.1 Considerations and Practical Approaches .....	32
11.2 Complexity and Cost/Benefit .....	33
<b>12. Next Steps .....</b>	<b>33</b>
<b>13. Appendix: Integration Implementation Examples .....</b>	<b>34</b>
13.1 Data Flow For Surveillance .....	34
13.2 Instrument Integration and Flow to National Laboratory Data Repository .....	36
13.3 LIS Integration .....	38

## FIGURES

Figure 1. An LIS Supports the Mission of the Laboratory .....	6
Figure 2. Functions of an LIS .....	7
Figure 3. Role of an LIS in Clinical Care .....	7
Figure 4. Role of an LIS in Public Health .....	8
Figure 5. LIS for Patient Care vs LIS for Public Health .....	8
Figure 6. Decentralized LIS .....	9
Figure 7. Centralized LIS .....	9
Figure 8. Central/National Laboratory Data Repository .....	10
Figure 9. Layers of Interoperability .....	12
Figure 10. Use of Standards for Integration .....	14
Figure 11. Use of APIs .....	16
Figure 12. Integration Server/Engine .....	17
Figure 13. Options for Integration .....	19
Figure 14. Data Push vs Pull .....	22
Figure 15. EMR and LIS Communication .....	24
Figure 16. Integrated LIS Communicating Across Facilities .....	24
Figure 17. LIS Instrument Integration .....	25
Figure 18. Direct Instrument Data Capture (Scenarios 1–4) .....	26
Figure 19. Transmission of VL Results from “Spoke” facilities .....	30
Figure 20. Complete Workflow From Facility Identifying Suspect Case, Collection of Specimen, Completion of Test and Return of Results to Surveillance System .....	32
Figure 21. Examples of Architecture with Integration Engine .....	36
Figure 22. Instrument Integration Process Overview .....	37
Figure 23. Instrument Integration System Overview .....	38
Figure 24. LIS Integration Overview .....	39

# 1. INTRODUCTION

The purpose of this guide is to:

1. Provide an overview of integrated laboratory information systems (LIS)
2. Remove misconceptions regarding the functionalities of LIS that need to be implemented and
3. Empower country leadership to understand how to apply integrated laboratory systems in their respective environments.

This guide will position country leadership to make decisions on appropriate next steps for the information systems in use, as well as the future of laboratories that do not have systems in place.

## 1.1 Symbol Glossary

The following icons have been used to help readers easily locate information relevant to specific responsibilities or fields:



### Laboratory Scientists

The microscope symbol highlights concepts and details any laboratory scientist needs for using or making decisions about LIS.



### Informatics Personnel

The database symbol identifies details about integrated LIS that are helpful for an informatics person to have as they support the laboratory with their systems.



### Epidemiologists or Surveillance Personnel

The magnifying glass symbol identifies concepts that epidemiologists/surveillance personnel need to have for incorporating laboratory data into public health.

## 1.2 Acronyms

**APHL** ....Association of Public Health Laboratories

**CDC** .....US Centers for Disease Control and Prevention

**EHR**.....Electronic health record

**EMR** ....Electronic medical record

**EQA**.....External quality assurance

**ETL**.....Extract, transform and load

**FTP**.....File transfer protocol

**GF**.....Global Fund for HIV, TB and Malaria

**HIS**.....Hospital information system

**HMIS**.....Health information management system

**IT**.....Information technology

**LIS** .....Laboratory Information System; Laboratory Information Management System

**LMICs**....Lower- and middle-income countries

**PT**.....Proficiency testing

**SFTP** .....Secure file transfer protocol

## 2. LABORATORY INFORMATION SYSTEMS

There are various types of data management systems laboratories may use to manage data and report results. In this guide, the following definition of an LIS is being used (from APHL's 2019 guide, [Laboratory Information Systems Project Management: A Guidebook for International Implementations](#)):

**Laboratory information management systems or laboratory information systems are computer-based information management systems created specifically for laboratories, to support workflow, track data from the start to the end of the testing process, store data, and provide correct and complete information to laboratory staff, managers, and customers in a timely manner allowing for decision making by clinicians, epidemiologists and other stakeholders.**

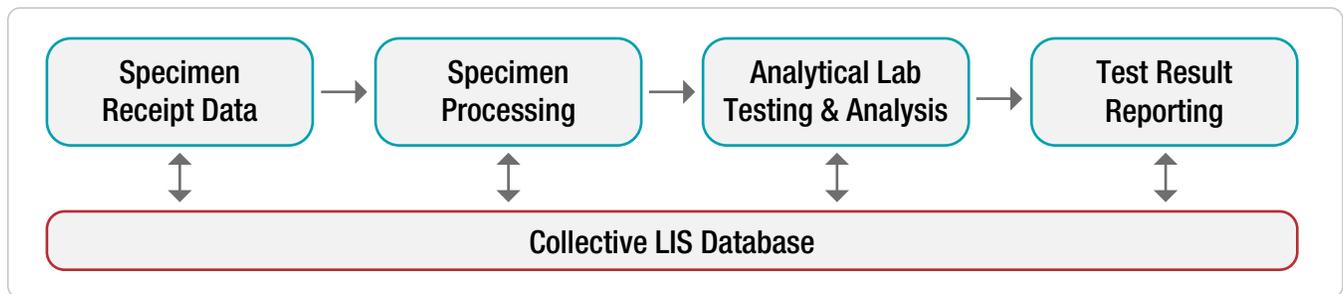
An LIS has advantages both for individual laboratories and national-level public health through:

- Improved laboratory data management
- Improved laboratory efficiency
- Improved quality
- Adoption of international standards
- Prompt, efficient delivery of accurate and complete data to laboratory staff/managers
- Workflows support
- Information tracking during the testing process
- Collection, storage, archiving and analysis of data
- Reporting of test results for patient care
- Reporting of data to MOH and other agencies
- Improved and appropriately managed data security.

### 2.1 LIS Functions

The functionality in the LIS increases the efficiency of the laboratory staff, reduces transcription errors and provides reliable data for decision making. An LIS has functionality to support all the main functions of a laboratory (**Figure 1**) and can nearly eliminate paper hand-written forms.

**Figure 1.** An LIS Supports the Mission of the Laboratory

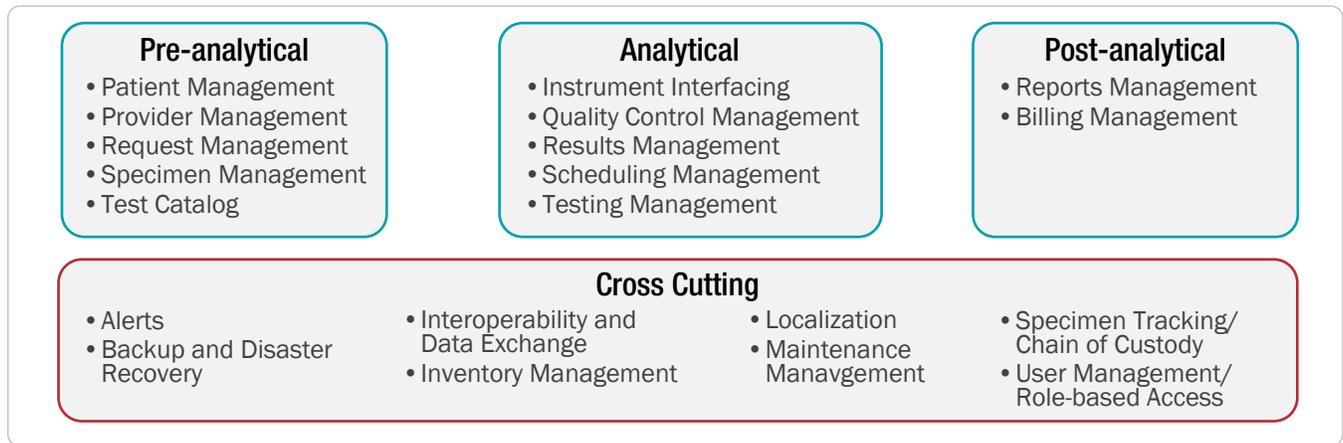


An LIS encompasses 16 processes associated with core business functions, such as specimen receiving, processing, analytical laboratory testing and test result reporting. These processes are grouped according to the phases of testing within a laboratory, with further essential functions within each overarching category (**Figure 2**):

- **Pre Analytical:** This step involves specimen collection, labeling, transport, receipt, rejection and some processing.
- **Analytical:** This is the laboratory testing phase and involves examination of the specimen, testing, review and interpretation of data.
- **Post-Analytical:** This occurs after testing when reports are created, reviewed and sent to designated recipients internal and/or external to the laboratory.
- **Cross-cutting:** This category includes functions that may be required during any or all of the above stages.

These requirements are regarded as the gold standard for high-level requirements of an LIS and have been used globally to select and develop LIS for the last two decades.

**Figure 2. Functions of an LIS**



These processes are more fully defined in [Requirements for Public Health Laboratory Information Management Systems](#), a 2003 collaboration between APHL, the US Centers for Disease Control and Prevention, the Public Health Informatics Institute, and US state and local public health laboratory partners.

## 2.2 The Role of LIS for Patient Care and Public Health

At any stage of the care spectrum—from surveillance to prevention to treatment—an LIS can help transform laboratory data into usable information.

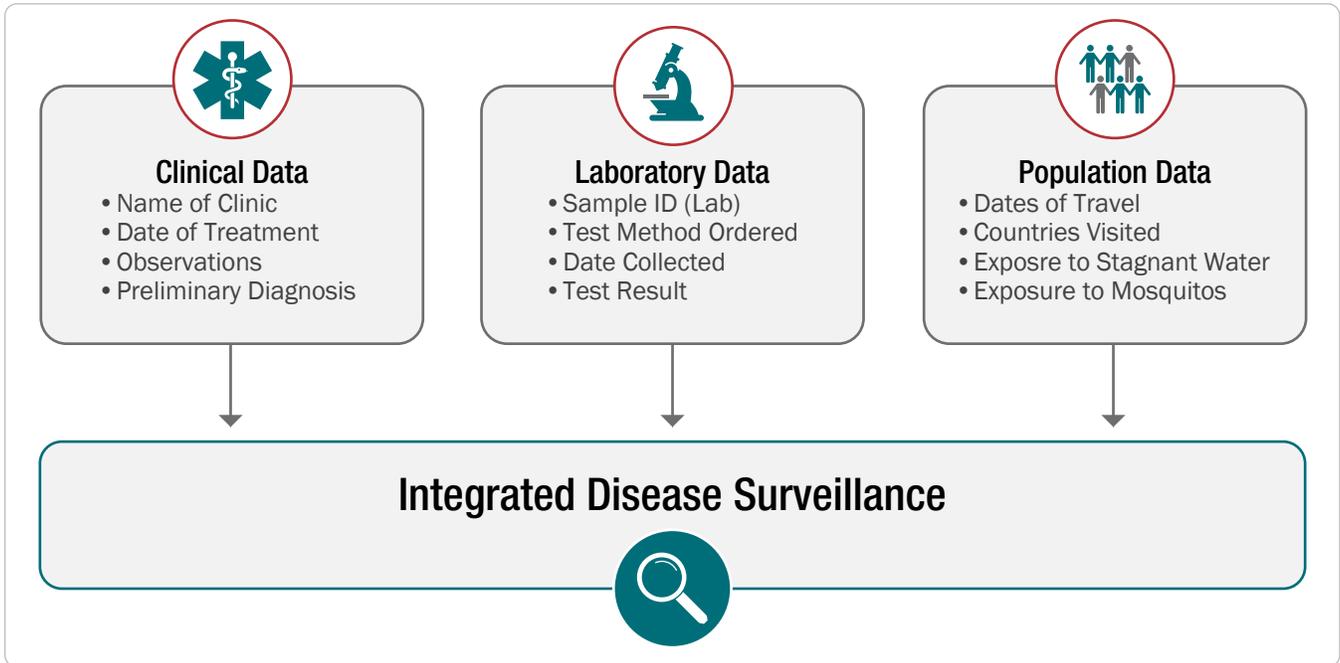
In clinical care, a care provider may request several types of laboratory tests for diagnosis and identification of organisms. The LIS needs to receive the request from the care provider’s system along with patient information, the associated specimen(s) and results of any tests conducted on the specimen(s), and it must return the test results to the care provider’s system (**Figure 3**).

Looking beyond a single patient to the health of a population, laboratory data is one of the key pieces of the puzzle in integrated disease surveillance. An LIS is key to collecting individual laboratory data and allowing it to become part of a larger picture of a population’s disease landscape. This surveillance information can then be leveraged to promote public health goals (**Figure 4**).

**Figure 3. Role of an LIS in Clinical Care**



**Figure 4.** Role of an LIS in Public Health



## 2.3 LIS Structure: LIS Module vs. Dedicated LIS

How an LIS is integrated into a laboratory or other information system and what the goal of that system is—patient care or public health—can dramatically alter its functionality and possible outputs (Figure 5).

### 2.3.1 LIS Module Within Larger Information System

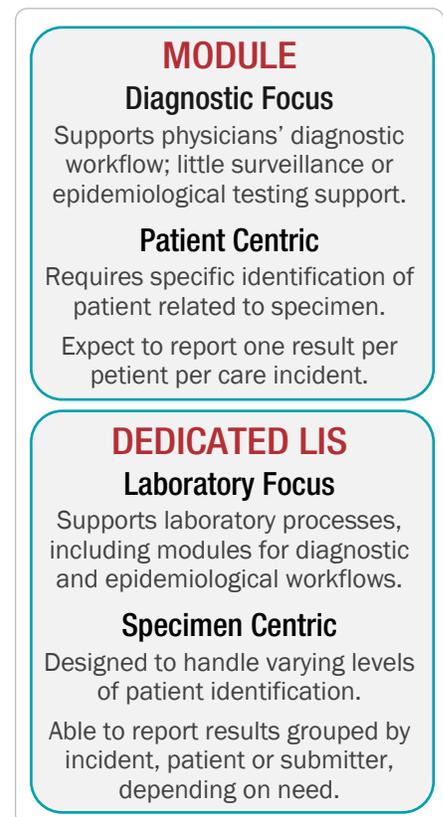
If patient care-oriented outputs are all that is expected of a laboratory, their LIS may exist as a module within a larger disease- or program-specific system or within a hospital information system (HIS) or health information management system (HMIS). This type of module would have a diagnostic focus that supports a physician’s workflow and tends to be patient-centric and requires specific identification of a patient related to a specimen, usually reporting one result per patient per care incident.

### 2.3.2 Dedicated LIS

For the opportunity to operate with more public health-oriented outputs, laboratories can implement a dedicated LIS with a laboratory focus that supports laboratory processes, including modules for diagnostic workflow. A dedicated LIS has specialized functionality unlikely to be available in an HMIS or HIS; this type of LIS is specimen-centric and designed to handle varying levels of patient identification and has the capability to report results grouped by incident, patient or date submitted. Because a specimen-centric LIS does not need a patient record for a specimen to move through the workflow, it can be used to perform passive disease surveillance.

An ideal scenario is one where a laboratory had a dedicated LIS and, for any HIS/HMIS that the LIS must communicate with, the two systems are integrated.

**Figure 5.** LIS for Patient Care vs LIS for Public Health



## 2.4 LIS Architecture

### 2.4.1 Centralized vs. Decentralized Systems

Electronic LIS come in a variety of software architectures. Some LIS are self-contained within a single laboratory (decentralized) while others might connect multiple labs to a single central system via the internet (centralized). Many LIS are now moving towards a centralized web-based architecture; even if an individual laboratory's LIS operates separately, they may still send all their data to a central repository for analysis and monitoring.

- **Decentralized LIS:** When each laboratory has its own installation of the LIS software (Figure 6).
- **Centralized LIS:** When a laboratory system has a central server (like a web server), and all workstations communicate directly with that server, regardless of which laboratory they are reporting from (Figure 7).

Individual, decentralized LIS can still communicate with other LIS—either directly from LIS to LIS or through a central data exchange—to share data for actions like specimen referrals.

### 2.4.2 Central Laboratory Data Repositories

A central laboratory data repository—or simply “central repository”—is a generic term often inserted into LIS discussions. Unlike a central data exchange, these repositories are intended as data warehouses for analytical purposes rather than communication such as serving as a source of data for dashboards, reports, data exports in csv/Excel format and for surveillance/case-based reporting (Figure 8). Though it might be feasible to use them to exchange data, that would likely require additional functionality and enhancements to the database. Central laboratory data repositories are more likely to be needed in the context of a decentralized LIS or in an environment that may be utilizing multiple types of LIS, a centralized LIS being one of them.

## Questions to Ask

- How is the LIS hosted?
- Is the LIS a stand-alone system or is it a module within a larger health information system/EMR?
- How does the LIS handle pre analytical, analytical and post analytical data?
- Does the LIS exchange data with EMRs?
- Does the LIS exchange data with surveillance/public health reporting systems?

A central laboratory data repository contains individual specimen records. Data can be aggregated, however the purpose of a laboratory data repository is to serve as a central storage location for all laboratory data, so aggregation would not generally be a feasible practice.

Figure 6. Decentralized LIS

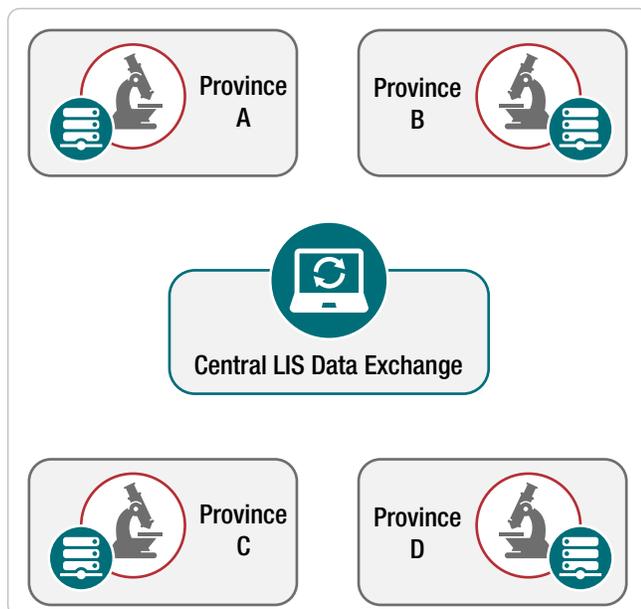


Figure 7. Centralized LIS

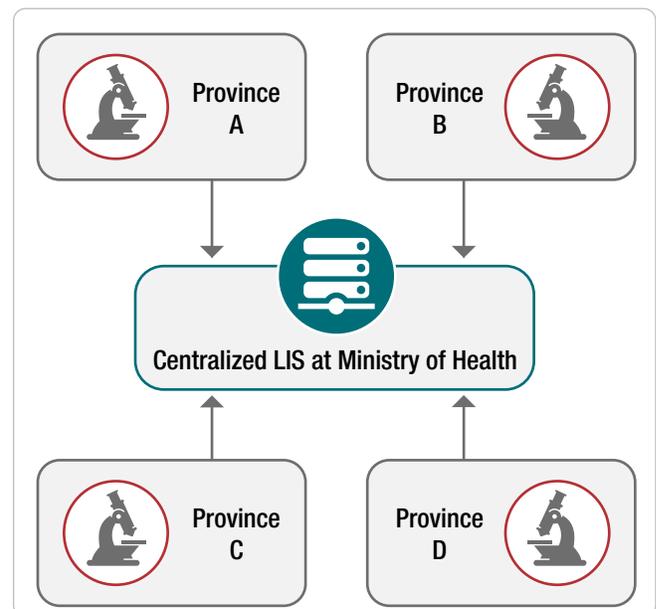
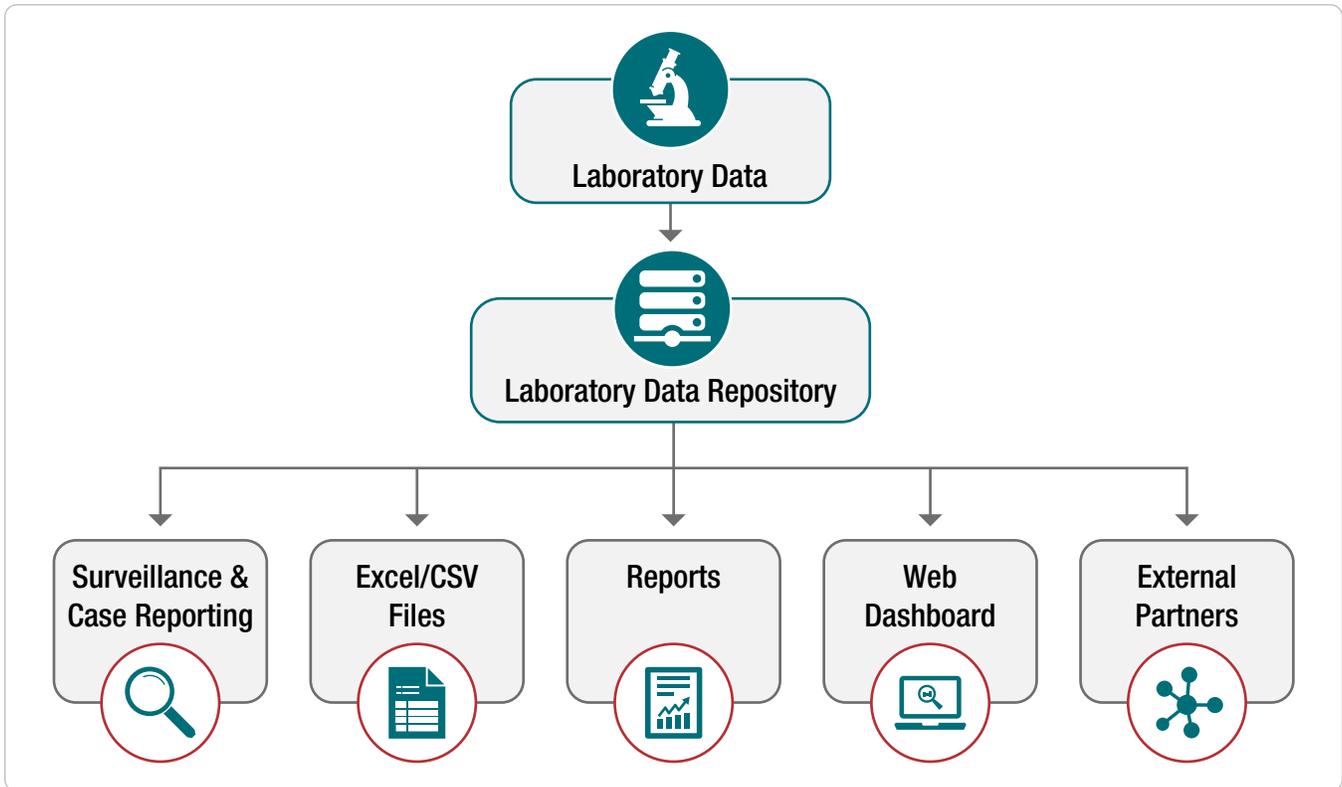


Figure 8. Central/National Laboratory Data Repository



## 3. ABOUT LABORATORY SYSTEMS INTEGRATION

### 3.1 The Importance of an Integrated LIS

While an LIS supports the internal operations and processes of a laboratory, there are many other systems in the average laboratory. Having an integrated LIS means that those systems can communicate and potentially automate processes, saving time and reducing human error. For example, the quality and reliability of laboratory data is impacted by conditions prior to sample receipt and the use of laboratory test results after reporting. An LIS integrated into outside systems can help eliminate some of those variables by enabling laboratories to quickly receive electronic test requests from submitters and report test results automatically and electronically to all relevant information systems. Within the laboratory, scientists interact with various systems besides the LIS—such as commodity management, specimen/freezer storage, instrument analysis and interpretation software—and it is critical for the LIS to be able to share data or integrate with these other systems.

It is becoming more common for some basic individual information to be entered into an electronic system like an electronic medical record (EMR) or case-based system before test orders are submitted to the laboratory. These systems, in turn, have the expectation of receiving results back from the laboratory electronically. In the management of public health outbreaks, data on a suspected case is initially captured in a form or surveillance system while a specimen is submitted to a laboratory for confirmatory testing. Depending on the pathogen (e.g., ebola virus disease), the laboratory results are required before public health action can be taken. The ability for each of these systems to interact electronically rather than manually transcribing the data between systems can improve the accuracy, timeliness and availability of information for all healthcare professionals and management staff. These improvements translate to better patient outcomes in terms of direct care and better management of the overall public health system's preparedness and response.

## 3.2 Interoperability: Getting the Tech to Talk

Information systems need to communicate to realize their full potential. The ability for systems to communicate with each other is often referred to as “systems integration” or “interoperability.” Systems integration is seldom an easy task, because each system speaks a different language and stores data differently. For systems to communicate, the developers for each system meet and decide the technical details of how the systems will talk to each other.

Representatives from each system will decide what types of communications and data will be exchanged and which system will initiate each communication. The definition will include which fields will be sent as part of the request and included in the response. These definitions not only include the specific data elements, they also describe the expected set of data to be received or transmitted back to the caller. The technical communications protocols and security will be agreed upon.

**NOTE:** Just as LIS or other systems used in a laboratory require technical support, introducing integrations within a laboratory setting will also need maintenance and support. The process of automating data or eliminating manual transcribing does not mean that systems can function without issues/errors.

Interoperability is the ability of computer systems or software to exchange and make use of information.

Data Integration is the well-defined exchange of data between one or more systems for the purpose of adding value to the systems, their users or the people they serve.

## 3.3 Essential Concepts for LIS Integration

Prior to making decisions regarding system integration, it is important to understand a few high-level concepts about LIS integration:

- Types of interoperability
- Options for system integration
- Standards
- Integration tools.

This will not require a computer engineering degree or a background in information technology. The information provided here aims for a high-level conceptual understanding as well as an appreciation for the options and complexity system integration can involve.

Technology changes fast. Connecting systems together will require knowledge and decisions about the type of communication layer to be used.

### Questions to Ask

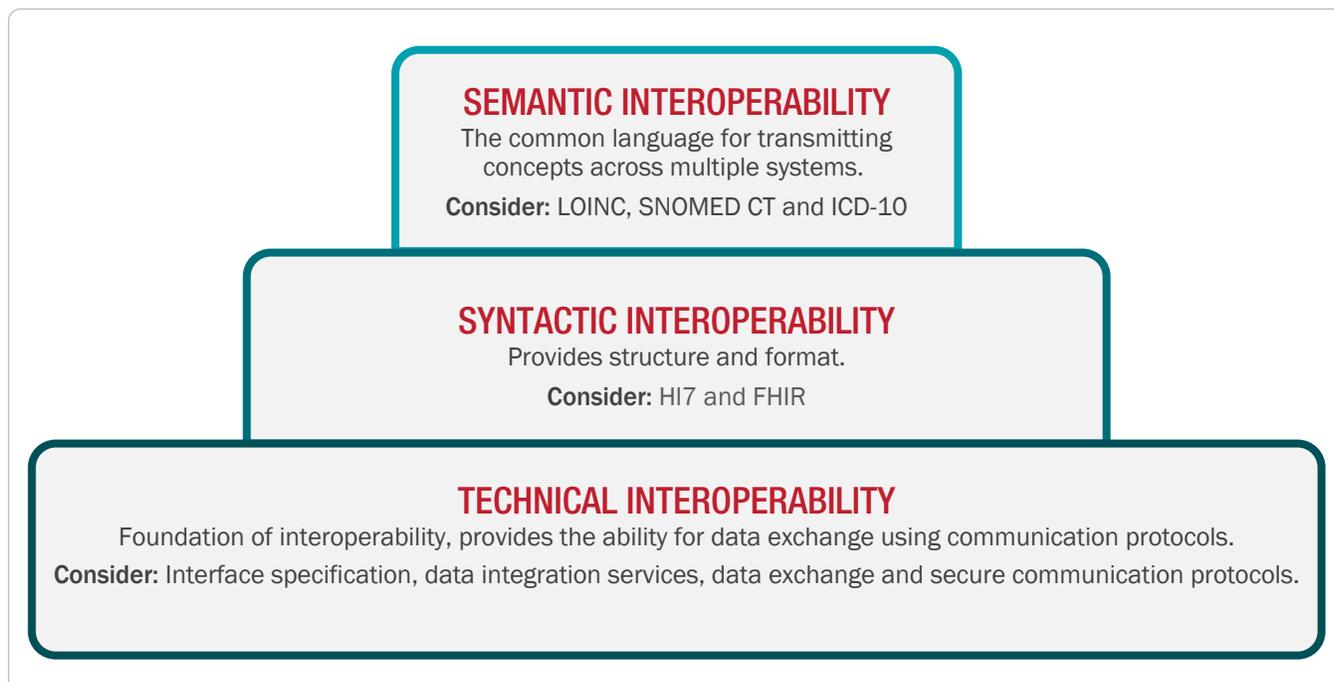
- Can the software be integrated with systems that are currently in place?
- What are the infrastructure requirements?
- Does the integration help automate workflows?
- Does it allow for multiple instruments to be viewed from one panel?
- Can the integration allow for increased volume of testing without need for more staff?
- Can the integration software be customized to my needs?
- Will training be provided and a maintenance plan?



## 4. TYPES OF INTEROPERABILITY

- **Technical Interoperability:** Technology that can connect and exchange information based on a standard implementation, or through intermediate interpretation/integration. This is where a data exchange format is defined and the standard used to format messages from one system to another is agreed upon.
- **Syntactic Interoperability:** The same word and message construction to communicate the same concept. This allows systems to communicate even if the interface or language is not the same. Describes the format of the information to be exchanged, including grammar and format. Examples: HI7 and FHIR
- **Semantic Interoperability:** Words and terminology that possess the same meaning. Systems share data that each system understands in a meaningful way. Example: a standard vocabulary to describe data exchange, so data elements are understood in the same way by all communicating parties.

Figure 9. Layers of Interoperability<sup>1</sup>



### Questions to Ask About Interoperability

- What legacy systems exist and how will they impact interoperability?
- Is there political support for interoperability?
- Do all stakeholders share a vision and agree on objectives, timelines and priorities?
- Are the necessary skillsets available in-house or will there need to be reliance on external resources?
- Is there a sustainable approach to interoperability (i.e., is it being viewed holistically and not as a one-off target or project)?

<sup>1</sup> Based on graphic from [Intelligent Medical Objects](#).

## 5. OPTIONS FOR SYSTEMS INTEGRATION

There are many different methodologies and technologies used for integrating systems, and technologies continue to evolve. The three most common methodologies used in lower- and middle-income countries are:

- Web Services/Web APIs
- File Transfers
- Direct Database Interactions

**NOTE:** All these methodologies can be applied in either a cloud or ‘on premise’ context. The methodologies comprise three aspects: architecture, data format and communication protocol.

### 5.1 Web Services / Web APIs

Web services, sometimes called web application programming interfaces (APIs), have become the most popular form of system interaction. Web services allows one computer system to contact another computer system using the same mechanism as a web browser contacting a website. However, unlike with a web browser, there is no user interface—just two computer programs exchanging information. This defines the data transmission protocols as well as the exact fields and data format. The API also defines what kinds of requests can be received by each system and what each system will be required to return.

The term Application Programming Interface (API) describes the interaction between two programs or applications. The API definition describes the exact “language” of how the systems will communicate, provides definitions for how two systems will interact and includes technical implementation.

### 5.2 File Exchange

One of the most common and simple methodologies for data exchange is for one system to extract data to a file, transfer the file to the other system, which then imports the file. This methodology is simple, easy to define and easy to understand. Many existing systems were built around this principle, and it is still a commonly used method of data transfer. The transfer may not occur in real-time due to the steps involved. However, this method is still commonly used because of its reliability and simplicity, it can handle unreliable internet communications and can be monitored by non-technical staff.

A common method used for moving files from one location to another is file transfer protocol (FTP), which is convenient for processing multiple files quickly and is a good delivery option for offline data use. For additional security with encryption, secure FTP (SFTP) is used.

### 5.3 Direct Database Interactions

It is not common, but it is sometimes possible for external systems to be granted permission to access another system’s database. The external system does not typically write directly into the target system’s primary data structure; instead, it writes the data into a temporary staging area in the target system’s database and the target system can then process and validate the data.

### 5.4 Extract, Transform and Load (ETL)

This is an extension to the direct database interactions already described, which adds data batching, data transformation and scheduling tools.

### Questions to Ask

- What is the volume of data and number of data sources?
- Will the integration need to be between legacy and modernized systems?
- Will the integration between systems need to be automated and allow for complex data analysis?
- Does the data governance strategy, that defines who can take action, on what data and how, align with your objectives?



## 6. STANDARDS

Standardization ensures that things originating from multiple sources are performed or structured in a common, predefined way. By implementing a uniform process, standardization facilitates data comparison and reconciliation, and allows for increased interoperability. It allows for a common language and set of expectations between systems.

Standardization can be applied to:

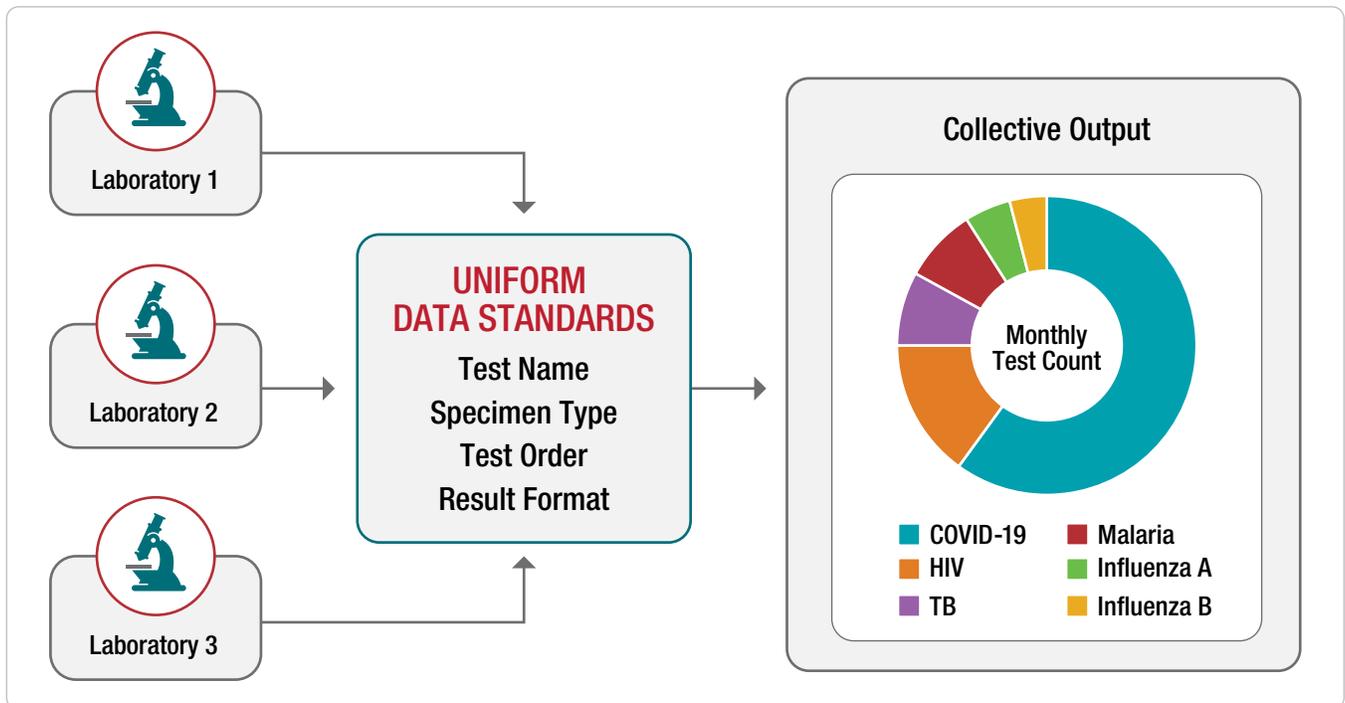
- Processes: This involves establishing consistent procedures for how tasks and processes are performed within a laboratory to reduce variation and increase efficiency.
- Tools: This applies to equipment and analyzers used in the laboratory.
- Data: These are rules for describing and recording laboratory data in meaningful and actionable ways.

LIS standardization covers:

- Test names
- Specimen types
- Electronic messaging
- Test order/test result format

Data integration allows diverse systems to communicate through the use of common data standards.

Figure 10. Use of Standards for Integration





## 6.1 Data Standards for Messaging

Standard data formats and protocols have been defined to help speed up the creation and definition of APIs.

### 6.1.1 Health Level Seven International (HL7)

[HL7](#) is an ANSI-accredited standards developing organization that provides a framework and standard for exchange, integration and retrieval of electronic laboratory data among other health data. It has defined multiple specifications for healthcare-related interoperability which have been widely adopted. The HL7 standards are a good start at identifying a standard data structure and the specific data elements to be exchanged.

### 6.1.2 Fast Healthcare Interoperability Resources (FHIR)

[FHIR](#) is an interoperability standard developed by HL7 for the exchange of data between healthcare providers, patients, care providers. It is based on HTTP protocol and clinical and public health laboratories as well as laboratory vendors are targets for this standard. FHIR allows for the development of tools for fast access and exchange of health data. It offers more flexibility over previous versions and allows systems to exchange data more easily than in the past, including supporting a variety of open web formats like XML, JSON and RDF.

### 6.1.3 ASTM for Instrument Interfacing

[ASTM](#) International is an international standards organization that develops and publishes standards for dimensions and design of laboratory instruments to ensure laboratories deliver quality. ASTM's more than 12,000 standards are in use globally to increase laboratory efficiency and productivity by enabling integration and use of data from multiple instruments from varied providers. For example, if a laboratory equipment supports the ASTM data interchange protocol, that data can be collected automatically and written to a database through configuration of the equipment, use of the ASTM module as a parser and configuring the data export module to an MS SQL database.

### 6.1.4 Standardization in Laboratory Automation (SiLA)

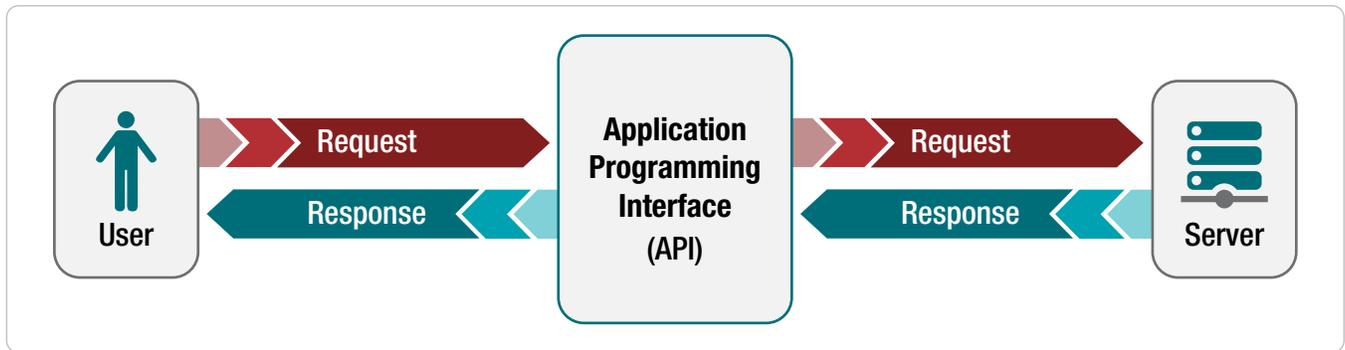
[SiLA](#) is a non-profit organization that provides a framework for the exchange, integration, sharing and retrieval of electronic laboratory information. These standards define how information is transported from one system to another including the language, structure and data types to be used. This standard is significant for laboratories as it focuses on the connection between processing devices and information systems and can include simple items like a thermometer to complex ones like pipetting robots. It enables a separation between laboratory scientists that will define their needs or requirements and the technical experts that are responsible for the implementation.

SiLA uses the gRPC framework with HTTP protocol and protocol buffers. SiLA has a large development community which functions in the common programming languages—such as Python, C++, C#, Java, Go, Ruby—that can be used for implementation. SiLA's goal was to address the needs for the interfacing and integration of laboratory devices used in the drug discovery industry and their scope includes interfaces to laboratory information systems as well as remote access to automated systems including a vendor-independent interface definition that applies to all devices.

## HL7 vs. FHIR

- HL7 v2 supports XML while FHIR uses RESTful web services and technologies such as XML, JSON and RDF. RESTful is a widely used data standard that defines operations within an API and allows for data migration between servers and clients. There is a less steep learning curve for FHIR than with previous standards, as many developers are familiar with these technologies. Two advantages of FHIR are:
  - RESTful API replaces point to point interfaces with one to many and therefore exchanging data is easier including initiating new data exchanges.
  - RESTful increases the options of integrating health systems with additional devices such as mobile apps, mobile devices.
- The interoperability method used for HL7 is syntactic, while FHIR is syntactic and semantic.
- HL7 v2 has many columns that are optional, while FHIR has specific resources that can handle particular data.
- HL7 v2 has limited LOINC support, while FHIR allows embedding of LOINC.

Figure 11. Use of APIs



## 6.2 Data Standards for Coding

When sending values for specific data elements, there are standardized value definitions that help ensure systems are referring to the same dataset. LOINC,<sup>1</sup> SNOMED<sup>2</sup> and ICD10<sup>3</sup> are all widely used standards in the healthcare industry.

- **LOINC:** A system that applies unique codes to precisely identify test methods, test panels and other identifiers; LOINC offers the widest set of codes for laboratory-specific work and is therefore the most-used standard in laboratories to identify test methods.
- **SNOMED and ICD10:** These systems have codes that are less specific to laboratories. Their codes and systems overlap significantly with each other but have less overlap with LOINC's laboratory identifiers.

Some organizations, like the World Health Organization (WHO), may require data be sent using the ICD10 standard.

Understanding which standard each electronic system uses, and which organizations use those standards, is important for the data to be easily interchangeable between systems. It is possible that laboratories may need or want to use more than one set of standards, depending on who they are communicating with. For example, a laboratory may use the LOINC system for identifying their test methods, then use SNOMED or ICD10 codes for the outcomes of those tests and test panels.

### How to Select a Standard

With the various choices available, laboratories are often faced with the question of how to choose the best one. The answer will depend on several factors. Below are some considerations:

- **Relevance:** which standard addresses your needs and different scenarios in your context?
- **Compliance:** which standard can help you meet accreditation or other requirements for certification?
- **Compatibility:** which standard integrates with existing or planned systems and applications, instruments?
- **Cost:** What will be the time, money and technical/human resources required to implement and maintain the standard?
- What are the advantages and disadvantages of using a specific standard and impact on performance, reliability and usability?
- Which standards have robust documentation and are easily available?

1 Logical Observation identifiers Names and Codes: [loinc.org/](http://loinc.org/)

2 Systematized nomenclature of Medicine Clinical Terms: [www.snomed.org/](http://www.snomed.org/)

3 10th revision of the International Classification of Diseases and Related Health Problems, a medical classification list by the WHO: [icd.who.int/browse10/2019/en](http://icd.who.int/browse10/2019/en)

# 7. INTEGRATION TOOLS

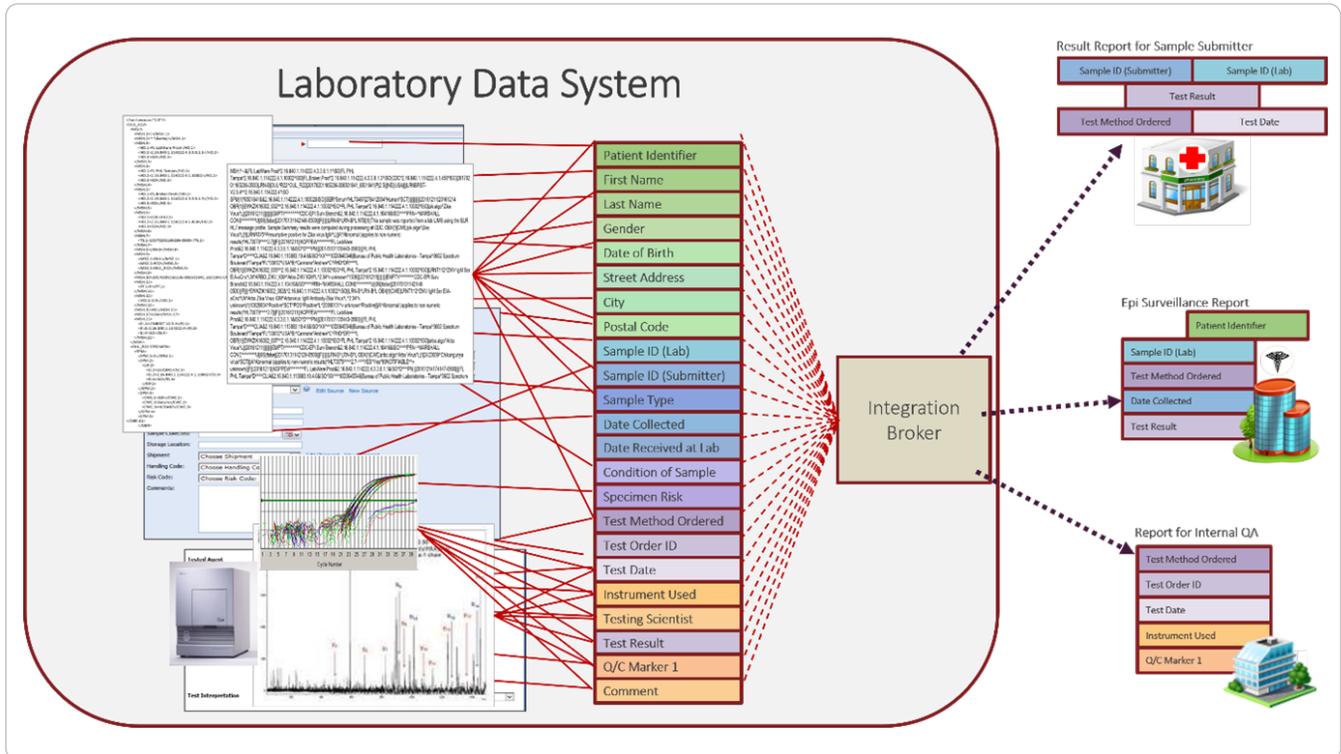


The common terms for the software that does the communicating is “integration server” or “integration engine.” This integration software “listens” for requests from external systems; it can then interact with its own internal software to either store incoming data or retrieve information to send back to the requesting system. The integration software might also initiate contact and send a request or data to an external system’s integration software.

## Questions to Ask

- Scalability?
- Option of reusable architecture?
- Plan to deal with and control changes?

Figure 12. Integration Server/Engine



Even when a common language or API has been defined, each system will use different software to perform the work. Integration tools are generic platforms that provide tools for the developers to implement their own specific solutions. Many commercial LIS will have custom software created. Some systems designers might prefer not to pay a license for a commercial piece of software or even to use open-source software; the vendor may instead write their own integration module for better efficiency, cost savings or other considerations. Other LIS developers utilize third-party integration platforms. While third-party tools need significant configuration, they can serve as stable tools which the developers can build onto and focus on the API rather than underlying technology issues. Third-party integration tools can range from very generic to highly specialized. A well-known tool like Microsoft’s SQL Server Integration Server gives a developer all the communications tools they need to create an API regardless of the industry. There are free integration engines that can also be used. Visit [www.laboratory-etools.org/](http://www.laboratory-etools.org/) to learn more about different types of integration tools.



## 8. PREPARING FOR INTEGRATION

The goal of this guide is to make the idea of system integration easier to understand. While the technical aspects of integration will be the responsibility of informatics/IT developers, there are steps that laboratory leaders can take to ensure they are fully informed of the process and aware of the outcome.

### 8.1 Examine the Workflow

When planning to create or improve the integration between two systems, the first and most important step will be to write down a detailed explanation of the existing workflow, often referred to as the “As Is.” Then write a detailed workflow of how the systems will operate in the future to mimic and improve the original workflow, usually termed the “To Be.”

#### 8.1.1 As Is

Knowing details about the existing workflow will inform which systems should have electronic interfaces and what integration methodology would be best suited for each interface.

Key questions to ask about the existing workflow include:

- What are the individual steps performed?
- What data elements are collected at each step?
- What data elements are sent from one system to another?
- What are the unique identifiers used to match data between systems (e.g., unique patient identifier, specimen identifier)?

In instances where a national ID is not in use, it is advised that there be agreement among the various organizations about identifiers that will be used to identify patients and specimens.

Implementation managers must develop a long-term strategy for personnel and funding. No matter what software vendors and developers tell you, software development and long-term maintenance are seldom cheap or easy. Developing functionality to allow systems to communicate with an LIS is not the same as installing Microsoft Word on your computer. The detailed definition of how the two systems will communicate will take time and lots of interactions between the developers, managers and users of each system. The implementation of the plan will take highly technically trained staff or software developers. There is testing and more testing, and there will always be changes needed even after the software is in use.

#### 8.1.2 To Be

Determine how the workflow will operate when the system has been integrated. Several different integration models can ensure data are available everywhere they are needed:

- Each LIS, EMR and surveillance system contains a catalog of the systems they need to contact and the details of how to contact them directly.
- A single LIS for the entire country is installed at a central location and each individual location logs onto the system via the Internet. Any external system sending test orders or requesting results simply contacts that single system.
- Each laboratory has its own LIS, which sends all data to a central laboratory data exchange. Other systems that need laboratory data contact that central data exchange to send or request data.
- Hybrid LIS which works with the surveillance system or EMR locally, and contacts a centralized system for other functions such as specimen referral.

**Figure 13** provides a matrix of integration options; there are pros and cons to each of these models and considerations for choosing a specific model.

Figure 13. Options for Integration

Integration Option	Description	Pros	Cons
<b>Individual instances of LIS, EMR and surveillance systems</b>	Each system contains a catalog of systems they need to exchange data with and information on connecting to each system directly.	Systems are physically near each other, so connectivity and data access is fast and reliable.  Ideal for information that only needs to be shared within the facility.	Cumbersome to connect to systems outside the facility, as the catalog of information about how to connect to other systems can be a challenge to maintain.  Maintenance is spread out across many locations.
<b>Centrally installed LIS for the country, accessed by individual logins</b>	Surveillance and other systems contact the central LIS.	All data are in one location. Single point of maintenance.	Connectivity from remote locations can be an issue.
<b>Individual instance of LIS at each laboratory</b>	Each LIS sends data to a centralized data repository; surveillance and other systems contact this repository for laboratory data.	All data are in one location.	There is often a time lag between the local data and the data getting to the centralized location, which can delay the other systems.  Connectivity from remote locations can be an issue.
<b>Hybrid LIS</b>	LIS is integrated locally with surveillance system and/or EMR and sends data to a centralized system/repository.	High availability of the data within the local facility.  Data eventually makes its way to a central location exchange between locations and other needs.	Maintenance is spread out across many locations.



## 8.2 Integration Needs Analysis

It may seem like every system needs to be able to communicate with every other system, but this is not practical. Use this section to help identify priority areas of integration and understand your overall needs and desired final outcomes.

### 8.2.1 Identify Core Systems

Create a list of the core system types a laboratory utilizes, such as:

- LIS/LIMS
- Proficiency testing (PT), external quality assurance (EQA), internal quality control
- Analytical tools
- Centralization
- Visualization
- Electronic test orders and results
- Instrument data capture
- Storage/archival

**NOTE:** See Global Fund’s [www.laboratory-etools.org/](http://www.laboratory-etools.org/) for more information.

## 8.2.2 Data Set Characteristics

Review the data elements to be transferred and assess if they will be known or vary, as well as how frequently the data set needs to be updated. This will determine use of file transfer (direct database (high overhead for complete dataset replacement) or APIs (supports transactional updates)) and the size of the data asset where large data sets need file transfer or direct database connection options.

## 8.2.3 Identify Existing Systems

List out the current systems that are already implemented, parties responsible for maintenance and support of these systems, and facilities/locations where they are in use.

## 8.2.4 Prioritize System Interactions

Prioritize the list by which systems have the highest need to interact. Keep in mind that some systems might be required to interact because of government policy. Consider:

- Improvement to patient outcomes
- Staff workload reduction
- Error reduction
- Increase speed and accuracy of information for management and policy/program improvement.

## 8.2.5 Identify Relevant Surveillance Systems

It will be essential to determine how many integrations will need to be managed and maintained to support laboratory test confirmation for surveillance systems. This could mean integration between LIS at each facility and the surveillance/reporting system which results in multiple integrations or between a central laboratory data repository and the surveillance/reporting system.

## 8.2.6 Determine Contact Initiation Roles

When designing the system as a whole and the interaction between systems, you will need to determine which system will initiate contact with another system. There are different factors which might affect the decision and they affect the reliability, timeliness of the data and effort to implement.

## 8.2.7 Identify Existing APIs

When designing an overall systems interaction map, consider which systems already have APIs in place. Some systems might already have standardized file formats they accept for data import (e.g., WHONET). Other systems like DHIS2 already have a defined and running API as part of the system. Even some LIS have existing APIs to allow external systems to retrieve data or have functionality to transmit data. These existing APIs may determine the overall architecture you design.

## 8.2.8 Define Data/Results Reporting Responsibilities

During the API definition, each country will need to decide if the LIS will be responsible for sending the results back or if the receiving system will be responsible for contacting the LIS to ask for results.

These considerations are important for interactions such as:

- **Sample referrals:** Two LIS may exchange a test order and the test results. In a tiered laboratory network, lower tier laboratories can electronically refer specimens to a higher tier laboratory for testing, and the testing laboratory can return results to the lower tier laboratory via the same method.
- **Central data storage:** If all test results are sent to a centralized data repository, it can be complex to determine where the data should go, especially if there might be more than one destination of the data.

## 8.3 Implementing Integration

Apply the analysis for interactions each system might have with other systems. See **System Integration Scenarios** section.

### 8.3.1 Identify Systems with Possible Data Exchanges

List pairs of systems with information that could be shared with each other. It is not necessary to list every combination of systems; some systems will obviously not need to communicate.

### 8.3.2 Identify Systems with Current Data Exchanges

List which systems currently move data from one system to another via paper, electronic interface or manual transcription. This could include combinations which do not currently exchange information due to workload.

### 8.3.3 Data Flow and Complexity

Review how data currently flows from one application to another as well as any planned data flows since solutions for a large number of data sources continuously sending data to a single receiving system will require a different approach than data sending from laboratory instruments. The need to have the most up to date version of data will require use of APIs, while the need to deliver different versions of data to different consumers may not warrant the use of APIs. If the data exchange requires significant processing and transformation of data, then ETL is preferred; less extensive transformation can be done using API management platforms.

### 8.3.4 Identify Exact System Interactions

For the highest priority systems, write down exactly what data one system would request or send to another system. Interactions which occur frequently or are time sensitive may be prioritized over interactions which are not as frequent.

A few basic examples of interactions are as follows:

- **EMR ↔ LIS**
  - EMR asks LIS for test catalog and sends patient information and test orders to LIS.
  - LIS sends patient or specimen results to EMR.
- **LIS → EMR**
  - Search for patient and ask for unique identifier.
  - Send test results from LIS to EMR.
- **LIS ↔ Analyzer**
  - In a bi-directional exchange, the LIS would send information on the specimens to be tested along with specimen details to the analyzer and the analyzer would return results back to the LIS.
  - In a uni-directional exchange, data flows only from the analyzer to the LIS once results are completed.

### 8.3.5 Collect List of Current Standards

Coordinate lists of standardized values and terminology within your country, in addition to the general international standards for specific data elements, such as:

- Healthcare facility identification codes
- Laboratory identification codes
- Unique patient identifiers
- Specimen identifications.

Unless otherwise specified, a system provider will likely utilize their own naming conventions during the installation process, which can create confusion later when trying to exchange, centralize or analyze data.

### 8.3.6 Define How Systems Communicate

During the definition of the communication between two systems, both sides will need to review all data elements being exchanged and discuss standard conventions for values.

## Data Push vs pull

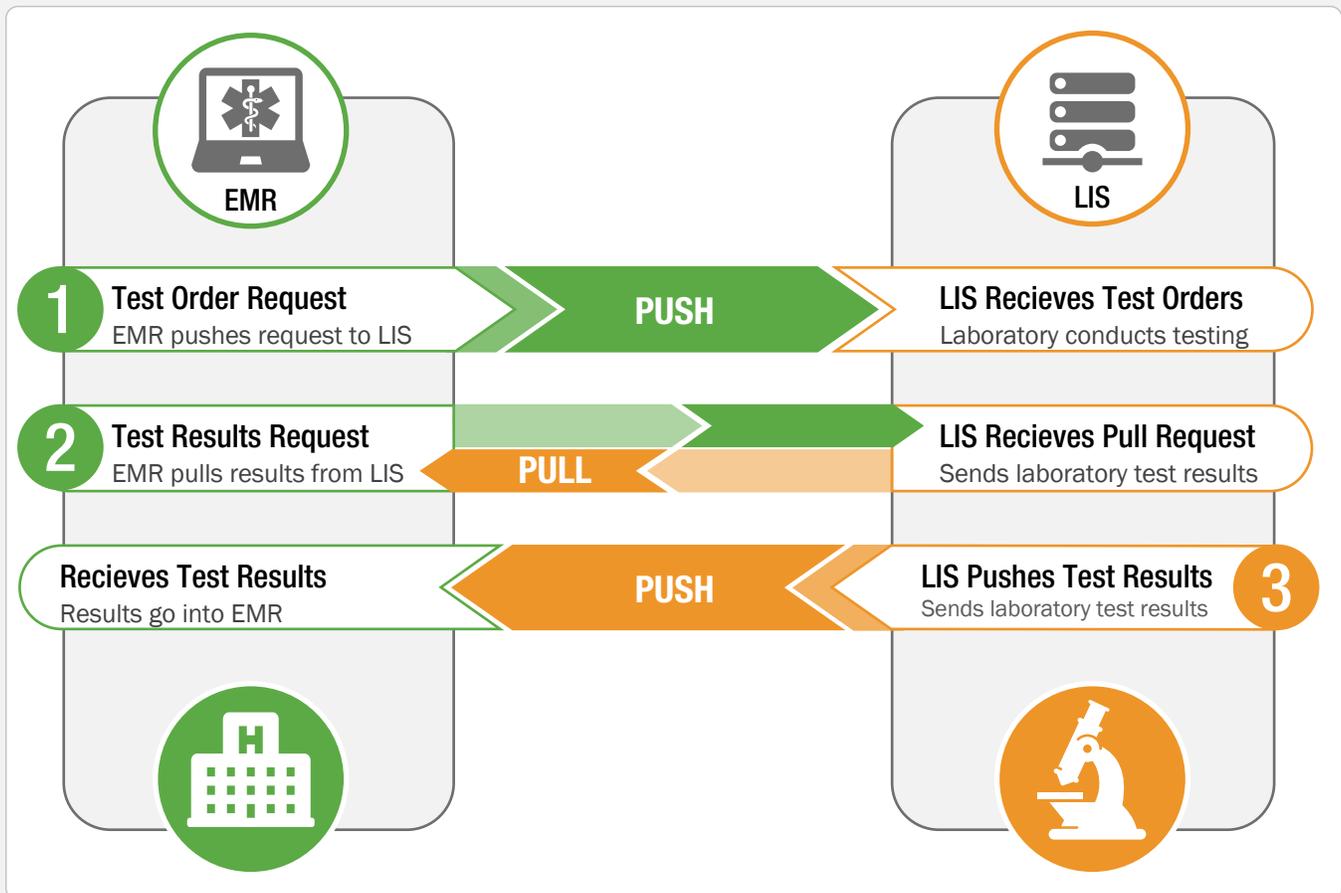
Data can be either “pushed” or “pulled” to a destination system depending on which system initiates the movement or request. This is usually identified during the integration needs analysis step.

For example, test orders from an EMR issued to an LIS would be an example of a “push” because the workflow is initiated in the EMR. Once test results are ready, the LIS may send these to a temporary location, with the EMR set up to “listen” for laboratory data pushed from the LIS. If the EMR requests test results without any knowledge of the test completion, this is a data “pull.”

Sharing data with a central laboratory data repository is also an example of a “push” from an LIS to the repository. Typically, this type of exchange is easier to manage if the central location accepts data and then receives requests for that data (i.e., data is pushed to it and then pulled back out). Theoretically, this arrangement limits the extra information the repository must contain—it only needs the security/login credentials for each remote application, not where they are located or how to contact them—which keeps the level of complexity and administration down at the central level.

However, in the case of test results, clinicians need test results as soon as they are ready. Where speed is important (e.g., real-time reporting), consider implementing functionality that both allows the EMR to request data from an LIS or central location and allows the LIS or central system to push data to the EMR.

Figure 14. Data Push vs Pull



## 9. SYSTEMS AVAILABLE FOR LIS INTEGRATION

As long as one system knows the details of how another system is willing to communicate, they can exchange information. However, there are different models that can make the communications more effective depending on the system's needs and the existing infrastructure within a country. This section outlines the needs and considerations for integrating LIS with a variety of systems.

### 9.1 Submitting Systems

Submitting systems send data—such as patient information, tests needed and specimen/test referrals—to the LIS.

#### 9.1.1 Electronic Medical Record Systems (EMR)

The ability for an EMR and LIS to exchange information is one of the most logical and important system interactions related to laboratory work. This connection allows a clinician working on a patient record in the EMR to know exactly what tests are available from the laboratory, and directly request the tests to be performed. The collection facility and laboratory know precisely what specimens to collect and have an electronic list of tests to perform. If the local laboratory cannot perform a specific test at that time, they can simply refer the specimen to another laboratory with that capability, electronically transmitting the data to that laboratory's LIS. That referral laboratory immediately knows to expect the specimen, has all relevant information and can plan accordingly. No matter which laboratory performs the tests, the results should be available in the EMR for the clinician to view as soon as they are reviewed and approved by the testing facility. This scenario is a single example of better patient outcomes when information systems communicate.

In a single healthcare facility with an EMR and LIS, it might make sense for the two systems to communicate directly with each other regarding patients within the same facility, especially if there is a poor internet connection going out of the facility (Figure 15).

However, as in the example above, the LIS may need to refer a specimen to another laboratory or the EMR might need to look up a full history of the patient's test results, which may not be in the local LIS. These actions would require the EMR to be integrated beyond the healthcare facility's closed system (Figure 16).

#### 9.1.2 Remote Registration, Test Orders and Results

Where a fully functional EMR might not be present, a clinician could use a remote application to enter a patient's registration information and test orders directly into an LIS system and look up the results for the specimen or patient. With current technology, this application could be accessed with a laptop or handheld device and could be created by anyone—as long as it conforms to the communications interface defined by the LIS, which enables integration.

#### 9.1.3 Other LIS (LIS to LIS)

Laboratories will need to refer specimens to other laboratories. Using their local LIS, the laboratory staff should be able to send a specimen to another laboratory and all information about the test orders, specimen and patient should flow automatically to the other LIS. Similarly, the results from the testing laboratory should flow back to the originating LIS.

Peer-to-peer models—where one LIS directly contacts another LIS—do exist but are less common than models with a central data exchange, which forwards the data to the correct LIS.

#### 9.1.4 Point-of-care Testing

Point-of-care tests (POCTs) can be performed either outside a physical laboratory building or at a small health facility that does not have a complete laboratory infrastructure. The goal is to be close to the site of patient care and therefore results need to be available quickly and reliably. The POCT device needs to communicate with the LIS so that results can be available in the LIS once the test is completed. This communication may be done with an intermediate device/middleware/POCT data management system that is then integrated with the LIS. Connectivity can be one way (i.e., from POCT to middleware to LIS) or bi-directional (i.e., from LIS to middleware to POCT and back to LIS).

For full integration, all POCT instruments and users need to be linked with the LIS. This will enable monitoring of the POCT instrument including quality control, calibration and maintenance in addition to patient ID and test results.

Figure 15. EMR and LIS Communication

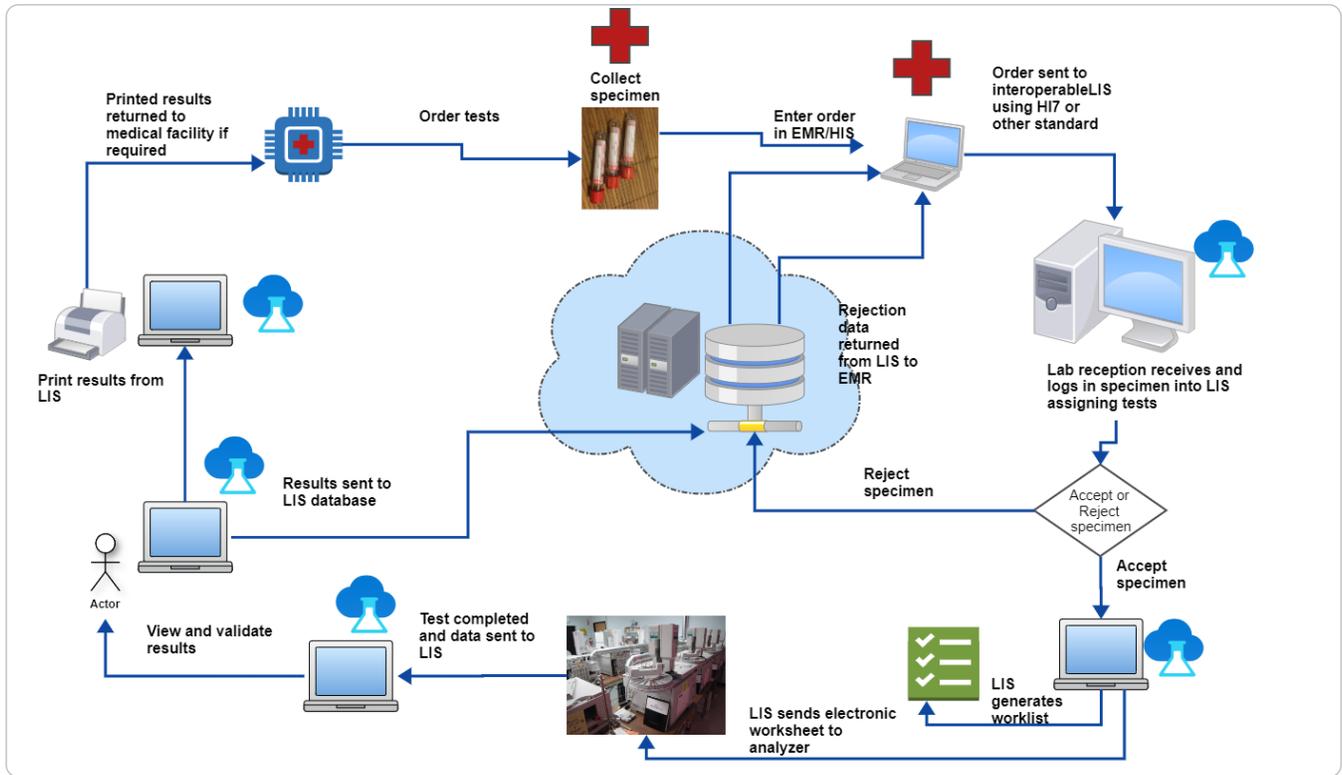
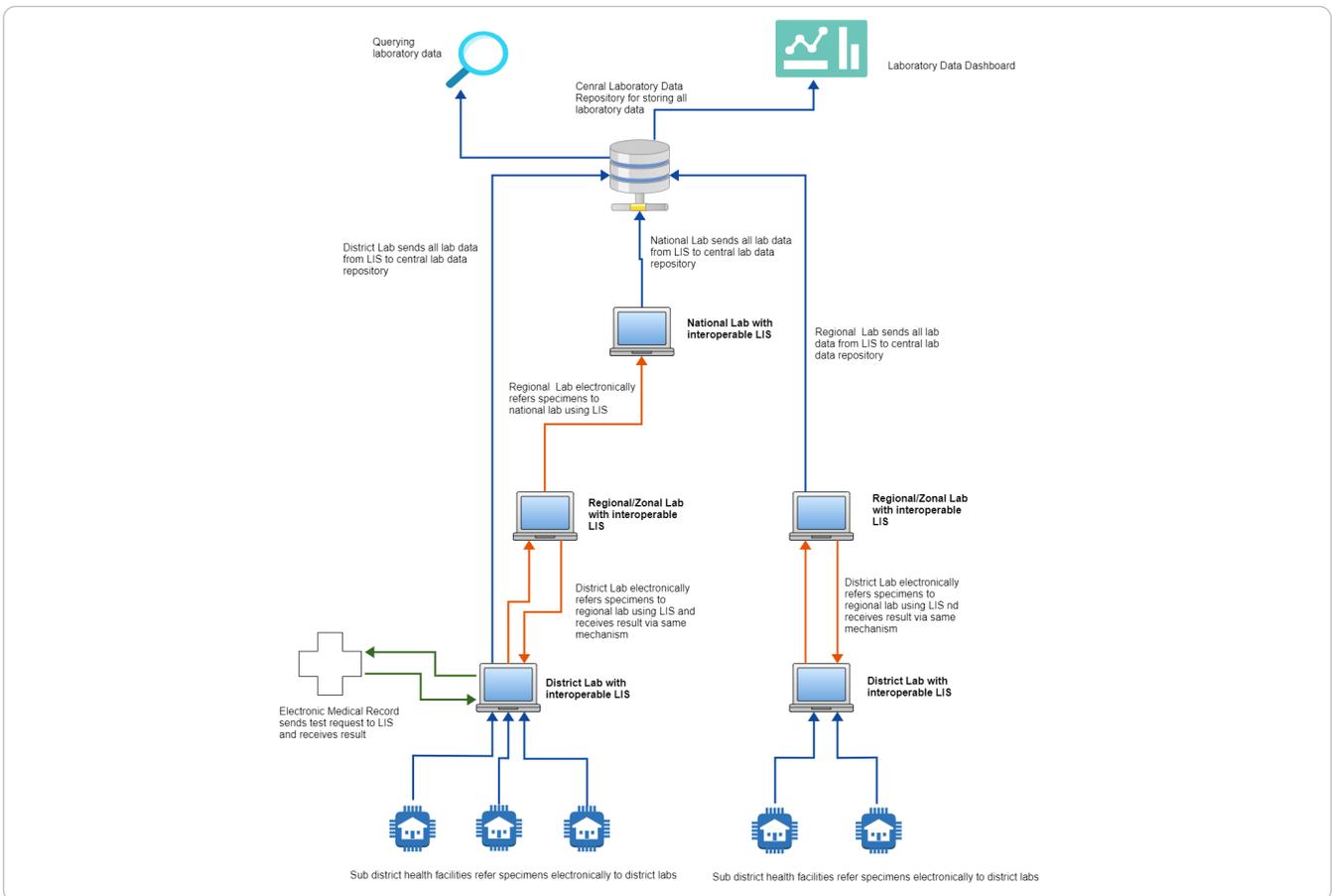


Figure 16. Integrated LIS Communicating Across Facilities



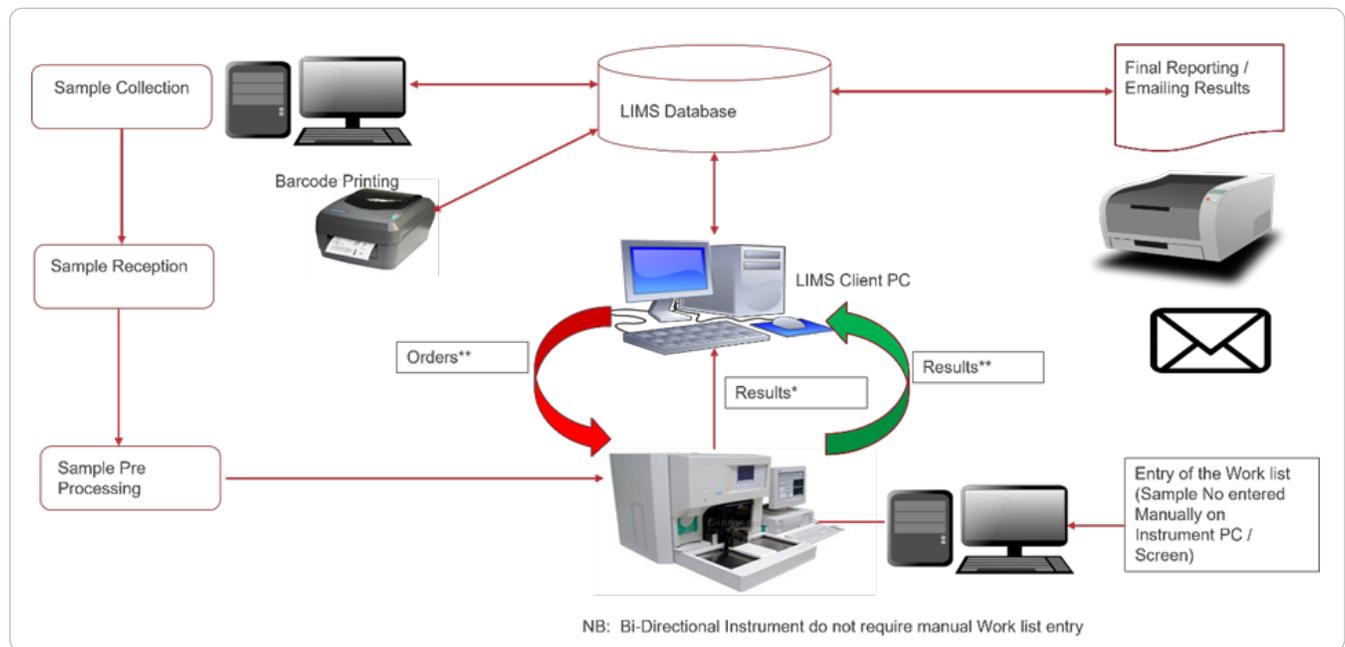
## 9.2 In-laboratory Systems

These are systems that need to capture data within a laboratory and feed these data into the LIS.

### 9.2.1 Laboratory Instruments

Within the laboratory, a critical piece of electronic data transfer is the ability for the LIS to directly capture data from instruments. This sounds straightforward but is currently a missing piece in many laboratories and requires manual data entry of results from the device into the LIS. There are different technical ways to capture data from instruments and send data to instruments.

Figure 17. LIS Instrument Integration



### 9.2.2 Instrument Interfacing Perquisites

- **Hardware:**
  - RS-232/USB/TCP/IP port.
  - Connection between analyzer and interface device – usually a workstation/PC installed by lab analyzer provider.
- **Software:** Usually set up by instrument provider to control the laboratory analyzer and output of data to devices.
- **Data format:**
  - RS-232: The protocol to exchange data between lab analyzer/analyzers and external devices.
  - ASTM or HI7: Standard for communication between lab analyzer and information system.

## 9.3 Direct Data Capture from Output Ports

Data can be captured directly from the instrument's output ports (e.g., USB, printer port, etc.) and transferred into the local LIS. Once the data is in the LIS, it follows the regular data.

- **Scenario 1: Hard-wired Connection**

In an increasingly common method, a manufacturer has a hard-wired connection to their instrument from a computer. They have full two-way control and communication with the instrument from the computer. The controlling software often stores the data in a local proprietary format, or the data can be extracted to an external file. The file transfer software finds the instrument data either directly from the manufacturer storage or the extracted files. The data is then transferred to another waiting computer, similar to the way a web server is waiting

for requests. Once the file is received the individual data elements are parsed from the file and then transferred to the LIS or, if no LIS is present, it is sent to a central data repository. A common question in this scenario is why do you need a second computer running the parsing and data transmission software? Often, the manufacturers do not want any other software installed on their computers.

- **Scenario 2: Self-contained Instruments, Physical Cable Connection**

In a variation on scenario 1, many instruments are self-contained and do not require an attached computer from the manufacturer. In this case, a non-manufacturer computer is physically connected through a cable to the instrument and the data is captured as it is sent out the port, like sending data to a printer. The computer runs raw data capture software that monitors the port the instrument cable is plugged into and captures the raw unformatted data. The parsing software then takes over and breaks down the data into individual data elements that are ready for transmission

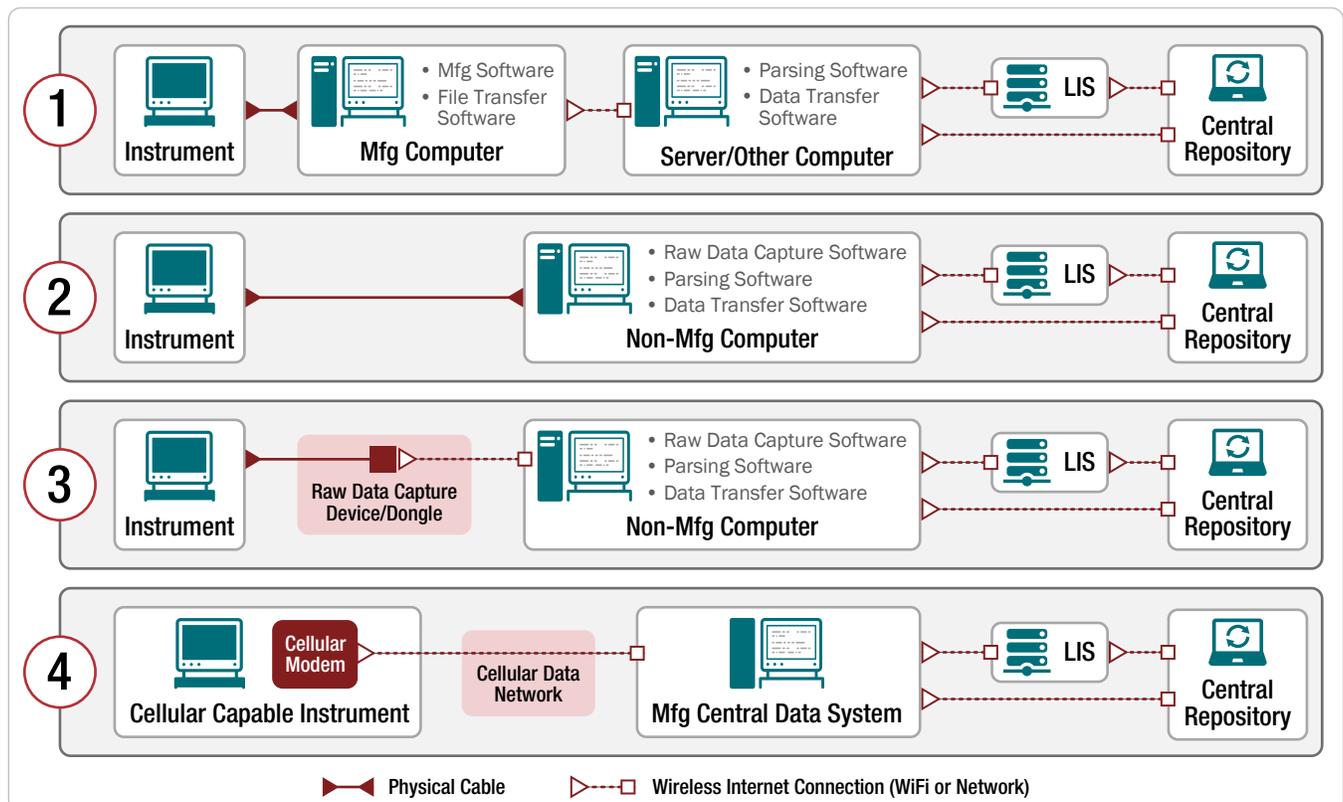
- **Scenario 3: Self-contained Instruments, No Cable Connection**

This scenario is very similar to scenario 2, but there is no physical cable. Many people find it difficult to find or make the cables necessary to connect an instrument to a computer, or the distance might be difficult. You can purchase generic data capture “dongles” that connect to RS-232, USB or other types of ports. These dongles capture data that is sent out of the port, like the printer example in scenario 2. The device then transmits the data to the data computer. When the raw data is received the parsing software again deconstructs the data into individual data elements that are ready for transmission.

- **Scenario 4: Self-contained Instruments, Cellular Connection**

As instruments are pushed to smaller, remote locations, the instruments become more self-contained and there may not be a computer at the facility. The instrument contains a cellular modem (or attachable cellular modem) and the data are sent to the manufacturer’s central data system via the cellular data network. If the location has WiFi and an internet connection, the transmission can take place over WiFi but often cellular is the only option. Users can access the data through the manufacturer’s website, or the manufacturer may be willing to forward the data to a data system within the country; it is also possible for a LIS or central repository to contact the manufacturer’s central data system and request the data.

Figure 18. Direct Instrument Data Capture (Scenarios 1–4)



## 9.4 Direct to Centralized Data Repository or Central Data Exchange

More instruments are getting installed at small/lower-tier laboratories and healthcare facilities which have an EMR or LIS in place. Traditionally, staff at these laboratories would have to print results directly from the instruments for each patient to return to clinicians. With instrument integration, data capture software can retrieve the data from the instrument and send it directly to a central data exchange system or central laboratory data repository using cellular technology. Then the results can be accessed remotely by applications using standardized electronic interfaces which could include laptops or hand-held devices used by clinicians or the remote laboratory staff.

## 9.5 Instrument to Manufacturer's Central System

Some instruments manufacturers have created their own data transmission capabilities (via WiFi or cellular) which allow instruments to send data to a designated location (determined by the manufacturer or the client), including the manufacturer's centralized cloud storage system. Users can look up or analyze data within the manufacturer's cloud system or forward the cloud data to the country's own centralized systems. The manufacturer-supported centralization can sometimes be a more cost-effective data centralization methodology because the cost is spread across the manufacturer's entire customer base. Also, because the company created the instrument, they are uniquely situated to keep the software up-to-date as changes are made.

## 9.6 Equipment Inventory and Consumables

Most LIS only have the capability to track basic information about consumables, equipment and personnel, despite the fact that laboratory staff usually need more than just basic information. Equipment inventory management systems can bridge this gap in functionality by recording details about the instruments such as maintenance contracts, repair and calibration history, and maintenance schedules—or, if being done in-house, manage the scheduling of calibrations and maintenance.

An LIS can integrate with an external equipment inventory management system and provide important alerts to laboratory staff. Laboratorians are more likely to be logged into an LIS than the equipment tracking system and are thus more likely to see alerts about equipment maintenance or calibration needs. For similar reasons, the LIS might be an easier place to log equipment issues with an integrated system that information could still be sent to the equipment management software. Eventually, this could include real-time inventory monitoring or even real-time test catalogs at each laboratory, which are updated constantly from individual LIS to reflect the available of equipment for testing.

It is important for laboratory management staff at the local and national levels to know the status of equipment and track how often equipment is out of service. Laboratory staff can provide useful input about how they would best be able to keep this information up-to-date—whether entering information in the LIS or sending it via API to the equipment management system—for monitoring.

The LIS generates valuable data on usage of consumables within a laboratory as details of tests kits, reagents used, any failed and/or repeated tests are captured electronically. Integration with an inventory/consumables management system would enable laboratory staff to have accurate data on stock management and be able to do better forecasting for their needs. In certain cases, the LIS may have the capability to manage basic logistics and inventory management functions. Integration with an inventory management module would allow for tracking of expiry dates, minimum and maximum stock levels, refill rates, product dollar values while applying usage information from the LIS.

## 9.7 Freezer Management

While it is always important to be able to find the storage locations of specimens based on information generated during the testing process, it is also highly beneficial to be able to search based on information from surveillance systems and studies. Epidemiologists often need to look at data from these surveillance systems and then easily find where the specimens are stored.

Most LIS can track the short-term storage location of a specimen as it moves through the laboratory, though not all have the capability to manage the long-term storage location of specimens. Long-term freezer management systems can be extremely useful as they allow for more information to be stored with the specimen such as specific studies or outbreaks they were part of, or other identifiers for groups of specimens.

An integrated LIS and freezer management system would allow someone to easily enter search parameters based on data from any of the surveillance or study systems and generate a “pick list” to find and gather the relevant specimens. Many laboratories will benefit from the ability to easily locate specimens related to outbreaks.

## 9.8 Quality Management, EQA

Very few LIS contain functionality to administer an EQA or PT system. Laboratories typically receive PT panels from the provider and then manually enter results into their LIS. Integrating the PT system used by the PT provider with the testing laboratory’s LIS would enable the laboratory to share results automatically, rather than transcribing or manually them, thus reducing errors.

**An integrated PT/LIS system could flag an individual who failed a proficiency test and block them from performing that function until they passed.**

Laboratory management staff should examine what information is in their external PT system and determine how it ties in with their LIS data, and what value it would add to have PT results accessible directly from the LIS user interface.

## 9.9 Personnel

Personnel management systems in LIS are typically very basic. Laboratory managers need to be able to track many aspects of their personnel beyond what is typically available within an LIS, such as vaccine administration, trainings, certifications, emergency contacts, current employment status at more than one laboratory and more.

Before investing in or developing an external system, laboratory management should investigate the possibility of having their LIS updated to manage all the necessary information. Integrating personnel-related information into an LIS allows laboratory managers to receive notifications whenever they are logged into the LIS, so they can be reminded when staff are behind on their vaccines, trainings or certifications.

If this information is currently kept outside the LIS, consider what information would be useful to someone who logs into the LIS more than a personnel tracking system. An API could be written to have the LIS contact the personnel system and ask for general notifications or even ask for specific information, such as out of date vaccinations or trainings. Similarly, the LIS could also be setup to accept data from a personnel system which would send the same sets of information.

## 9.10 Reporting/External Systems

### 9.10.1 Central Data Repositories

The value of sending laboratory data from individual LIS to central data repositories is just starting to be realized. The COVID-19 pandemic highlighted the benefits of having a centralized data system for many countries such as Mozambique and Kenya, whose central systems allowed the governments to monitor testing and results throughout the country. These same central repositories were also used as data sources for their national-level COVID-19 results validation programs.

The ability to monitor country-wide data from a central location has proved valuable from many different aspects:

- Workload analysis
- Specimen rejection monitoring
- Data quality review
- Instrument/Analyzer functioning
- Program and policy monitoring
- Public health response management
- Disease/test specific trend analysis
- Data exchanges with other systems like EMRs, outbreak case management, results distribution, LMIS
- Data correlations (e.g., workload to consumables).

If integration is well defined, it will provide any entity in the country—any LIS vendor, instrument manufacturer or data capture/collection software—the ability to conform to the standard and allow for the data to be centralized. Even if the entire laboratory system utilizes a single centralized LIS (e.g., a web-based system), a national laboratory data repository still has value. The live system is optimized for the daily workflow of the laboratories. Periodically copying the live transactional data to a separate data system that is optimized for data analysis is a common practice with large data systems. The methodologies for transferring the data between the LIS and the central repository are the same.

### 9.10.2 Sample Transport and Specimen Tracking

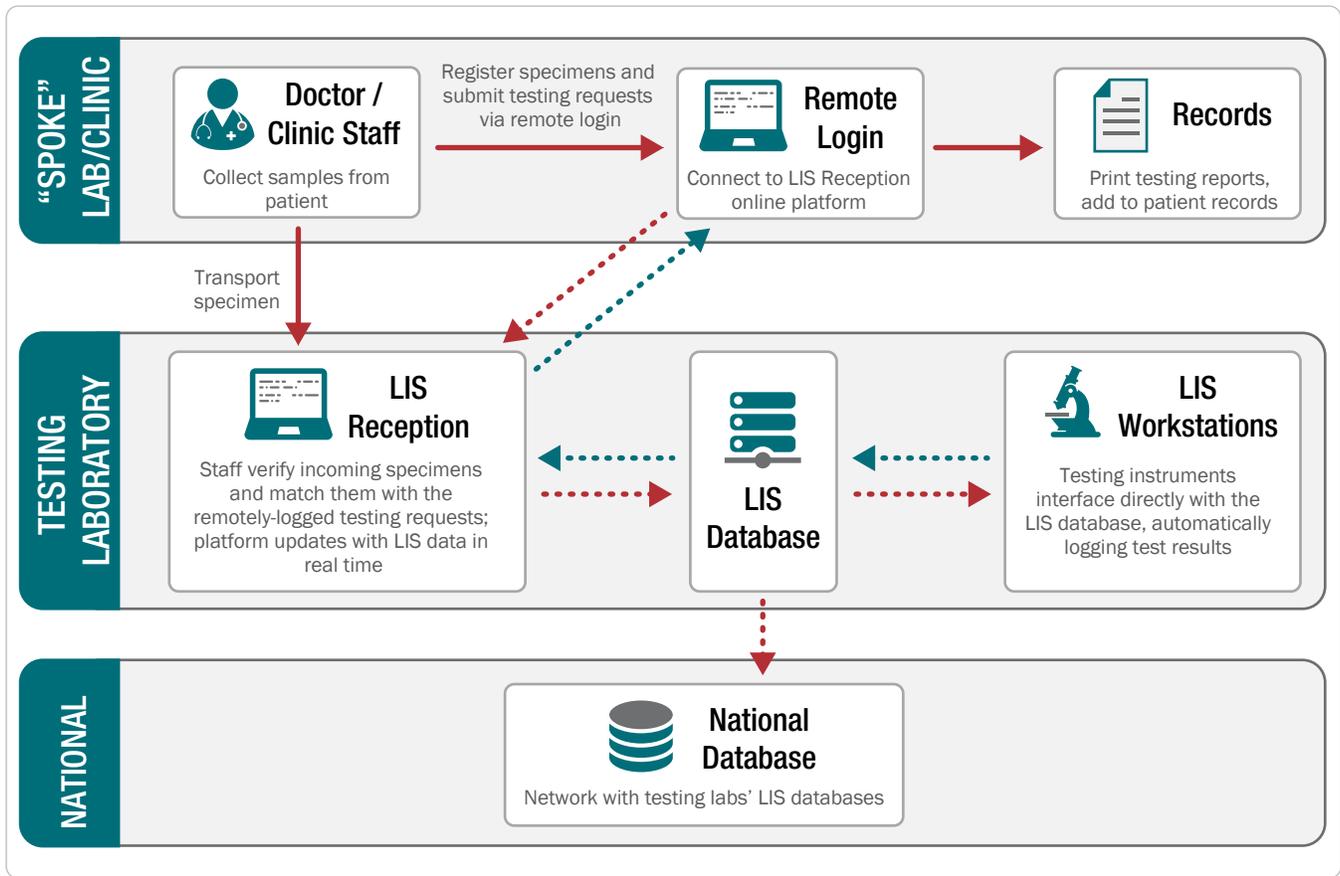
Specimens are often not tracked when shipped from one site to another. There may be a pre-registration function at the source facility that allows data to be logged into the target facilities system, but this is not an example of integration as they are working within one system.

If the source facility uses an LIS, integration would allow the source facility's shipment identifier to be stored in their LIS, enabling specimen location monitoring at any point in time. This could be a complicated and detailed integration with the shipper's system, or it could simply be a tracking link provided to the LIS user.

Specimen tracking can be used in a variety of contexts:

- **Hospital → Laboratory:** When specimens are shipped from a hospital to a laboratory, integration between the hospital information system and LIS becomes essential for specimen tracking. Integration between the systems allows the laboratory to know what specimens have been collected by the hospital, when they were collected and when they were shipped. Similarly, the hospital can track when the specimens were delivered, the testing status of the specimen and if results have been approved and released.
- **Laboratory → Laboratory:** When a laboratory that does not have the testing capacity refers the specimen to a laboratory with greater testing capacity, integration between the two systems is required for tracking. This becomes especially critical as the testing laboratory does not have direct interactions with the customer or submitter and is responsible for ensuring results are returned to the referring laboratory, which will then communicate results back to the submitter.
- **Surveillance System/Field Epidemiology/Specimen Collection → Laboratory:** The surveillance system can generate a request for a laboratory test based on the epidemiological data collected (e.g., from rapid response teams in the field); this information would need to be shared with the LIS in the testing laboratory. The integration would enable the testing laboratory to either determine when the specimen has been collected or to arrange for specimen collected and assign identifiers generated by the surveillance group.

Figure 19. Transmission of VL Results from “Spoke” facilities



### 9.10.3 National Systems

Many countries are working on standardizing key sources of data required by various health systems, such as:

- **National Health Care Identifier (ID):** Used for looking up patient information. This would include needing to create new patients and possibly merge patients through the interface.
- **Providers:** National lists of providers and information about those providers.
- **Test Catalogs:** National lists of laboratories and tests they are currently providing.
- **Personnel:** National lists of personnel working at the laboratories. See also the LIS to personnel interface scenario.
- **Electronic Health Records:** Country-wide or regional systems with easy access to a patient's health data.

## 10. LINKING LIS TO SURVEILLANCE SYSTEMS

LIS are in an ideal position to provide timely information to case tracking systems. While laboratories are not surveillance systems, they support the collection of critical data for the epidemiological systems.

Many countries that have central laboratory data repositories, such as Zambia, Kenya, Tanzania and Mozambique, have realized the value of centralized electronic data and have started to implement the collection of epidemiological data through the specimen registration process. These datasets include specialized forms to collect programmatic data related to HIV viral load, HIV Early Infant Diagnosis, tuberculosis and COVID-19.

Case tracking support can be done directly from each individual LIS or from a central data repository. Some countries may prefer that the LIS centralize the data so there is a single point of maintenance and interaction with external systems. A centralized system allows the case tracking system to only contact a single system to get test results.

Interfacing LIS to surveillance systems for case tracking purposes is a good example where planning and documenting the user workflow and variations on that workflow are critical. Case tracking systems often assign a case ID, but the case ID may not always be available at the time the specimen is collected. Some case tracking systems require the user to call a central office to open a case, others utilize text messaging and still others have a web interface or application for users to directly enter the data and receive a case ID. The workflow needs to be carefully documented so users know which unique identifiers are important, when a case ID is generated, where each piece of data is to be entered and how the LIS data is eventually matched with data in the surveillance system.

### 10.1 Tightly Coupled Data Flow

In an ideal world of fully integrated systems, an EMR would have an electronic interface to a suspect case tracking system, allowing it to get a case ID and send information about the patient directly to the tracking system. The EMR could then send the case ID along with test orders and specimen information to the LIS. The results from the LIS could be sent directly to the tracking system with the case ID for easy data matching and a quick return of test results to the case managers.

In a more limited scenario but similarly efficient, any patient with a suspect case would get a case ID assigned. That case ID would be sent along with the test orders and be attached to the specimen data within the LIS.

### 10.2 Loosely Coupled Data Flow

In many cases an EMR is not used at the clinician level, and a patient may be sent to the laboratory to get tests performed before the clinician notifies the surveillance people and a suspect case is opened. In cases like this, it is important to have both the clinician and the laboratory receiving department collect and enter a patient identifier that is unique within the country. That patient ID is the unique identifier, which is then used to match the LIS data to the case tracking data. It is also important to identify and document which system initiates the data exchange. In a case like this, the LIS may not know the specimen is part of a suspect case and not know to forward the data. The most efficient method would be for the case tracking system to request data from the LIS for the patients within its system. This will likely be a repeated request because follow-up testing could be performed. Ideally a case ID would be included with any continued testing and the LIS would then know to automatically send the data to the case tracking system. Alternatively, the LIS could send all testing data related to surveillance efforts to the appropriate case tracking system for matching to suspected cases.

Both scenarios described show the need for planning and documentation to match LIS test data to any surveillance system within a useful time frame.

When planning the LIS and case tracking interactions it is important to consider the uniqueness of the various identifiers:

#### Case ID

Unique across all surveillance programs.

#### Specimen ID

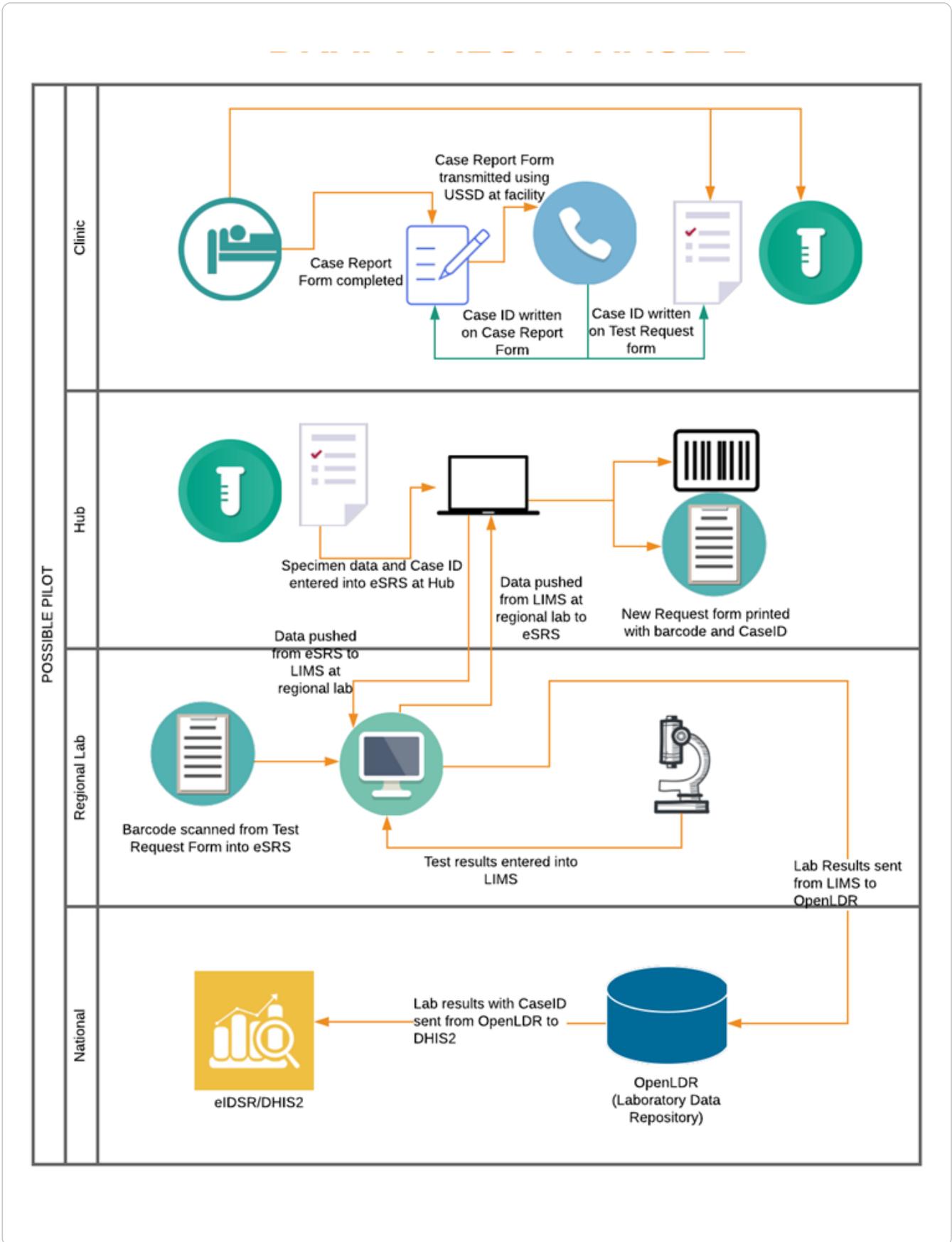
Unique across all LIS sending data to the surveillance program; often a nationally unique identifier.

#### Patient ID

Unique across the country.

If testing is related to a public health event, it may be necessary for an LIS to share data with a surveillance or case-based reporting system such as DHIS2, SORMAS and WHONET.

**Figure 20. Complete Workflow From Facility Identifying Suspect Case, Collection of Specimen, Completion of Test and Return of Results to Surveillance System**



# 11. TO INTEGRATE OR NOT TO INTEGRATE

## 11.1 Considerations and Practical Approaches

After the workflow is well documented, consider the value a fully electronic interface will provide, and gather answers to questions such as:

- How much staff time will an interface replace?
- Will a significant improvement be seen in the speed of data reaching its destination?
- How important is the speed of data movement?
- How often will the interface be used?
- Will an electronic system help alleviate any errors introduced by hand transcription of data?

### 11.1.1 Data Speed

Getting accurate test results back to clinicians quickly has a big impact on patient outcomes and warrants the infrastructure necessary to achieve that task. At the same time, it is important to determine when real time test results are warranted. Consider asking the question, “what decisions will be made with the laboratory data and when will they be made” and design the frequency of data exchange accordingly.

### 11.1.2 Consolidated Reports

Integration can streamline the flow of data from orders/test requests to reporting out of results to physicians, health facility staff and patients.

### 11.1.3 Upkeep and Monitoring

A centralized system needs monitoring to ensure data is flowing and the quality is maintained. Consider the staff and the skills needed to monitor the systems, troubleshoot problems and to contact people to resolve issues. Some systems might warrant quick turnaround, while others might be able to wait longer.

### 11.1.4 Staff Training

Consider how well the skills of existing staff match up with the requirements of each integration methodology. For example, a file transfer system will require someone with far less technical skills to develop and monitor than a Web Services API.

### 11.1.5 Costs

Costs will depend on different factors, such as:

- **Degree of integration:** What needs to be integrated? Will the integration be one to one? One to many? Many to many?
- **Size of integration team:** Consider the complexity of effort for the integration, including programmers/developers, laboratory technicians/scientists.
- **Reusability:** How easily can the data be extracted and can a new system easily connect using the same methodology applied?

## 11.2 Complexity and Cost/Benefit

The cost of getting two systems to communicate can be significant. The cost of integration breaks down into many different components, including:

- Staff to manage project
- Staff to participate in the API definition (technical and laboratory staff)
- Development and testing costs
- Implementation and testing
- Training in the management, monitoring and maintenance of the system
- Long term maintenance (internal personnel or external contracts)
- Onetime or recurring software licenses.

## 12. NEXT STEPS

Ensuring an integrated LIS requires consideration of several different pieces, as has been outlined in this guide. To move forward with an integration project, ensure the initial steps outlined in this document have been agreed upon.

Some immediate next steps to be considered are:

- Examine the existing workflow and plan for any changes needed.
- Conduct a needs analysis by understanding systems and stakeholders including current use of systems across the laboratory.
- Analyze the information gathered to determine the best integration approach and develop a roadmap.
- Ensure you are considering connecting:
  - People
  - Processes
  - Systems
  - Data.

It is important to remember that the concept of an integrated laboratory implies a completely digital environment with no manual work and seamless work and data flow. Recent developments in technology including the Internet of Things, artificial intelligence and machine learning will begin playing a major role in ensuring full integration as they will improve lab connectivity and automation. The steps listed above need to be considered in conjunction with these new technologies.

# 13. APPENDIX: INTEGRATION IMPLEMENTATION EXAMPLES

## 13.1 Data Flow For Surveillance

This example uses a scenario from active surveillance where suspect cases have been identified:

The suspect case may be seen at a clinic or in their home, with an epidemiology form completed based on the information collected. The epidemiology form is then entered into the surveillance system at a hub or other designated site. If a care provider recommends the collection of a specimen, collection is done separately from the epidemiology form, with no identifier used to link the laboratory specimen with the epidemiological data. The specimen is then sent to the regional laboratory for testing and results are returned to the care provider or clinic. However, as the epidemiology and laboratory data follow two different “pathways,” there is no way to link the final laboratory result to the epidemiology data for that case besides name and address—which are usually not the most reliable way to connect data sets. In most cases, the epidemiology data remains as a suspect case in the system and the laboratories report their data separately. While data integration is needed between the epidemiology and laboratory systems, the data and workflow hinder an effective system integration.

To work towards data integration, several discussions were held between the Ministry of Health’s Laboratory and Epidemiology teams. Below are the proposed solutions and related considerations.

### 13.1.1 Specimen IDs

**Proposed Solution:** Modify the workflow and data flow to include a Specimen ID on the case notification form used to enter individual case-based data into the USSD system. The Specimen ID will be specific to a facility and will always be associated with a case. After testing is completed, the laboratory will log into the electronic Integrated Disease Surveillance and Response (e-IDSR) system and use the facility and Specimen ID to identify the case and enter the laboratory result.

**Considerations:**

- Case notification form must capture essential information for matching cases with specimens: requesting facility, Specimen ID and specimen collection date.
- Point of collection sites will need training on assigning specimen identifiers. If these identifiers are to be printed, supplies will be required at each facility.
- Laboratories will need to be able to access the internet, search for a specific facility, Specimen ID and collection date, to enter the laboratory result. There is also the possibility of errors from this manual data entry.

### 13.1.2 Case IDs

**Proposed Solution:** Further modify the workflow to add a Case ID on the laboratory requisition investigation form so all test requests entered into the LIS will include a Case ID. This can be used to electronically match the data from the LIS and the data from e-IDSR.

**Considerations:**

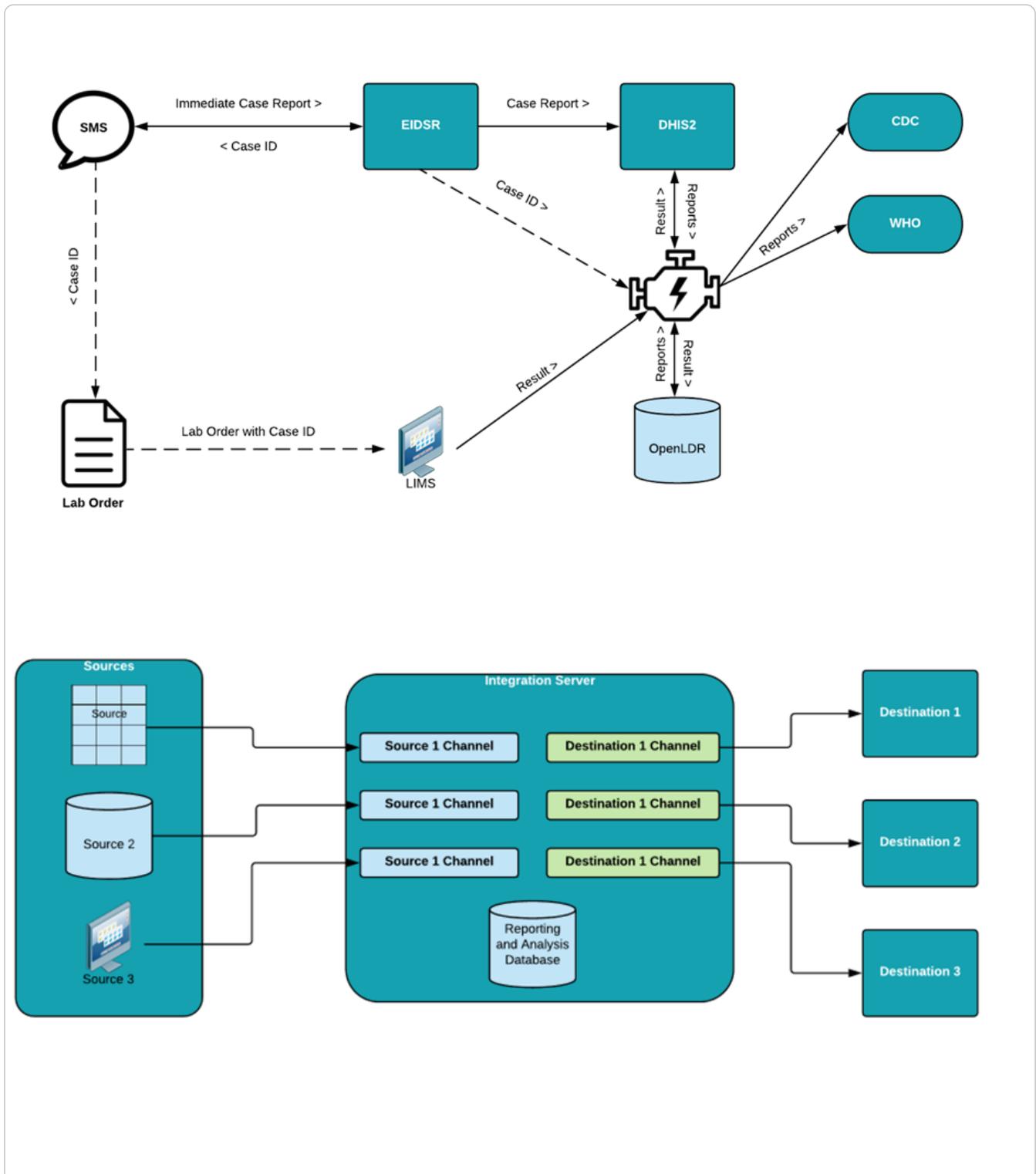
- Point of collection sites will need training on documenting Case ID correctly on laboratory investigation forms as truncated IDs will hinder matching cases with findings. This approach relies on Point of collection being able to obtain the Case ID before the specimen is collected.
- Collaboration will be required by developers of both systems—LIS and e-IDSR—to agree on the data to be exchanged and the method to be used. There will be modifications required to e-IDSR/DHIS2 and to the LIS to incorporate the identifiers required for a data exchange.
- This approach will also need determination of whether the exchange will occur at the level of the laboratory or between the Open Laboratory Data Repository (OpenLDR) and e-IDSR.
- It will be important to prioritize the laboratories/LIS with which data will need to be exchanged with the IDSR such as microbiology section, to ensure modifications factor in both process and technology changes needed.

### 13.1.3 Submission of Aggregate Data

**Proposed Solution:** Submission of aggregate laboratory data to e-IDSR from the OpenLDR. This will allow for confirmation on number of cases for a priority notifiable condition or disease.

**Consideration:** Case confirmation would not be possible through aggregate laboratory results reporting.

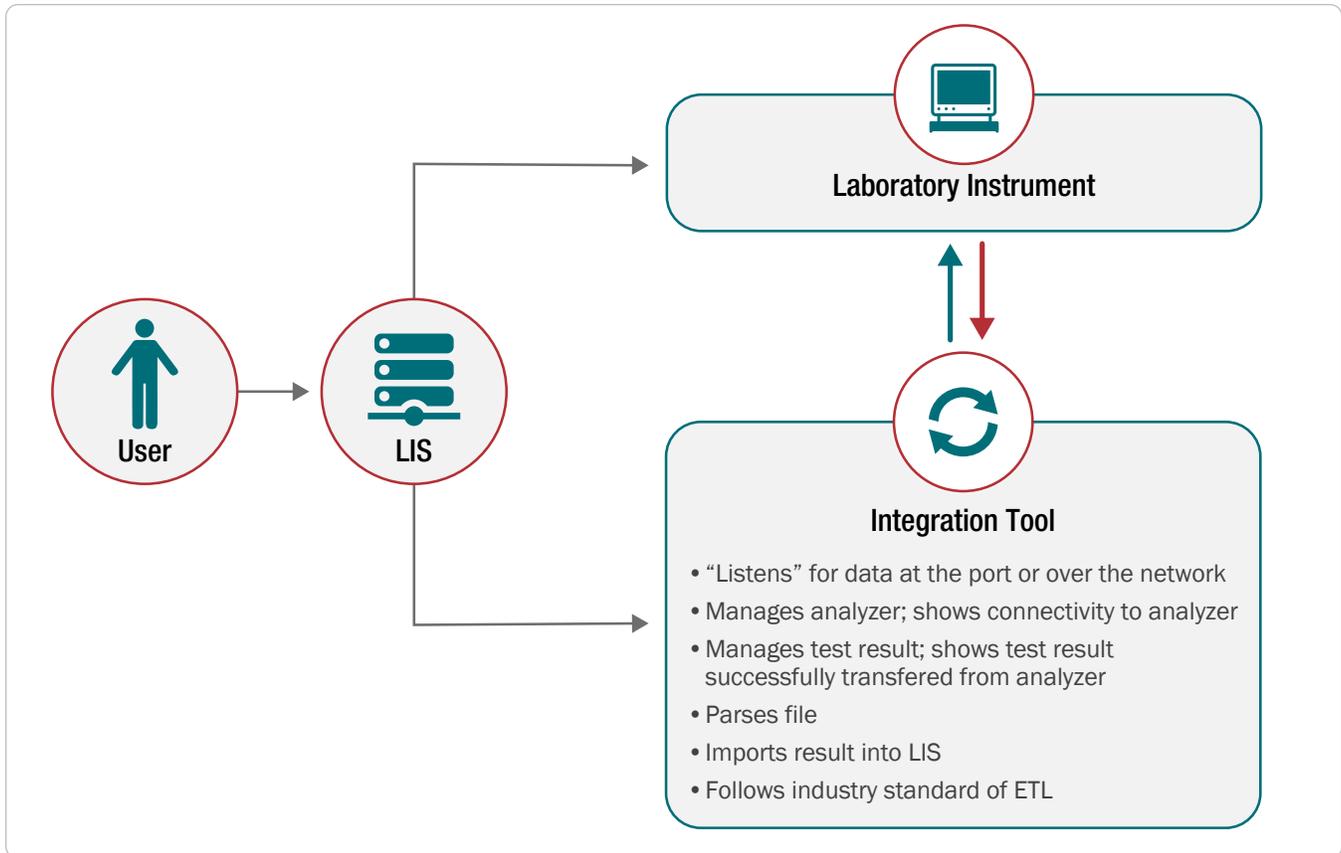
Figure 21. Examples of Architecture with Integration Engine



## 13.2 Instrument Integration and Flow to National Laboratory Data Repository

Instrument integration allows users to upload excel files with prescribed forms, parse and show data inside it.

Figure 22. Instrument Integration Process Overview

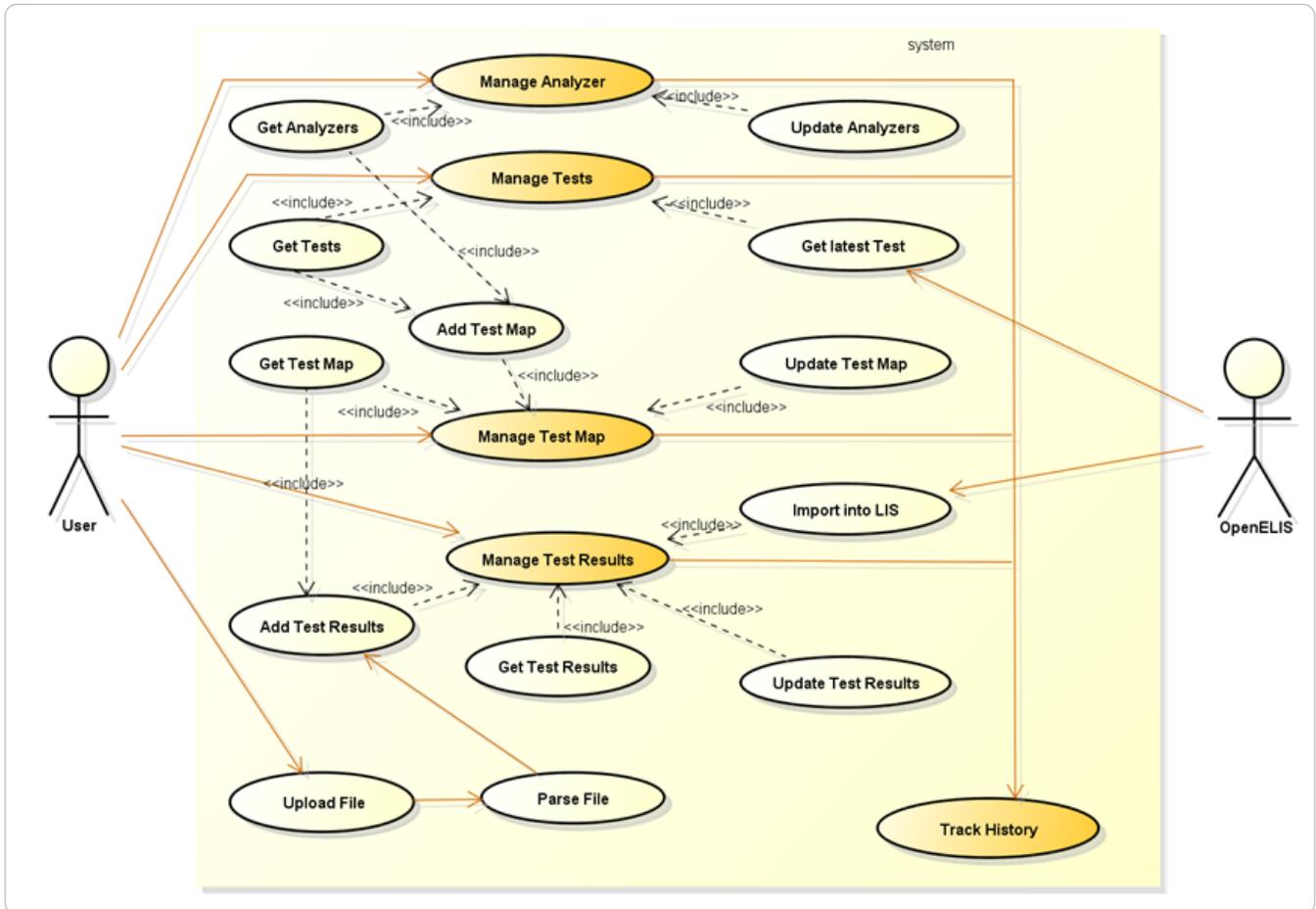


An Instrument Integration Tool has the following features/use cases:

- **Manage analyzers:** Show and modify the connectivity to all analyzers and its status.
- **Manage test result:** Show all test results that successfully transfer from the analyzers through up-load-file, parse-file features and import test results into the LIS.
- **Manage tests:** Show all tests from system. Get and add the latest tests from LIS to system.
- **Manage test map:** Get, update and create the test map that mapping the test result between ana-lyzer and OEG.
- **Upload file:** upload excel file with prescribed forms.
- **Parse file:** Parse data from excel file and save it.
- **Track history:** Track all history of data at the time it is transferred from the analyzer to the time it is transferred into LIS system.

The figures below illustrate some of these system use cases in more detail. NOTE: "User" indicates the individual using the Instrument Integration Tool, and "LIS" is the database the system uses to store the analyzer's output data.

Figure 23. Instrument Integration System Overview

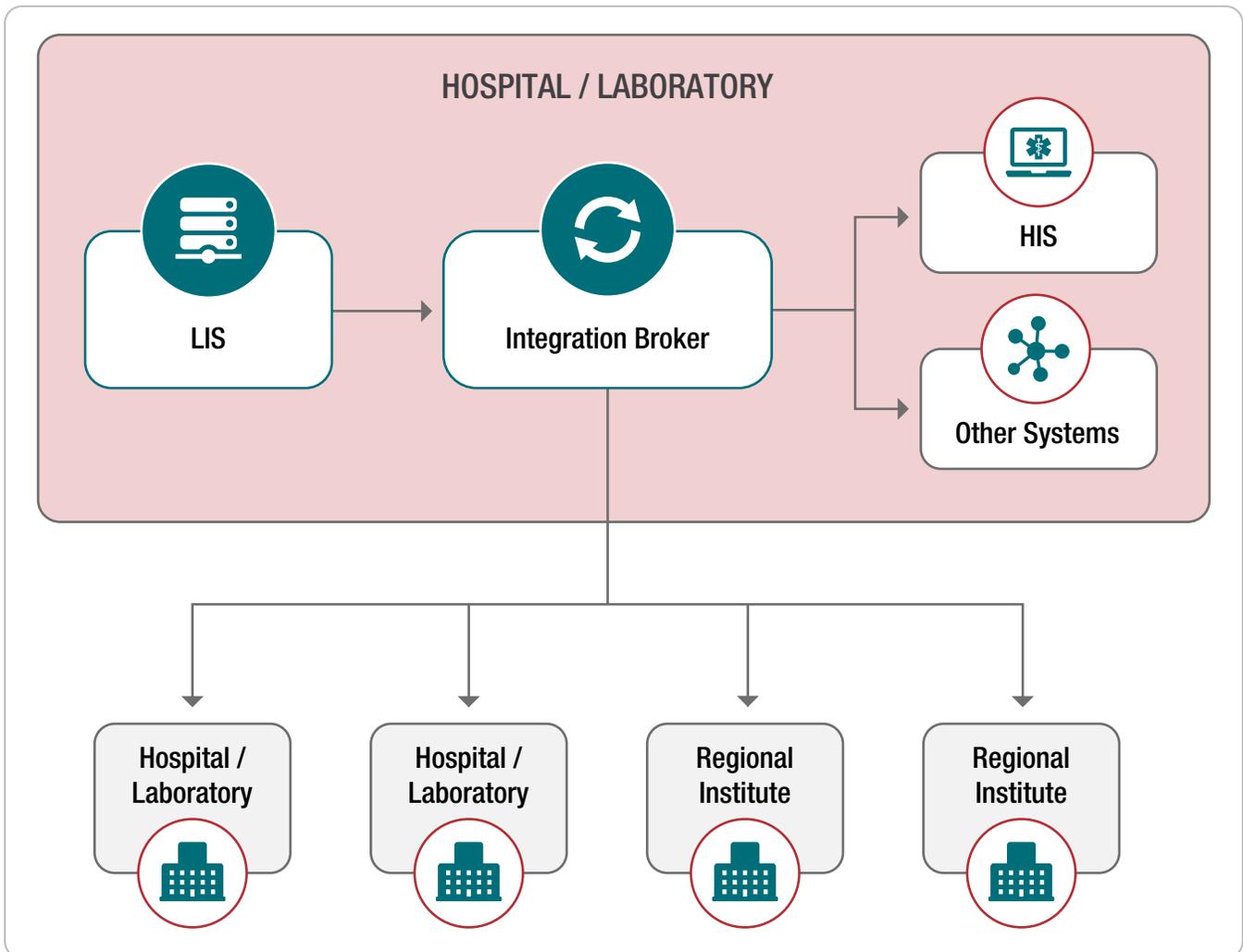


## 13.3 LIS Integration

When integrating an LIS:

- The interfacing between systems should not be a vendor- or system-specific activity. This is not scalable.
- The interfacing between systems should flow through a centralized integration broker and integration team.
- The interfacing between organizations should also flow through their respective integration brokers, ultimately creating a network of networks.
- Implementing standards in the healthcare organization will prepare the organization to standardize data exchange with external trading partners.
- Major HIS vendors should be involved in the standards process.

Figure 24. LIS Integration Overview



## Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.



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