Office of the National Coordinator for Health Information Technology

Strategies for Enhanced Laboratory Data Interoperability

Partnerships | **Policy** | **Standards**

ONC Partnership Activities: Regenstrief Institute

Cooperative Agreements: Technical and content development of LOINC® (Logical Observation Identifiers Names and Codes*)

2022 Survey: Understanding the use and implementation of LOINC by U.S. based laboratories

2023 and beyond: Continued study of LOINC community needs

*https://loinc.org/

Multi-stakeholder Partnership: SHIELD

- Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD)
- Federal, academia, and industry partnership
- Charge: Build, implement, and support a comprehensive solution for interoperability throughout the laboratory data life cycle
- Goal: 100% lab data integrity

"Describe the SAME test the SAME way ANYWHERE in the Healthcare ecosystem".

https://bit.ly/SHIELDLabCodes

Coordination: Federal Partners

- Leaders across four federal partners: ONC, CMS, CDC, FDA*
  - Charge: Catalyze meaningful progress in laboratory interoperability
- Activities
  - Identify high impact transformation/change opportunities
  - Identify and coordinate agency actions
  - Contribute to the ONC's Laboratory Interoperability Report to Congress

*Centers for Medicare & Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA)

Laboratory Interoperability Congressional Report

- The H.R.2617 - Consolidated Appropriations Act, 2023 requires that ONC conduct a study and submit a report on lab interoperability by **December 2024**.
- ONC is coordinating a Federal response

HTI-1* Request for Information: Laboratory Data Interoperability

- Consensus that lab interoperability would benefit from:
  - Consistent use of standard terminologies
  - Improvements to the use of LOINC
  - Shared terminology mapping between manufacturers and laboratories via the LOINC - In Vitro Diagnostic (LIVD) specification

*Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)

Standards: USCDI Version 4

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

Care Team Member(s)
- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests
- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging
- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information
- Encounter Type
- Encounter Identifier
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Facility Information
- Facility Identifier
- Facility Type
- Facility Name

Goals and Preferences
- Patient Goals
- SDOH Goals
- Treatment Intervention Preference
- Care Experience Preference

Health Insurance Information
- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Identifier
- Payer Identifier

Health Status Assessment
- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment
- Smoking Status

Immunizations
- Immunizations

Laboratory
- **Tests**
- **Values/Results**
- **Specimen Type**
- **Result Status**
- **Result Unit of Measure***
- **Result Reference Range***
- **Result Interpretation***
- **Specimen Source Site***
- **Specimen Identifier***
- **Specimen Condition Acceptability***

Medical Devices
- Unique Device Identifier - Implantable

Medications
- Medications
- Dose
- Dose Unit of Measure
- Indication
- Fill Status
- Medication Instructions
- Medication Adherence

Patient Demographics/ Information
- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Patient Summary and Plan
- Assessment and Plan of Treatment

Problems
- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures
- Procedures
- Performance Time
- SDOH Interventions
- Reason for Referral

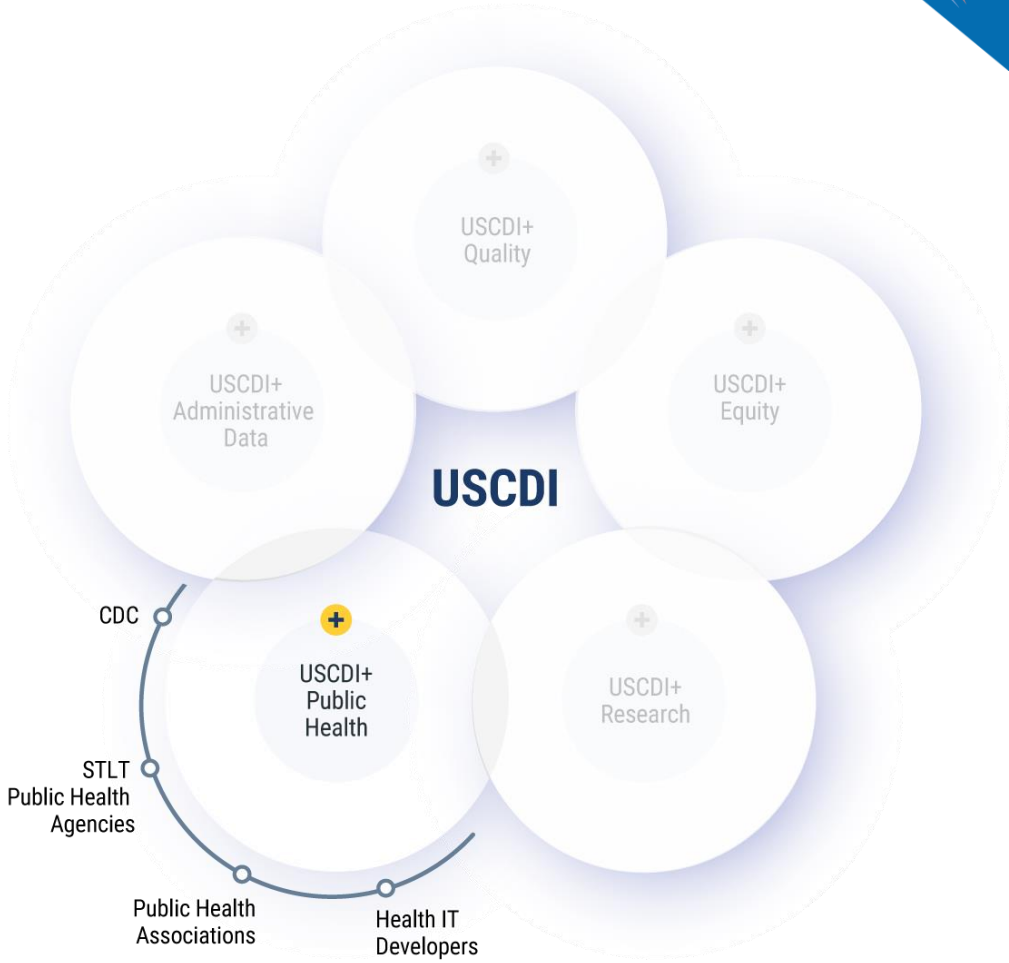
Provenance
- Author Time Stamp
- Author Organization

Vital Signs
- Systolic Blood Pressure
- Diastolic Blood Pressure
- Average Blood Pressure
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth- 36 Months)

USCDI United States Core Data for Interoperability

USCDI+ for Public Health

- Capture the data needs of public health that fall outside the scope of USCDI; improve data quality and availability
- Current priority areas:
  - Case-based Surveillance
  - **Lab Data Exchange**
  - Bi-Directional Exchange with Healthcare and Other Partners
  - Maternal and Child Health
  - Resource Reporting / Situational Awareness
  - Risk Behaviors & Health Equity



https://www.healthit.gov/topic/interoperability/uscdi-plus

Office of the National Coordinator for Health Information Technology

Contact ONC

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Phone: 202-691-2062

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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ONC 2023 ANNUAL MEETING

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Regenstrief Institute
Better Care. Better Health.

Strategies for enhanced laboratory data interoperability: Role of terminology standards in laboratory data exchange
December 15, 2023

Marjorie Rallins, DPM, MS

Executive Director, Health Data Standards

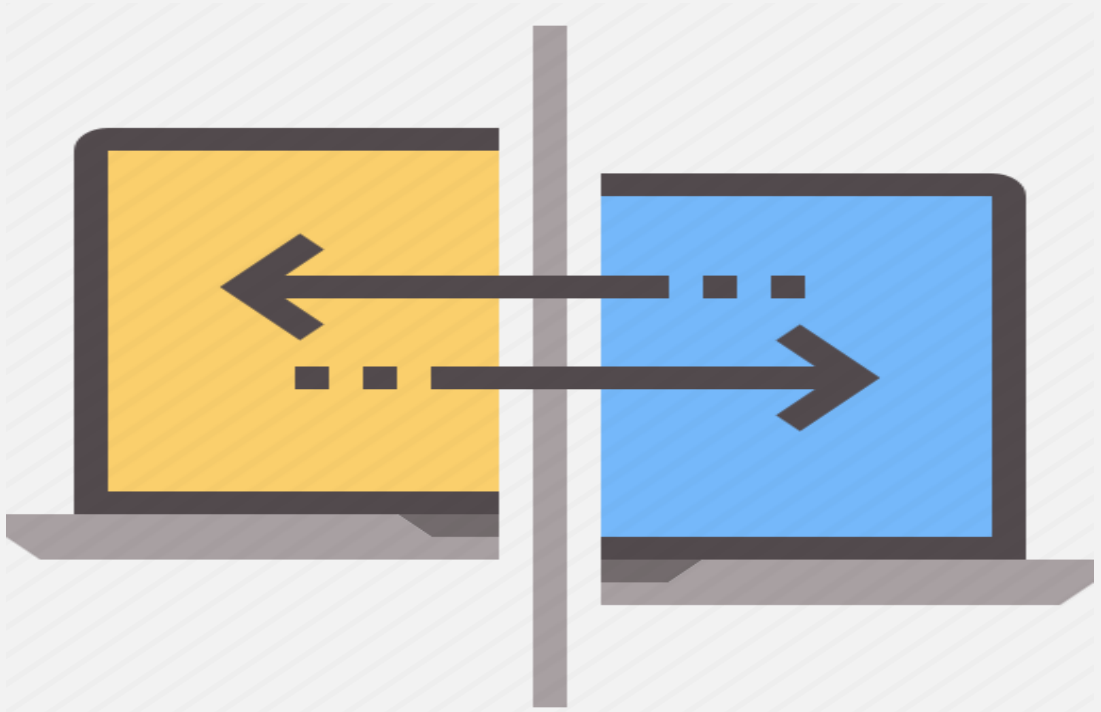
Regenstrief Institute

LOINC® from Regenstrief

UCUM

Health information exchange – semantic interoperability

- Decades long journey (4-5)
- Laboratory realm at the leading edge
- Laboratory Information Systems
  forefront of health information system adoption and innovation



Health information exchange – semantic interoperability

Clinical insights

Laboratory generated data at the core

- delivering effective clinic care
- supporting public health surveillance
- advancing research
- facilitating the administrative aspects of health care e.g. managing costs.

Vocabulary standards: foundation/payload, semantic interoperability

Clinical vocabularies*

- LOINC
- SNOMED
- RxNorm

Administrative code sets*

- ICD 10
- Current Procedural Terminology, CPT®

Other standards*

- FHIR
- UCUM

- Focus on semantic interoperability, decades long, with phases
  - Early phases: terminology development: terminology models, terminology content etc
  - Rethinking earlier work: fit the needs of users, support interoperability?
    - Consider information models rather than conveying everything in the vocabulary?
    - LOINC committees; rethinking of some attributes e.g. method
  - Computable frameworks, CPT, ICD
  - Increase FHIR focus & policy, facilitate effective interoperability

*this is not an exhaustive list

LOINC and SNOMED CT: critical to interoperability

Complementary

LOINC® — QUESTION

SNOMED CT — ANSWER

Tobacco smoking status?
72166-2

Non-smoker (finding)
8392000

LN 72166-2 Tobacco smoking status | SCT 8392000 Non-smoker

Message field identifying the question/observation

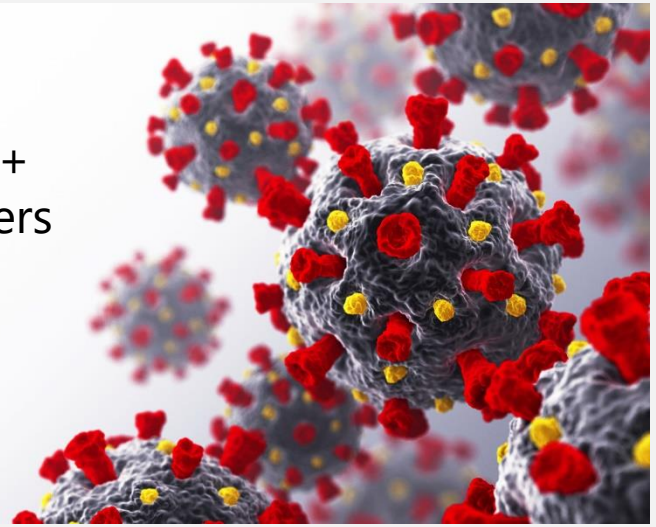
Message field **identifying the answer/result**

Collaborative

LOINC® from Regenstrief

SNOMED International — Delivering SNOMED CT

ONC+FDA+CDC+
APHL+ IVD+others



The LOINC Ontology: A LOINC and SNOMED CT Interoperability Solution

- Links robust clinical semantics of SNOMED CT with the rich observation and measurement content in LOINC.
- Easy for implementers to have a unified approach (via a common structure) to implementing both standards.
- Provide a single solution that meets clinical and regulatory requirements, globally

"Globally, implementers are operating in an ecosystem of standards that fosters an element of interdependence and the need to work collaboratively and effectively together."

Don Sweete, CEO SNOMED International

Ecosystem concept

- Useful means to approach interoperability, particularly in the laboratory space.
- SHIELD:
- ecosystem, partnerships and initiatives
- goals to drive adoption and development of solutions to address challenges and realize opportunities associated with laboratory interoperability Implementation

Thank you!

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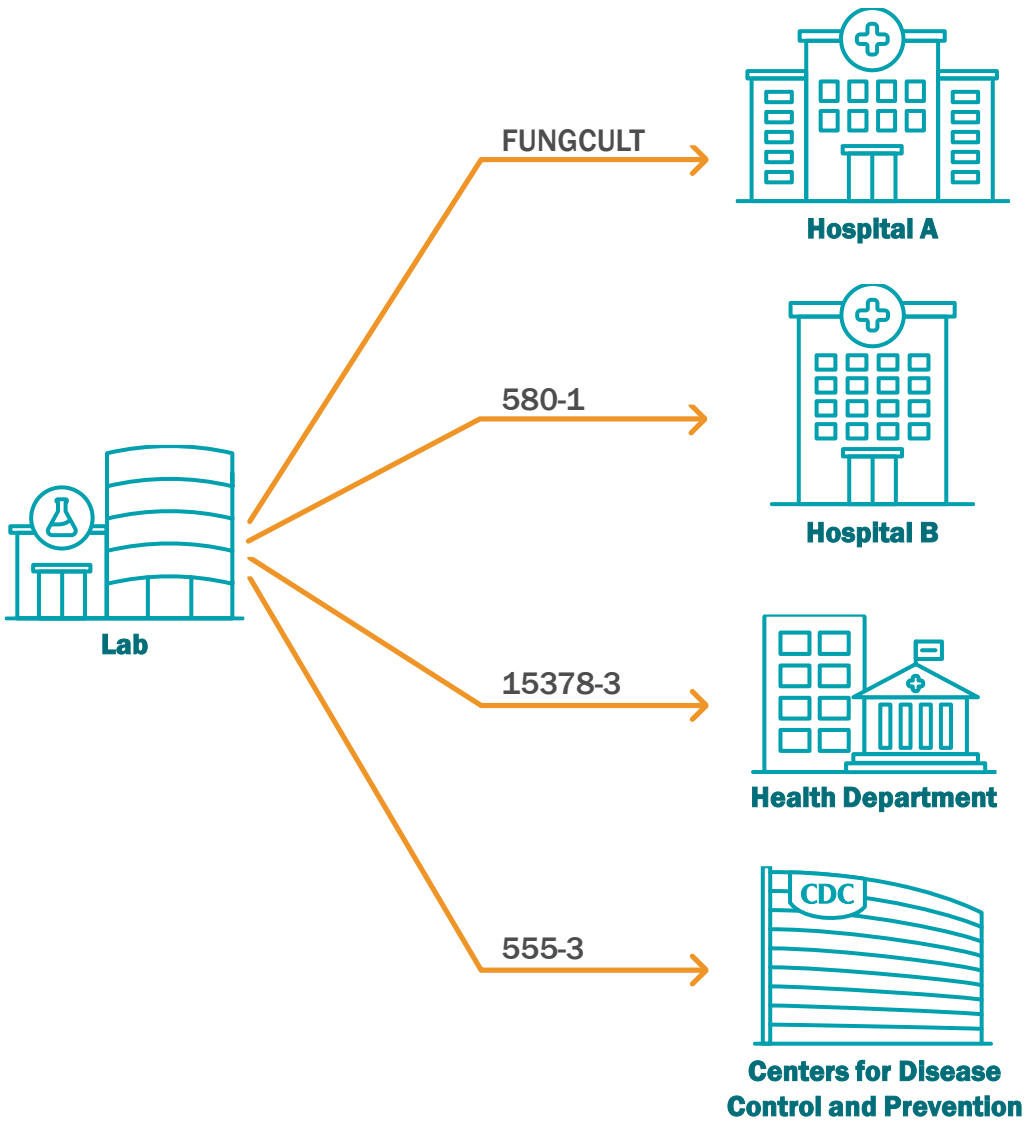
Challenges in Laboratory Data Exchange

ONC Annual Meeting | December 15th 2023

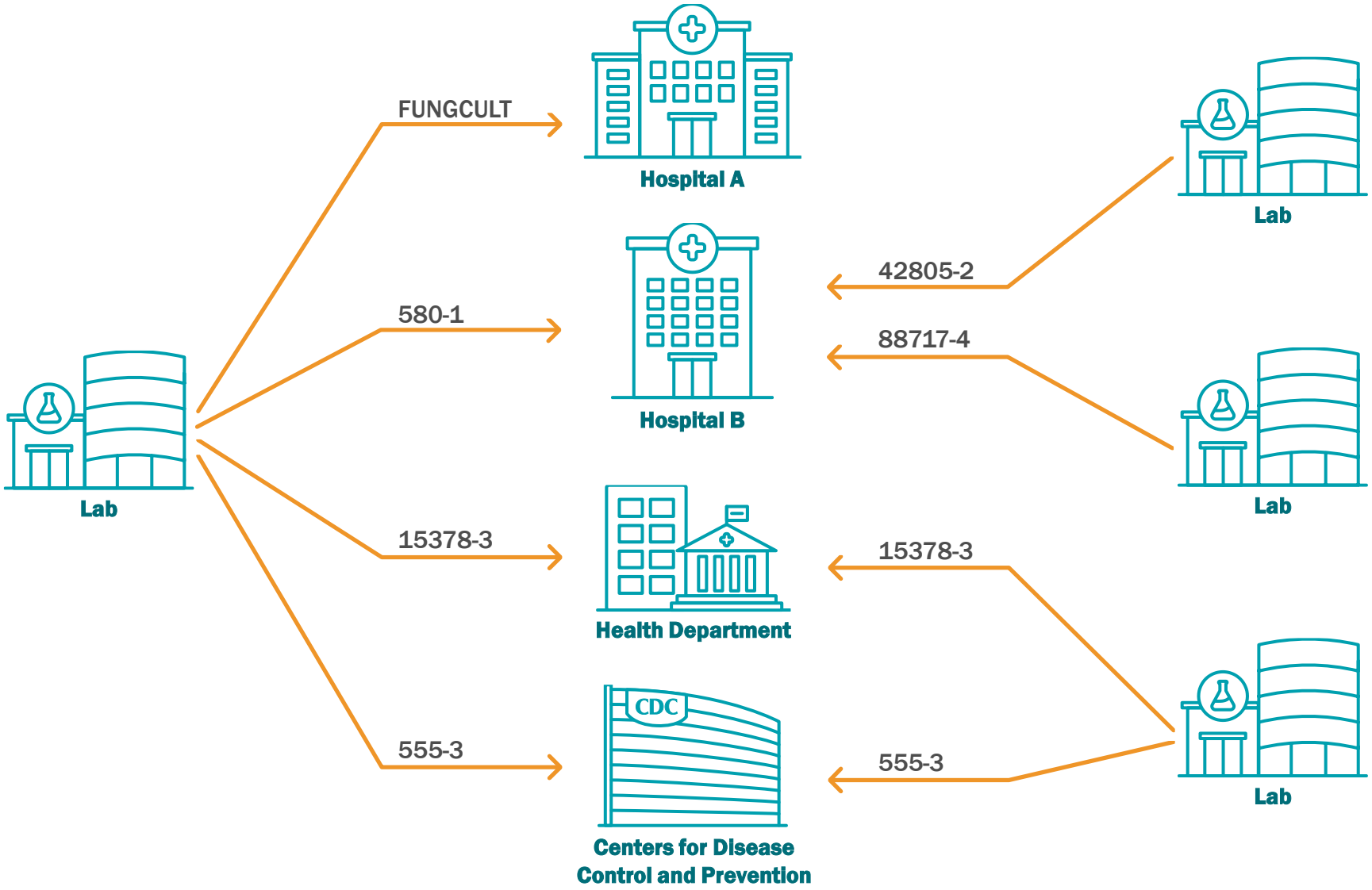
Dari Shirazi | Deputy Director of Informatics, APHL

Vocabulary Management



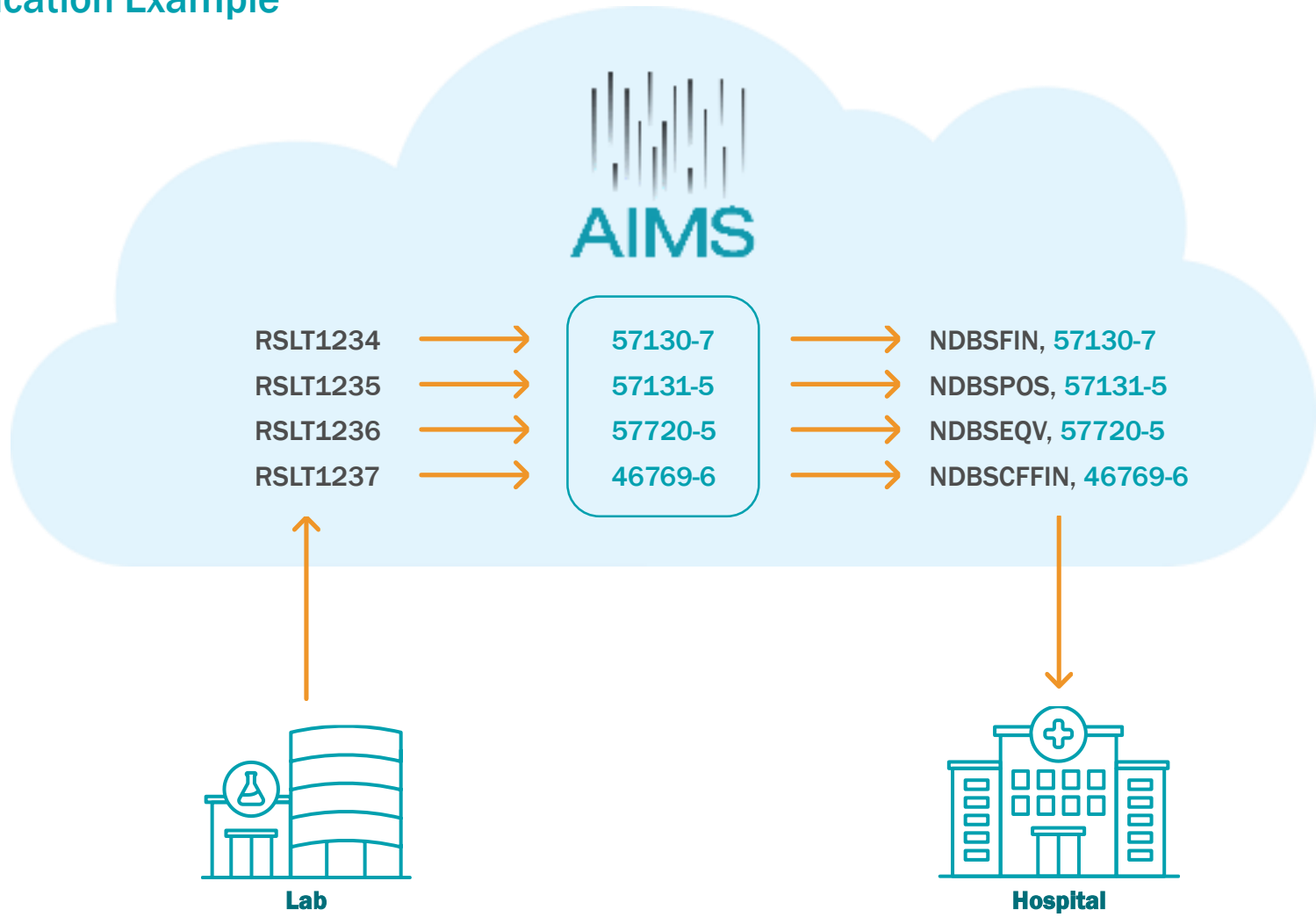
- Lab information systems use internal code
- These internal codes need to be mapped to standards like LOINC, SNOMED, CPT, etc.
- Different partners use different codes even for the same test

Vocabulary Management



Building Flexibility

Result Communication Example



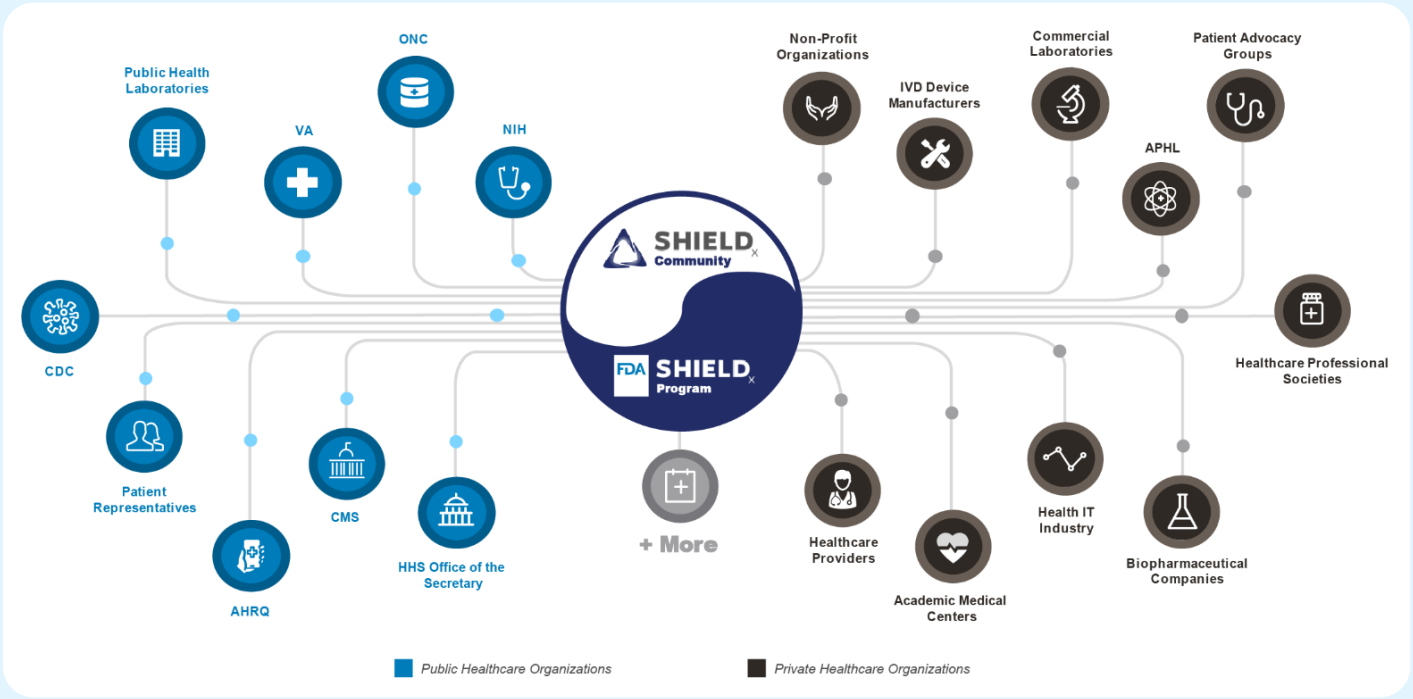
A Data Exchange Ecosystem

Systemic Harmonization and Interoperability Enhancement for Laboratory Data

SHIELD

MISSION

Describe the SAME test the SAME way ANYWHERE in the Healthcare ecosytem.



2023
SHIELD Workgroups Form & Roadmap Published

2021
Strat. Planning & Assessment Begins

2020
The Pandemic Hits

2019
SHIELD Begins Pilot Site Evaluation

2017
The SHIELD Committees Form

2016
SHIELD is Founded by Mike Waters

2015
The Need for SHIELD is Identified

Implementation Strategies in the SHIELD Roadmap

Knowledge Management

Promoting an integrated approach to identifying, capturing, evaluating, retrieving, and sharing laboratory data and ensuring that data is understandable, reproducible, and useful

ACTION: standards alignment of data representation / development of laboratory data repository

Systems Thinking

Reengineering the laboratory data transfer process in a manner that prioritizes safety, integrity, and graceful evolution over time above all else

ACTION: production and expansion of "data reliability" metrics and Standards updates

Enhanced Analytic Data Storage

Developing an authoritative source for laboratory data representation that supports existing data models and is accessible by all entities that create or use laboratory data

ACTION: creation of an IVD Data Store / Hub

Ecosystem Engagement

Collaborating and sharing perspective across industry, agency, and discipline, as well as educating stakeholders about laboratory data interoperability

ACTION: Implementation of SHIELD identified standards, collaboration with Health IT stakeholders for feedback and validation (e.g., HL7, LOINC, SNOMED CT)

Laboratory Interoperability Data Registry WG

- Requirements
- Fields across Testing Areas
- Structure Definition

Standards / Vocab Updates WG

- Identify gaps in content for lab data
- Preferred standards use for lab data scenarios
- Implementation challenges

Real World Evidence WG

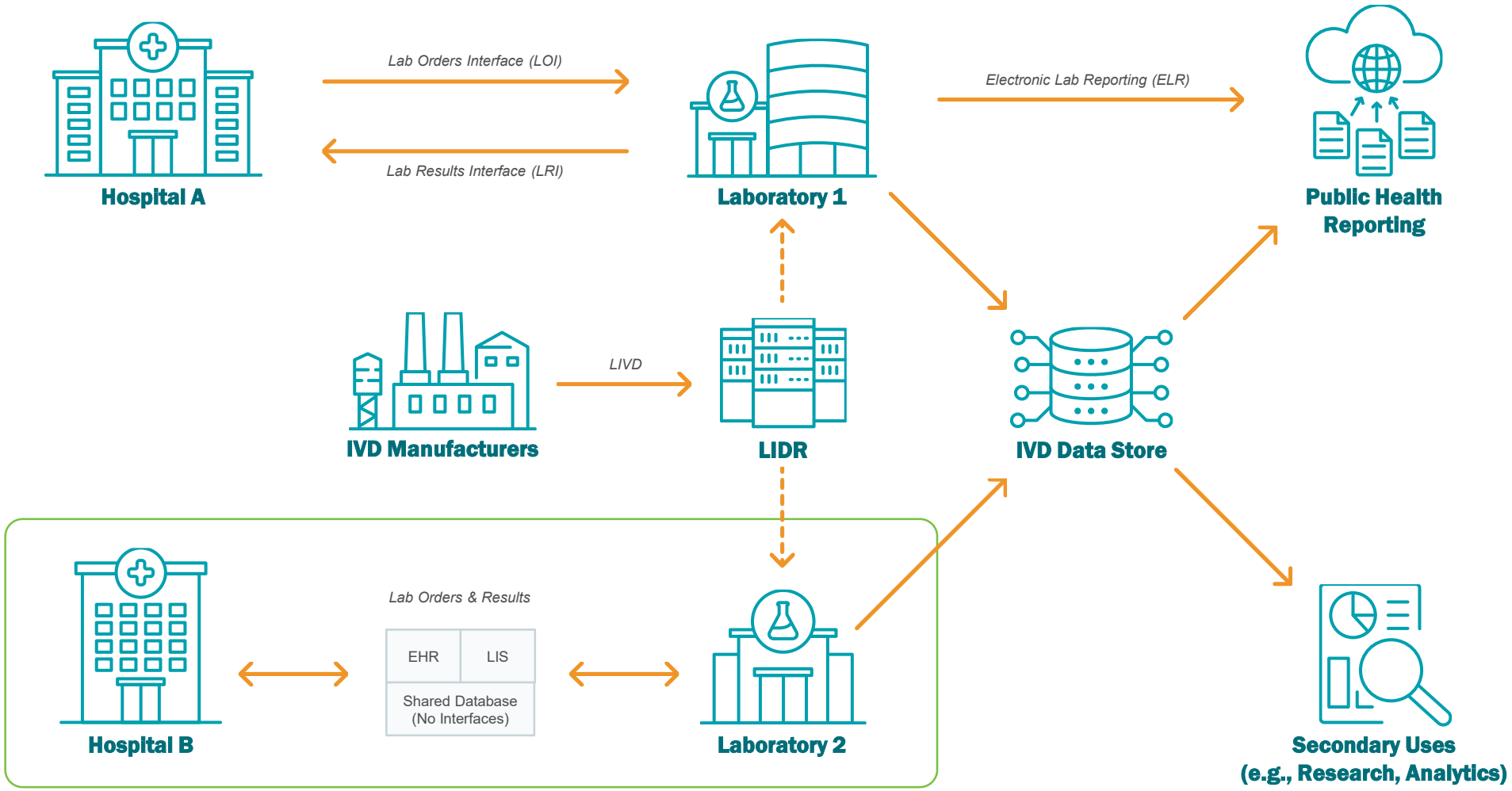
- Requirements
- Fields across Testing Areas
- Structure Definition

Communications and Branding WG

- Website
- Presentations
- Publications

Future State

Unique Device Identifier (UDI) + USCDI elements + LIDR = > reliable data for all



Outcomes of Laboratory Data Interoperability

By developing a robust infrastructure which improves the quality, interoperability, and portability of laboratory data within and between institutions and individuals, SHIELD will help enable enhanced public health reporting, healthcare research and innovation, Clinical Decision Support (CDS), regulatory decisions, outbreak monitoring, signal detection, and Real World Evidence.

Enhance Product Development

1. Develop toolkits for test developers to build innovative and FDA-approved testing methods
2. Better evaluate real-world test performance

Reduce Regulatory Burden

1. Reduce time-to-market for IVD test-makers
2. Predict market demand for tests to right-size manufacturing
3. Expedite the number of EUA to 510k conversions through accurate evidence

Improve Patient Safety

1. Reduce reliance on error-prone, manual practices.
2. Provide clinicians with more accurate, useful, structured, and computable treatment data
3. Increase precision of IVD testing

Enhance Health Analytics

1. Track surges in the pandemic including viral mutation detection
2. Understand the impact of variants on testing
3. Harmonization of laboratory data within and outside of health institutions

Contact SHIELDLabCodes@gmail.com

In Summary

CHALLENGE

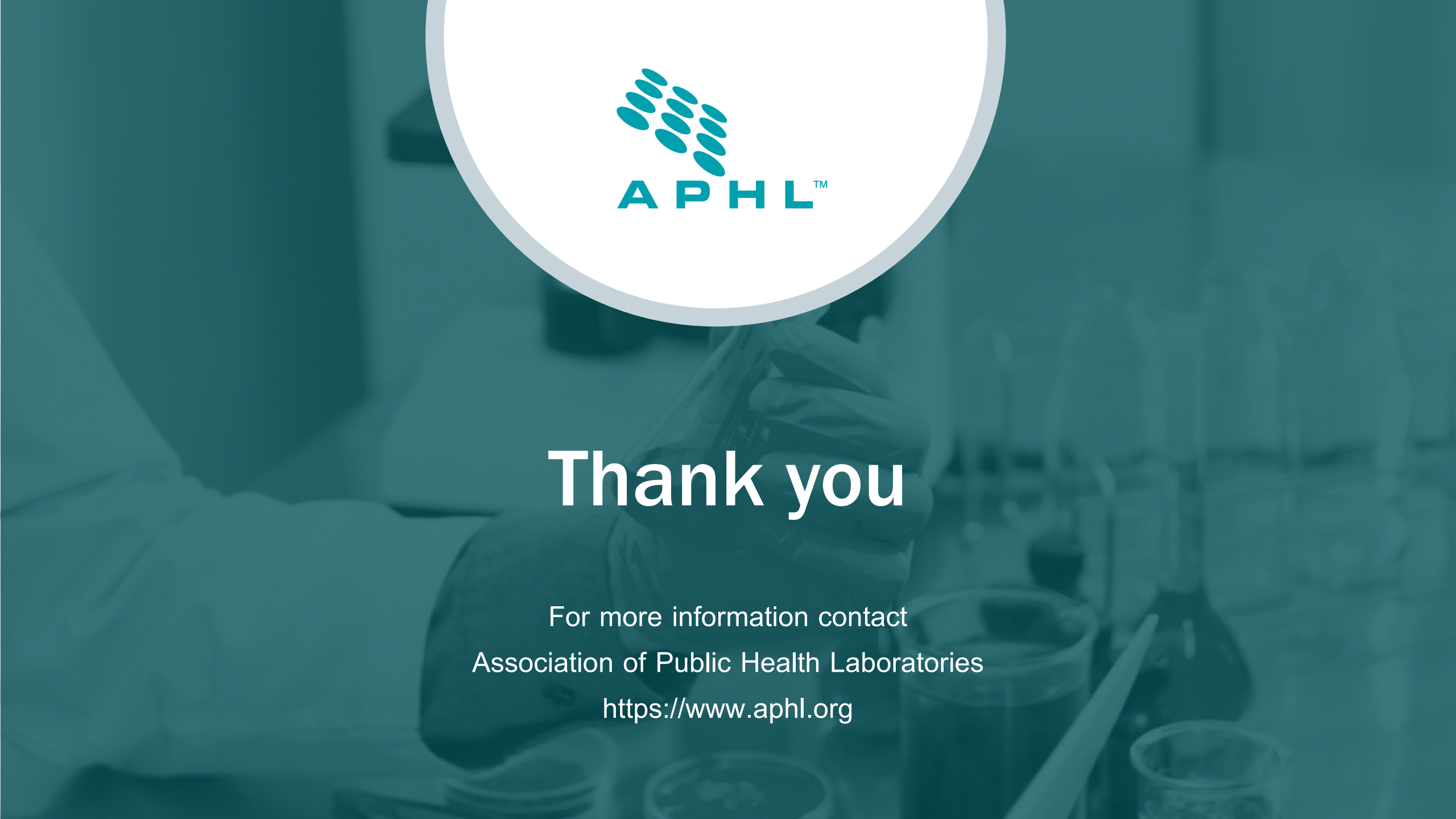
Biggest challenge in lab data exchange is lack of standardization

WORK

Work to improve standardization (e.g. SHIELD) is critical

SOLUTION

BUT we don't have to wait, intermediaries provide a solution that can resiliently handle the variability that exists today and evolve as additional standards are introduced (e.g. ETOR).



Thank you

For more information contact

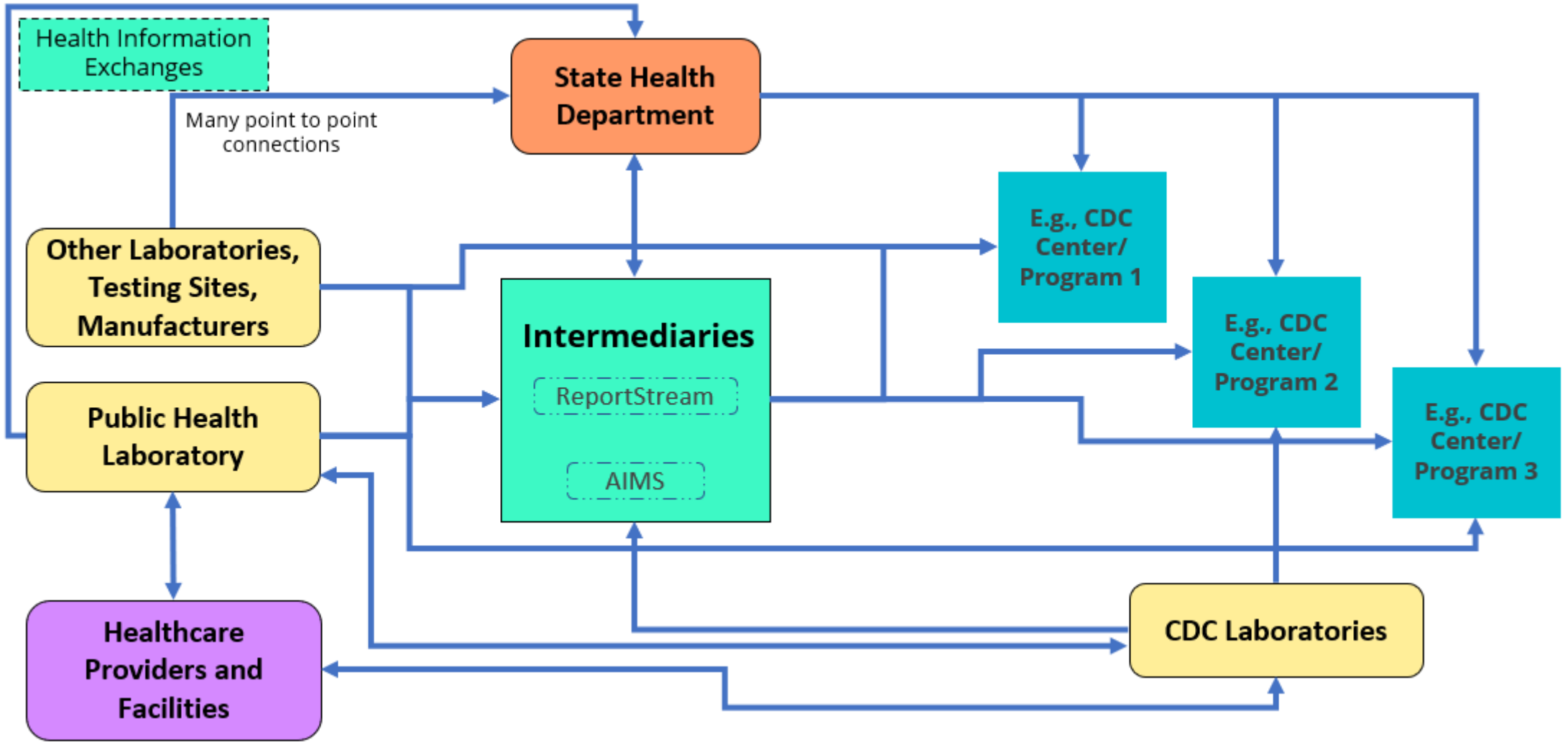
Association of Public Health Laboratories

https://www.aphl.org

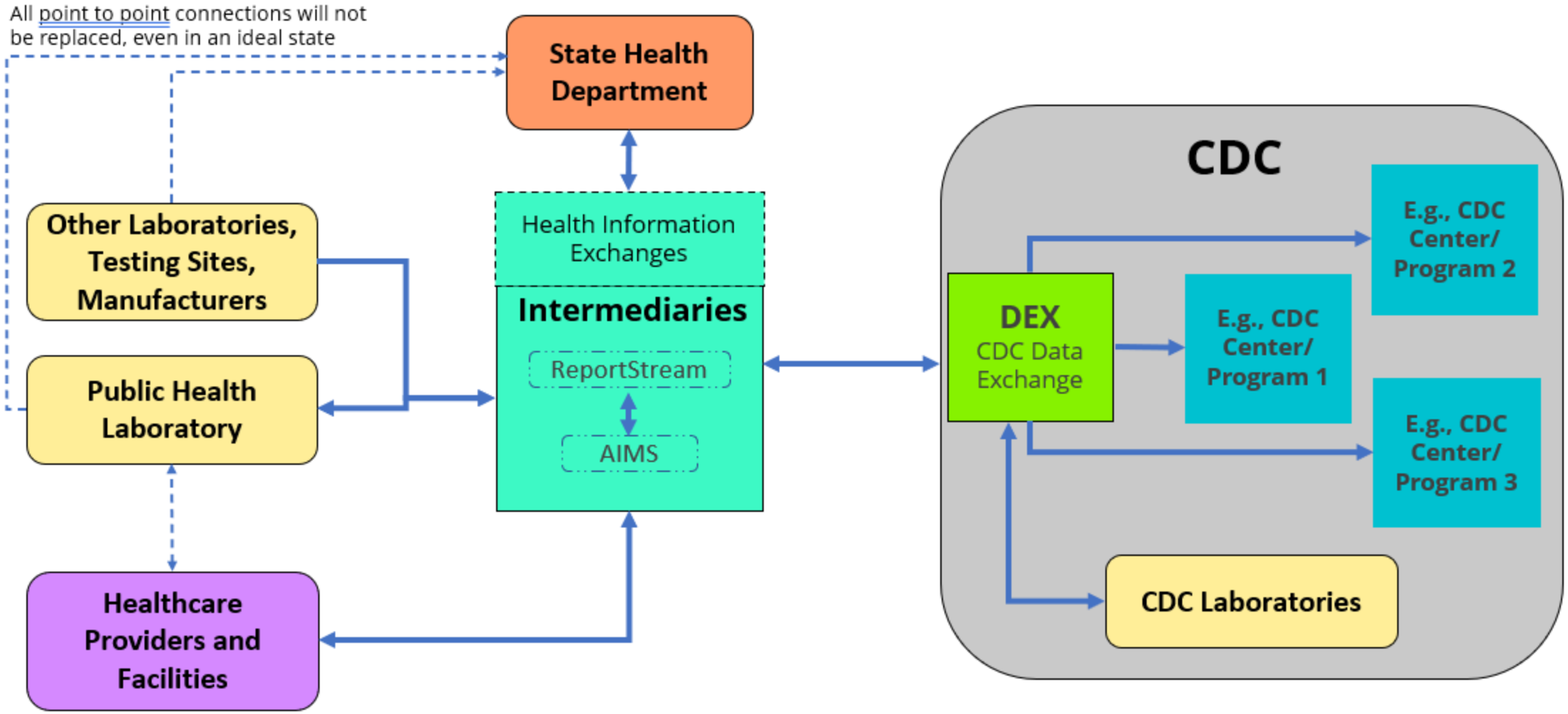
Intermediary: A Strategy for Enhanced Laboratory Data Interoperability

Jasmine Chaitram, MPH, MT
Chief, National Laboratory Response System Branch
Division of Laboratory Systems
Center for Laboratory Systems and Response

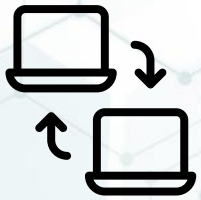
Current State of Laboratory Data Flows



Ideal State: Laboratory Results Data Flows to Public Health

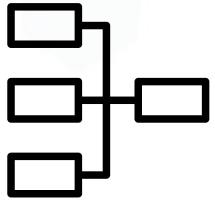


CDC Laboratory Data Exchange (LDX) Strategy



Modernize PHL Test Order and Results

Expand the use of intermediaries



Improve reporting to public health

Establish CDC front door

Enhance CDC's test order and reporting

Common Intermediary Capabilities

Security and Authentication

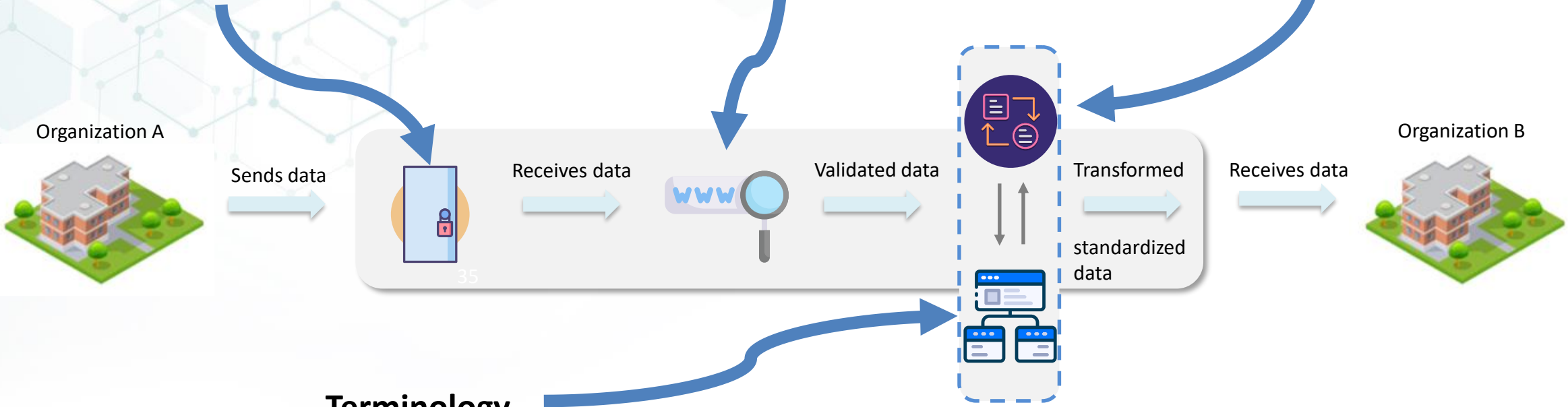
Confirms user identity and perform user management to safeguard against unauthorized access, corruption, or theft.

Validation

Ensures accuracy and quality of data before processing.

Transformation

Converts data from one format to another or derives new data from other elements.



Terminology

Maps data from one terminology standard to another.

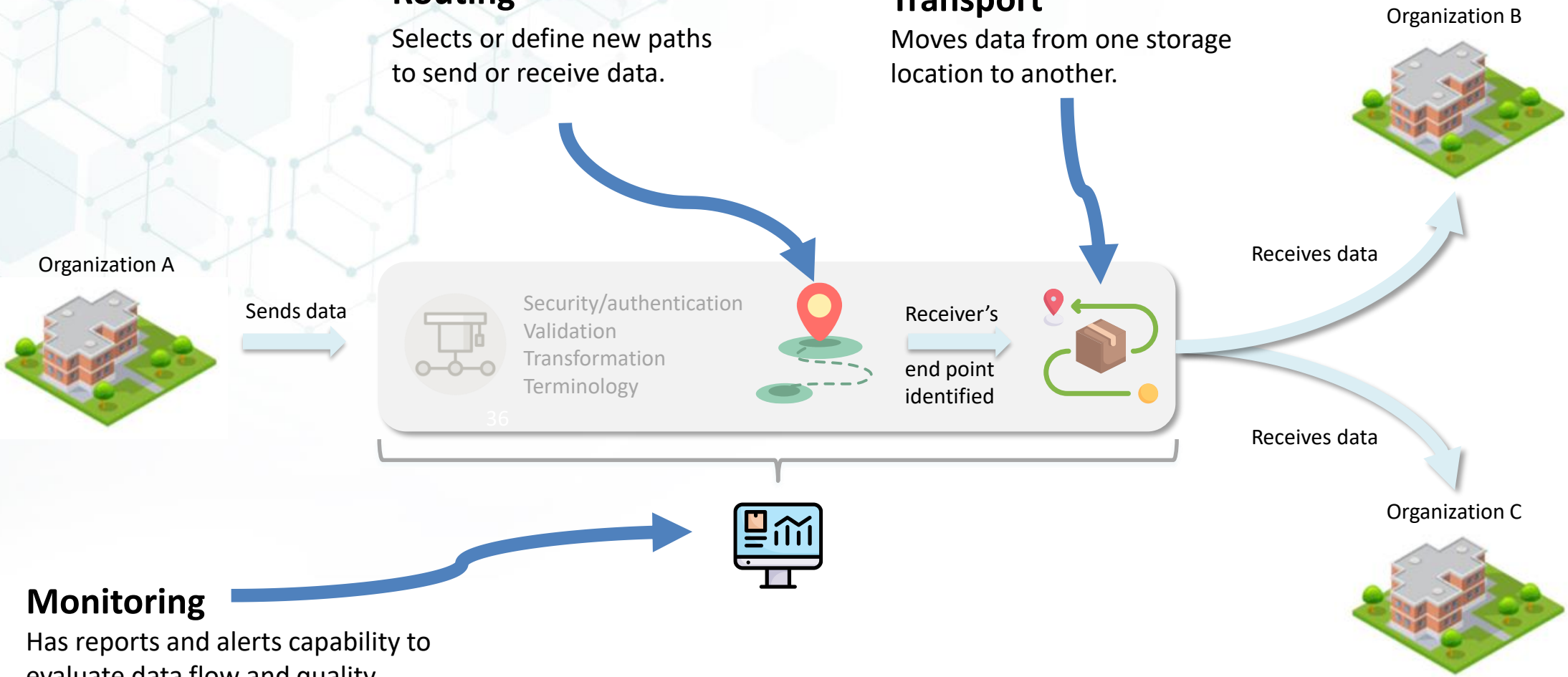
Common Intermediary Capabilities

Routing

Selects or define new paths to send or receive data.

Transport

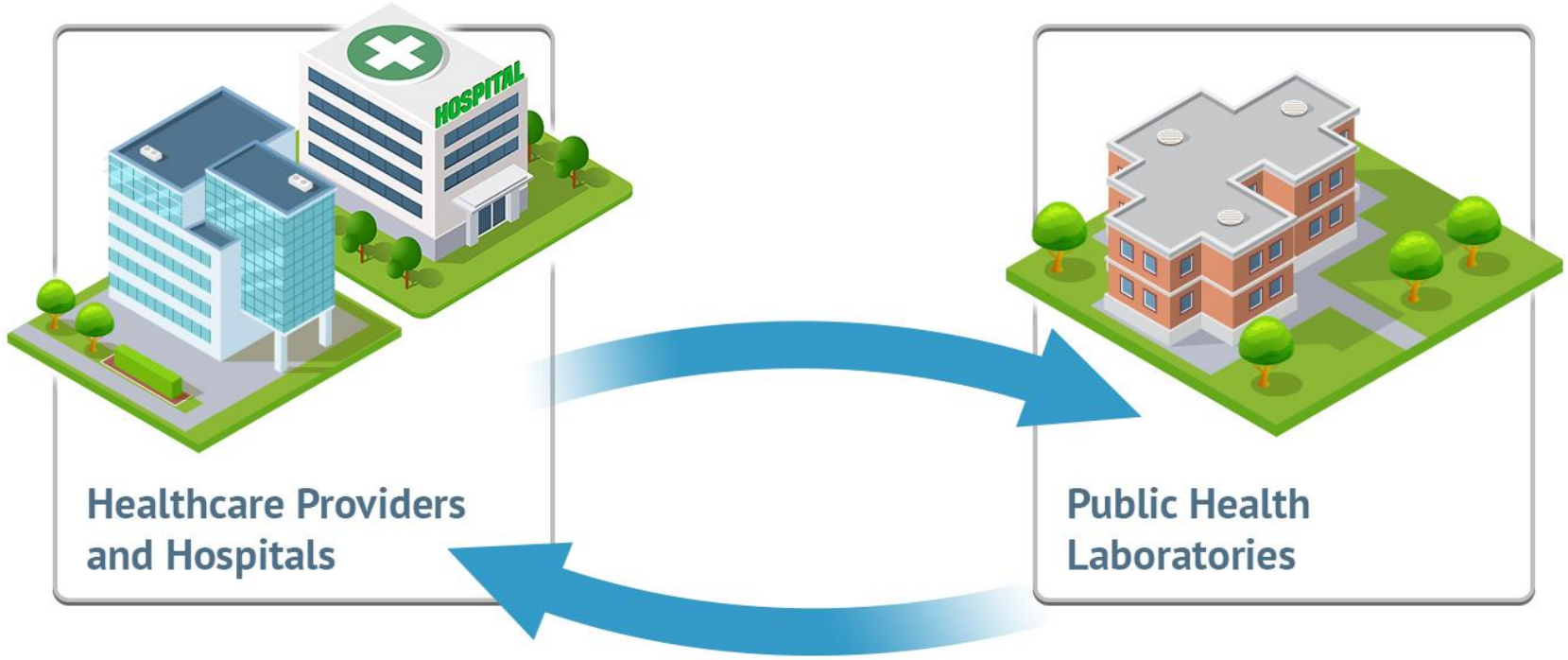
Moves data from one storage location to another.



Monitoring

Has reports and alerts capability to evaluate data flow and quality.

What is ETOR?


HOSPITAL
Healthcare Providers and Hospitals
Public Health Laboratories

Laboratory Data Exchange

ETOR – Electronic Test Orders and Results
ELR – Electronic Laboratory Reporting

Benefits of ETOR

Laboratories

- Data accuracy
- Improve Lab Workflow
- Cost efficiencies

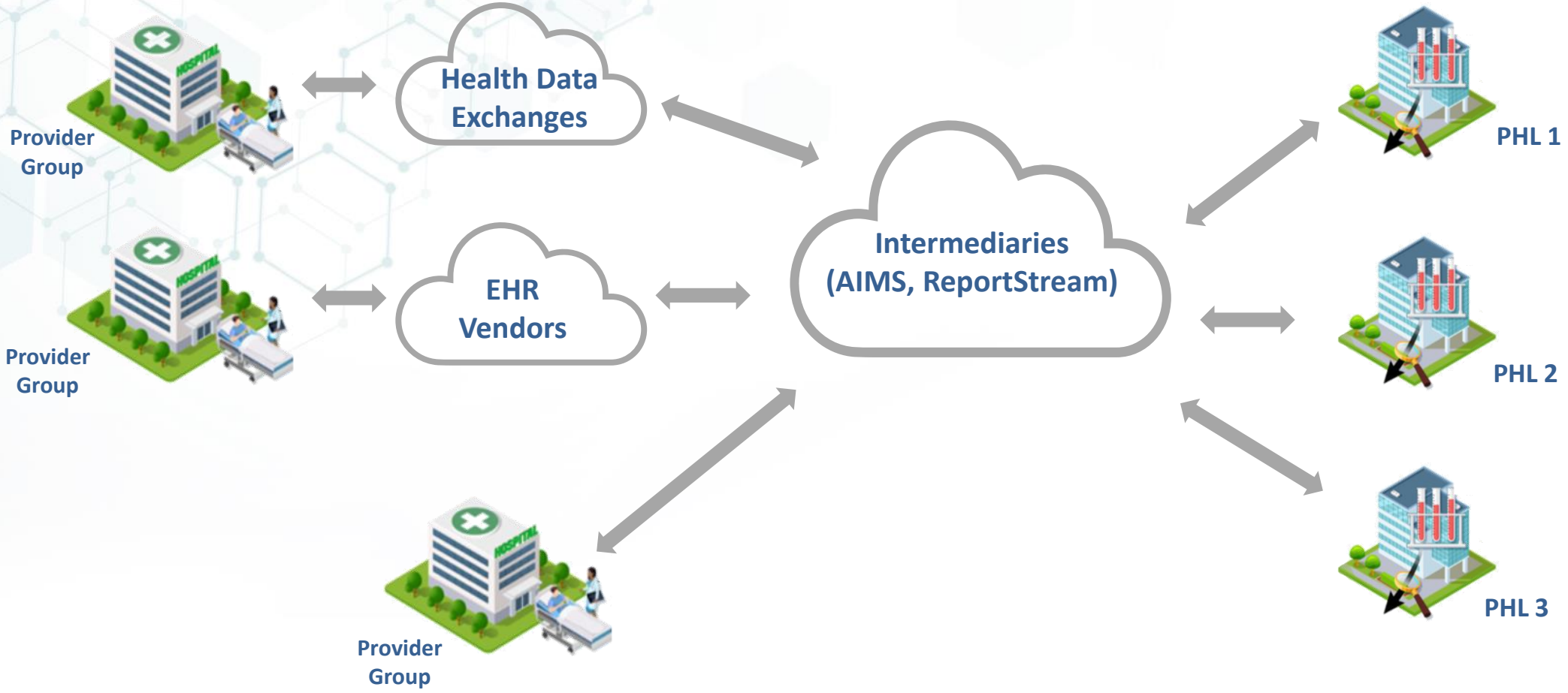
Healthcare

- Automated ordering
- Timely results
- Improved patient care

Public Health

- Reporting
- Response
- Surveillance

ETOR Future State - Intermediaries



CDC's Public Health Laboratory ETOR Initiative Program Updates

Alabama

HCO: Baptist Health

EMR: Oracle Health Millennium

LIMS: Neometrics

Florida

HCO: Orlando Health

EMR: EpicCare Ambulatory Base, EpicCare Inpatient Base

LIMS: PerkinElmer's Specimen Gate

Louisiana

HCO: Ochsner Health

EMR: Epic

LIMS: Neometrics

Iowa

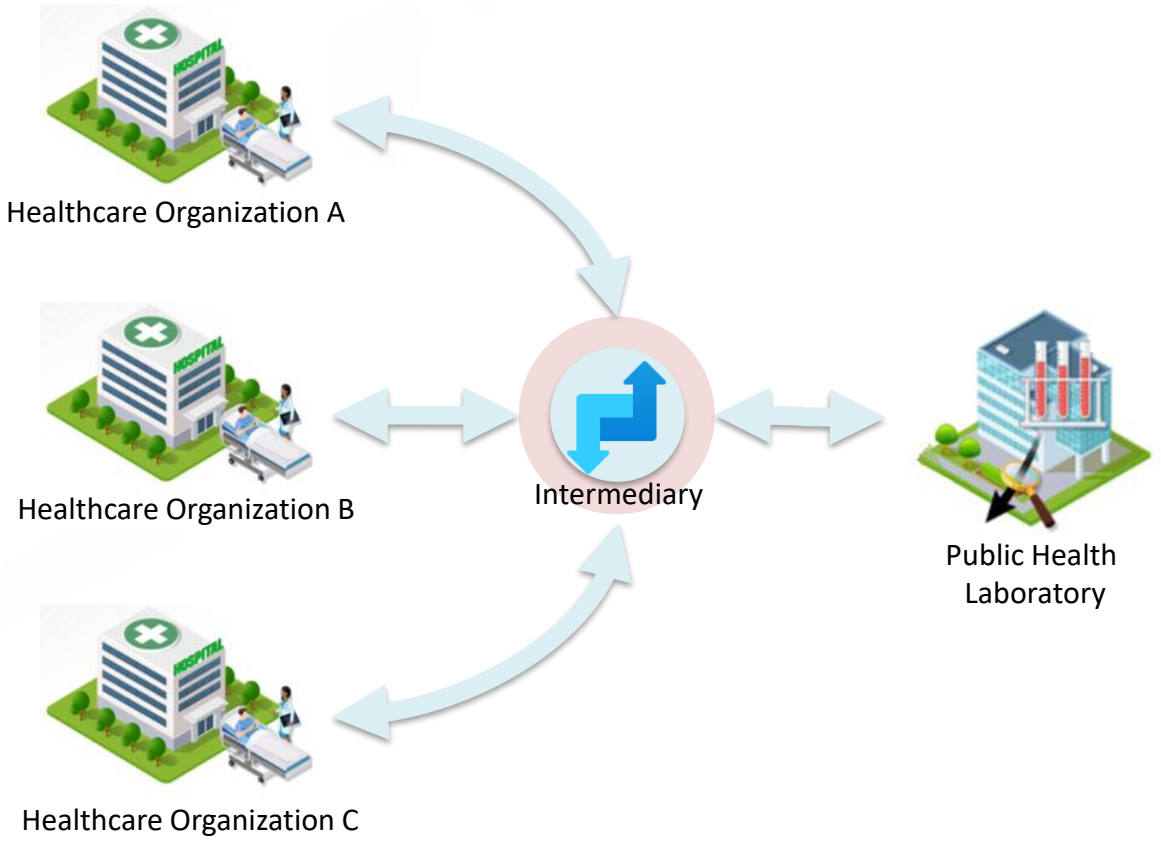
HCO: Fairbanks Memorial

EMR: Cerner-Millenium

LIMS: OpenELIS

Next Steps for ETOR

- Support the adoption of Laboratory Order/Result Interface (LOI/LRI) standard to test orders and results.
- Continue the development common architecture and services for intermediaries
- Develop a common legal agreement for the use of intermediaries across jurisdictions
- Facilitate interoperability between intermediaries



THANK YOU!

For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

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