Lab Data Semantic Interoperability: Advancing Value-Based 21st Century Cures

**SHIELD**$_x$ - putting IVD data standards to work

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Office of In Vitro Diagnostics and Radiological Health (OIR)  
Center for Devices and Radiologic Health (CDRH)  
Food and Drug Administration (FDA)
SHIELD Mission:
Accelerate lab data digitization; improve quality & interoperability of IVD data to:
• Improve access to high-quality RWE for regulatory decisions,
• reduce burdens to the healthcare ecosystem,
• promote innovative 21st century solutions to public health challenges,
• build NEST (diagnostic arm).

How? – SHIELD employs consensus processes to:
• leverage existing lab data standards and infrastructure,
• develop standards/tools to fill lab data interoperability gaps and
• expedite ubiquitous adoption & implementation of SHIELD infrastructure.

SHIELD Stakeholders (>50 institutions engaged):
FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, IVD Manufacturers, EHR Vendors, Laboratories, Standards Developers, PEW Charitable Trusts, NEST/MDIC, Academia
A specific IVD...

...‘asks’ a question of a specimen taken from a human body to...

... get an ‘answer’ to that question.

This can all be represented with standardized semantic codes. (e.g., UDI, LOINC, SNOMED-CT, UCUM)
TPLC – Prospective/Retrospective

Traditional Regulatory Pathway

Design ➔ Conduct ➔ Analysis

Pre-Clinical Testing ➔ (IDE) ➔ Clinical Studies ➔ Pre-Market Application ➔ Post-Market

New Hypotheses

Device Innovation

Informed Clinical Decision Making

Real-World Device Use
Physician and Patient Experience

Real-World Data/Evidence

Analysis ↔ Selection ↔ Data Generation

Healthcare Information

Claims Databases
Pharmacy Data
Social Media
Electronic Health Records
Laboratory Tests
Patient Experience
Registries
Hospital Visits
‘Fit for Purpose’

Data must be complete, consistent, accurate, and contain all critical data elements needed to evaluate a medical device and its claims.

Relevant & Reliable

Benefit vs. Risk

Real-World Data/Evidence

Analysis ↔ Selection ↔ Data Generation

Traditional Regulatory Pathway

Design → Conduct → Analysis

Device Innovation

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Patient Experience

Social Media Registries

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Healthcare Information

Design Conduct Analysis

Real-World Device Use

Physician and Patient Experience

Device Use

Pre-Market

Post-Market

Pre-Clinical Testing

TPLC Data Requirements

Informed Clinical Decision Making

Benefit

Risk
TPLC – Prospective/Retrospective

Pre-Clinical Testing

New Hypotheses

Device Innovation

Informed Clinical Decision Making

Pre-Market Application

IDE

Clinical Studies

Claims

Databases

Laboratory Tests

Pharmacy Data

Patient Experience

Social Media Registries

Electronic Health Records

Hospital Visits

Healthcare Information

Design Conduct Analysis

Real-World Device Use

Physician and Patient Experience

Analysis

Data must be understood to be used

Post-Market
TPLC – Prospective/Retrospective

Traditional Regulatory Pathway

Design → Conduct → Analysis

Pre-Clinical Testing → (IDE) → Clinical Studies → Pre-Market Application → Post-Market

New Hypotheses
Device Innovation

Informed Clinical Decision Making

Real-World Device Use
Physician and Patient Experience

Data corrupt/ambiguous

Real-World Data/Evidence

Analysis ← Selection ← Data Generation
Standards Empower Lab Data Utility

W/Standards: Quality in – Quality out.
W/O Standards: Garbage in – Garbage out

Context: An IVD device asks a question of a human specimen to get an answer.

IVD (Code Standard)
Who’s Asking (e.g., UDI)
Question (e.g., LOINC)
Answer (e.g., SNOMED-CT)

Structured Transfer
(i.e., LIVD => HL7)

Manufacturers

Patient Data
(e.g., IVD & PROs)

LIS/EHR Data Association
(i.e., HL7 w/CIMI)

Labs/Providers

Data Recipient
e.g., Patients, Providers, Industry, CDC, FDA, CMS

Data Utility
e.g., PRO Validation, Outbreak Signals, Decision Support

SHIELD Stakeholders:
FDA, CDC, NIH, ONC, CMS, VA, CAP, Industry, Labs, EHR Vendors, Standards Developers, Academia.

Systemic Harmonization and Interoperability Enhancement for Lab Data
Infectious Disease IVD LOINC Mapping Manual

Components*:
- Background/ Appendix
- Microscopic Examination
- Cultures
- Susceptibility Testing
- Resistance Testing
- Antigen Tests
- Nucleic Acid Tests
- Serology Testing

Features*:
- Mapping Examples
  - Examples in the manual
  - Link to externally populated
- How to deal with:
  - Qualitative/ Quantitative Assays
  - Multiplex Assays
  - Mapping Validation

*Includes but is not limited to.
### Digital Format for Publication of LOINC to Vendor IVD Test Results

**Date:** 6/01/2017  
**Authors:** Rob Bush, Ed Holmman PhD, Andrej Kratul PhD, Laurent Laridon, Clem McDonald  
**Email:** info@ivdconnectivity.org

<table>
<thead>
<tr>
<th>Publication</th>
<th>Equipment</th>
<th>IVD Test Result</th>
<th>LOINC</th>
<th>LOINC Long Name</th>
<th>Component</th>
<th>Proper</th>
<th>Time</th>
<th>System</th>
<th>Scale</th>
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<td>31B2</td>
<td>2350-7</td>
<td>Glucose [Mass/volume] in Urine</td>
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<td>mmol/L</td>
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<td>Glucose [Moles/time] in 24 hour Urine</td>
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# Digital Format for LOINC to IVD (LIVD)

## IVD Industry Connectivity Consortium (iicc)

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# September 29th, 2018

LIVD Connectathon

[https://ivdconnectivity.org/livd/](https://ivdconnectivity.org/livd/)
**Semantic & Syntactic Interoperability**
<table>
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<tbody>
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<td><strong>CG</strong> – Clinical Genomics</td>
</tr>
<tr>
<td><strong>DAM</strong> – Data Analysis Model</td>
</tr>
<tr>
<td><strong>eDOS</strong> – Electronic Directory of Services</td>
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<tr>
<td><strong>eICR</strong> – Electronic Initial Case Report</td>
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<tr>
<td><strong>ELR</strong> – Electronic Laboratory Reporting</td>
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<tr>
<td><strong>HL7</strong> – Health Level 7</td>
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<tr>
<td><strong>IVD</strong> – <em>in vitro</em> Diagnostic</td>
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<tr>
<td><strong>LAW</strong> – Laboratory Analytical Workflow</td>
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<tr>
<td><strong>LBL</strong> – Laboratory Barcode Labeling</td>
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<tr>
<td><strong>LDA</strong> – Laboratory Device Automation</td>
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<tr>
<td><strong>LIS</strong> – Laboratory Information System</td>
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<tr>
<td><strong>LIMS</strong> – Laboratory Information Management System</td>
</tr>
<tr>
<td><strong>LIVD</strong> – LOINC Transmission format for IVDs</td>
</tr>
<tr>
<td><strong>LOI</strong> – Laboratory Orders Interface</td>
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<tr>
<td><strong>LOINC</strong> – Logical Observations Identifiers Names and Codes</td>
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<td><strong>LRI</strong> – Laboratory Results Interface</td>
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<td><strong>LSH</strong> – Laboratory Specimen Handoff</td>
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<td><strong>LST</strong> – Laboratory Specimen Tracking</td>
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<td><strong>NAACR</strong> – North American Association of Central Cancer Registries</td>
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<td><strong>NMI</strong> – NNDSS Modernization Initiative</td>
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<td><strong>NNDSS</strong> - National Notifiable Diseases Surveillance System</td>
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<tr>
<td><strong>PH</strong> – Public Health</td>
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<tr>
<td><strong>SNOMED-CT</strong> – Systematized Nomenclature of Medicine – Clinical Terms</td>
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<td><strong>UCUM</strong> – Unified Codes for Units of Measure</td>
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### SHIELD Demo Projects (Partial List)

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<tr>
<th>Project</th>
<th>International Problem</th>
<th>Solution</th>
<th>ROI</th>
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<td>1. <strong>Infectious disease/antimicrobial resistance outbreak monitoring</strong></td>
<td>Ambiguous lab data impedes surveillance &amp; data transfer with patient</td>
<td>Implement SHIELD multi-agency/stakeholder standard infrastructure to improve accuracy and expediency infectious disease test data.</td>
<td>Real-time outbreak monitoring; patient data transferable; RWE thru TPLC</td>
</tr>
<tr>
<td>2. <strong>Standardize Lab Data to Enhance Patient-Centered Outcomes &amp; Improve Value-Based Care</strong></td>
<td>Poor lab data quality delays diagnosis/treatment &amp; repeat testing/billing</td>
<td>Link SHIELD-vetted lab data to diagnosis &amp; claims codes in provider EHRs &amp; MDEpiNet registries</td>
<td>Quality codes for all IVDs; improve the time to diagnosis for patients; reduce repeat testing/insurance billing when patients move between healthcare providers; RWE thru TPLC</td>
</tr>
<tr>
<td>3. <strong>Associate opioid diagnostics to patient reported outcomes &amp; prescription data</strong></td>
<td>Lack of reliable information leads to pain medication over-prescription, enabling substance abuse/addiction &amp; illegal controlled substance distribution</td>
<td>Link SOC tests (w/SHIELD quality coding) for opioid overdose in emergency department to filled opioid prescriptions, patient diagnoses and PROs across institutions/states.</td>
<td>Portable data trifecta (IVD data, PDMP data, PROs) to support patient provided information &amp; improve healthcare delivery that can follow a patient; RWE thru TPLC</td>
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