Introduction

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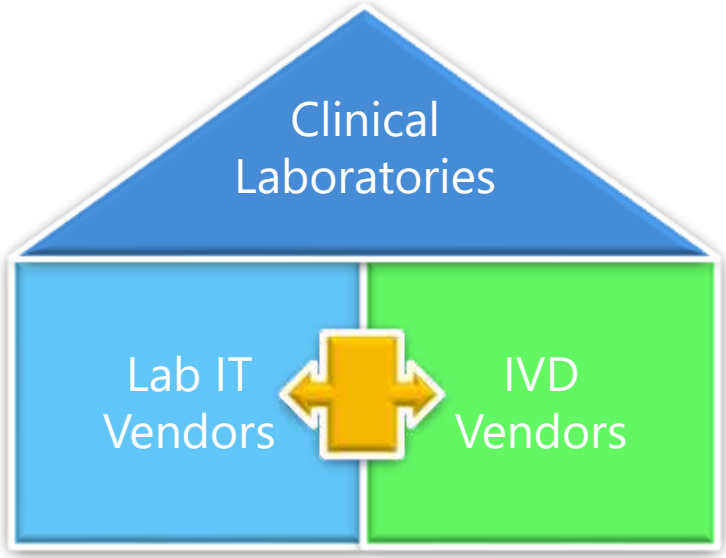
The IVD Industry Connectivity Consortium

- **Formed in 2009**
- **Mission**
  - Modernize connectivity between laboratory IT systems and analyzers
  - Enable clinical laboratories to achieve more and spend less
- **Members**
  - Abbott Laboratories, A&T, Beckman Coulter, Beckton Dickinson, BioMérieux, Data Innovations, Hitachi, IZASA SA, Orchard Software, Ortho Clinical Diagnostics, Roche Diagnostics, Samsung, Siemens Healthcare Diagnostics, and Sunquest Information Systems



To create and ensure adoption of an interoperable connectivity paradigm to reduce the complexity and variability of data exchange between IVD testing systems and healthcare informatics systems

COVID-19 Exposed Major Challenges

- No uniform, national data collection and aggregation methodology for acute epidemiology reporting and analysis
- No semantically standardized format to capture data at the source
  - Laboratory
  - POC
  - At-Home
- A lot of assumptions…
- On June 4, 2020 the **Department of Health and Human Services (HHS)** issued laboratory data reporting guidance for COVID-19 testing to "assure the timely and quality data reporting to state and federal public health agencies"

  … but very few were able to accommodate

What is SHIELD and how does IICC support it?

Systemic Harmonization and Interoperability Enhancement for Laboratory Data

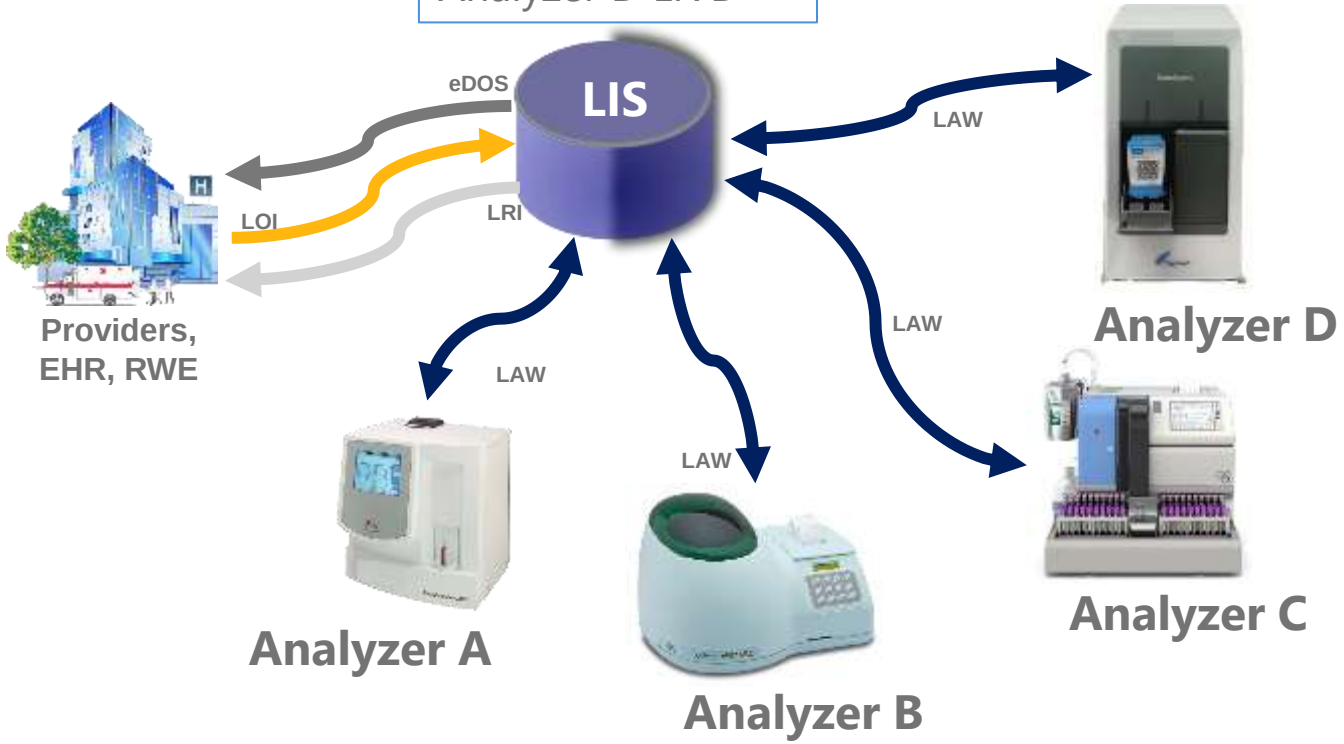
- Collaboration between FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, IICC, LOINC/Regenstrief, SNOMED, EHR Vendors, Laboratories, Standards Developers, Academia
- Unlock Electronic Health Data
- Emphasis on Real-World Data (RWD) and Real-World Evidence (RWE)
- LAW and LIVD directly support this initiative
- Started before COVID-19 pandemic, but now instrumental in developing a solution…

The need to engage the IVD industry

- Who does this apply to?
  - IVD Instrument and test manufacturers
  - Middleware and LIS suppliers
- **Short Term**
  - Provide LIVD test catalogs
- **Long Term**
  - Enable LIVD FHIR downloadable files
  - Implement LAW/AUTO16
  - Drive participation in IICC, LOINC, SNOMED, HL7 FHIR, and SHIELD

LAW and LIVD

Analyzer A LIVD
Analyzer B LIVD
Analyzer C LIVD
Analyzer D LIVD



Standard 1 - LIVD (LOINC for IVD)

- Industry format for publication of LOINC codes for identification of vendor IVD Test Results
- Human readable format for use by laboratory personnel
- Enables automatic mapping of IVD vendor test result by the LIS
- Developed in collaboration with

Standard 2 - LAW (Laboratory Analytical Workflow)

- Standardizes the data flow of IVD patient and QC **A**nalytical **W**ork **O**rder **S**teps (AWOS) and test results between instruments, middleware, and LIS systems
- Is a global standard published as the IHE LAW Profile
- A public standard, ready for implementation
- Substantially reduces connectivity installation cost and time
- Recast as CLSI AUTO16, replacing LIS01 and LIS02

Using IVD Test Result Data in Real World Evidence Workflows

- An IVD Test Result's journey to an electronic repository of Real World Data (RWD) begins at the IVD Instrument
- By definition, Real World Data must be Complete, Consistent, Accurate, and Contain all Critical Data Elements
- LAW and LIVD help IVD Test Results meet this criteria at the very beginning of the journey
- LAW and LIVD are the first steps to enabling Real World Evidence (RWE) based on IVD Test Results

How LAW Supports Real World Evidence

- Improves integrity of patient test result data
- Requires unique identification of order request at the test/panel level
- Supports LOINC, JLAC10, and SNOMED CT vocabularies
- Requires UCUM as the vocabulary for units
- Requires identification of the instrument performing the test and supports Unique Device Identifier (UDI)
- Provides the ability to capture and send structured, standardized data from the instrument
- The LAW content provides Complete, Consistent, Accurate, and Critical Data Elements to use IVD Test Results as Real World Evidence

How LIVD Supports Real World Evidence

- Supports vendor IVD instruments and manual test kits
- Requires identification of the equipment performing the test and supports Unique Device Identifier (UDI) for the IVD instrument
- Establishes the LOINC code for a specific configuration of an IVD Test Performed
- The LIVD mapping content provides Consistent, Accurate, and Critical Data Elements to support Real World Evidence workflows requiring Test Performed Identification of IVD Test Results (e.g. comparison of IVD Test Results)

Related FDA Activities

- Release of FDA Guidance on LOINC for In Vitro Diagnostic Tests (2018)
  - Released in support of LIVD
  - Intended to address concerns from IVD Manufacturers
- Announcement of Medical Device Safety Action Plan (2018)
  - Improve ability to synthesize data from different electronic health information sources through NEST (National Evaluation System for health Technology)
    - Supports vision to *"Establish a robust medical device patient safety net in the United States"*
    - CLSI AUTO16 (2019)
    - IVD Test Identifier and Value Set Mappings
  - Advance medical device cybersecurity
    - CLSI AUTO11

What's next for IICC?

- Enhance the LIVD standard in support of an authoritative Laboratory Information Data Repository (LIDR)
- Launch LIVD evangelization/educational program. Drive IVD manufacturer and national lab groups adoption program
- Further research and develop semantic interoperability standards that are secure, well-structured, and easy to implement and maintain by IVD manufacturers
- Drive adoption by IVD manufacturers through concerted effort of continued evangelization and education
- Expand LIVD and LAW functionality, including Value Set, UDI, LIVD on FIHR, Specimen Mapping, interface improvements, and integration with emerging frameworks (e.g. SOLOR)

Thank You!

www.ivdconnectivity.org