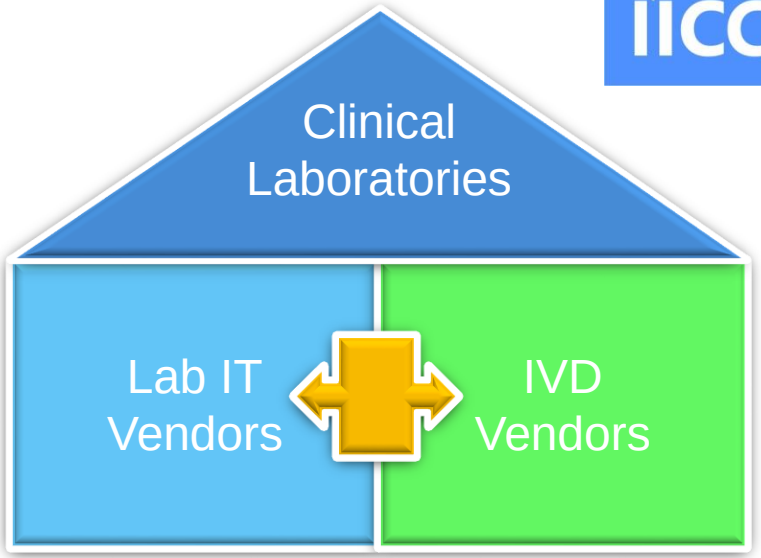
IVD Instrument Standards for Interoperability and the Harmonization of Laboratory Data

What is the IVD Industry Connectivity Consortium?

- 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, Sunquest Information Systems, and Systelab Technologies SA.



Mission: "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"

Improve IVD Instrument Connectivity

- Time and money spent on interfacing should be spent elsewhere
- The ideal endpoint is plug and play interoperability
- Complexity can be reduced via elimination of variability in standards implementation at three layers:
  - Use Case Layer (major variation)
  - Messaging Layer (major variation)
  - Low Level Layer (minor variation)

IICC Partnered with CLSI, IHE, and HL7

Technology Adoption
- Partner with CLSI
- Laboratory standards publication of AUTO16

Use Case Layer
- Partner with IHE
- Created IHE's LAW (Laboratory Analytical Workflow)

Message Layer
- Partner with HL7
- Build on the work of HL7's v2.x Standard

Low Level Layer
- Partner with HL7
- Build on the work of HL7's MLLP (Minimal Low Level Protocol)

LAW Laboratory Analytical Workflow

- Standardizes the data flow of IVD patient and QC analytical work order steps (AWOS) and test results between instruments, middleware, and LIS systems
- Is commercially available and ready for implementation
- Is a global standard
- Will be published as CLSI AUTO16, replacing LIS01 and LIS02
- Substantially reduces connectivity installation cost and time

LAW Laboratory Analytical Workflow

- Support for IA, CC, Hematology, Microbiology, and Molecular testing
- **Improves integrity** of patient test result data
- Requires **unique identification of each order request** at the test or test panel level
- Supports **LOINC**, JLAC10, and **SNOMED CT** vocabularies
- Requires **UCUM** vocabulary
- Requires **identification of the instrument** performing the test and supports **Unique Device Identifier (UDI)**
- Provides the ability to capture and send **better structured, standardized data** from the lab

LIVD LOINC for IVD

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

LIVD LOINC for IVD Content

- Supports **localization**
- Distinguishes between multiple **vendor IVD instruments** or **manual test kits**
- Supports **Unique Device Identifier (UDI)** for IVD instrument
- Captures the vendor's **test result identification information**
- Establishes the **LOINC code** for a **specific configuration** of an IVD Test Result

Vendor IVD Test Result Data

Data Element	Description
Vendor Analyte Code	**Vendor Transmission Code for LIS reporting or Analyte Identifier for manual tests**
Vendor Analyte Name	**The human-readable test result name**
Vendor Specimen Description	**Is it serum, plasma, urine, etc.**
Vendor Result Description	**mg/dL, mmol/L, Binary (positive/negative)**
Vendor Reference ID	**For example, a reference to a package insert**
Vendor Comment	**Any further clarification to help IVD test result identification by a human**

LIVD Table Format

- A spreadsheet format intended for use by a human
- The spreadsheet contains a worksheet for the mapping content, with each row of the worksheet containing an individual test result mapping to LOINC
- It is possible for a laboratory to combine spreadsheets from multiple vendors into a single spreadsheet

Demonstration of LIVD Table Format

See PDF Agenda Item #**15b**

https://wwwn.cdc.gov/cliac/Meetings/MeetingDetails.aspx#Docs

LAW & LIVD Summary

- An IVD Test Result's journey to an electronic data repository of Real-World Data (RWD) begins at the IVD Instrument
- 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

Next Steps

- Publish LAW as the CLSI AUTO16 standard
- Formalize the LIVD HL7 FHIR definition
- Explore Clinical IVD Value Set Mapping as part of the SHIELD initiative

References

- LAW Profile – http://bit.ly/ihe_law_profile
- LIVD Specification – http://bit.ly/iicc_livd

LIVD LOINC for IVD Participating Organizations

- Abbott Laboratories
- Advanced Medical Technology Association (AdvaMed)
- Association of Public Health Laboratories (APHL)
- BD Life Sciences
- bioMerieux
- Cerner Corporation
- Epic
- Geisinger Health System
- Health Level Seven® (HL7®)
- IHE Pathology and Laboratory Medicine (PaLM) Technical Committee
- Intelligent Medical Objects, Inc
- Medical Device Innovation Consortium (MDIC)
- Orchard Software
- Phast
- Regenstrief Institute, Inc.
- Roche Diagnostics International, Ltd
- Swiss Laboratory Interoperability Interest Group (Joint Venture of FAMH.ch, IHE-Suisse.ch, HL7.ch, SULM.ch)
- U.S. Centers for Disease Control and Prevention (CDC)
- U.S. Food and Drug Administration (FDA)
- U.S. National Library of Medicine, National Institutes of Health (NLM/NIH)
- Vernetzt, LLC

Thank You!

www.ivdconnectivity.org