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

SHIELD$_x$- putting IVD data standards to work

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Center for Devices and Radiologic Health (CDRH)
Food and Drug Administration (FDA)

SHIELD$_X$

Systemic Harmonization and Interoperability Enhancement for Lab Data

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

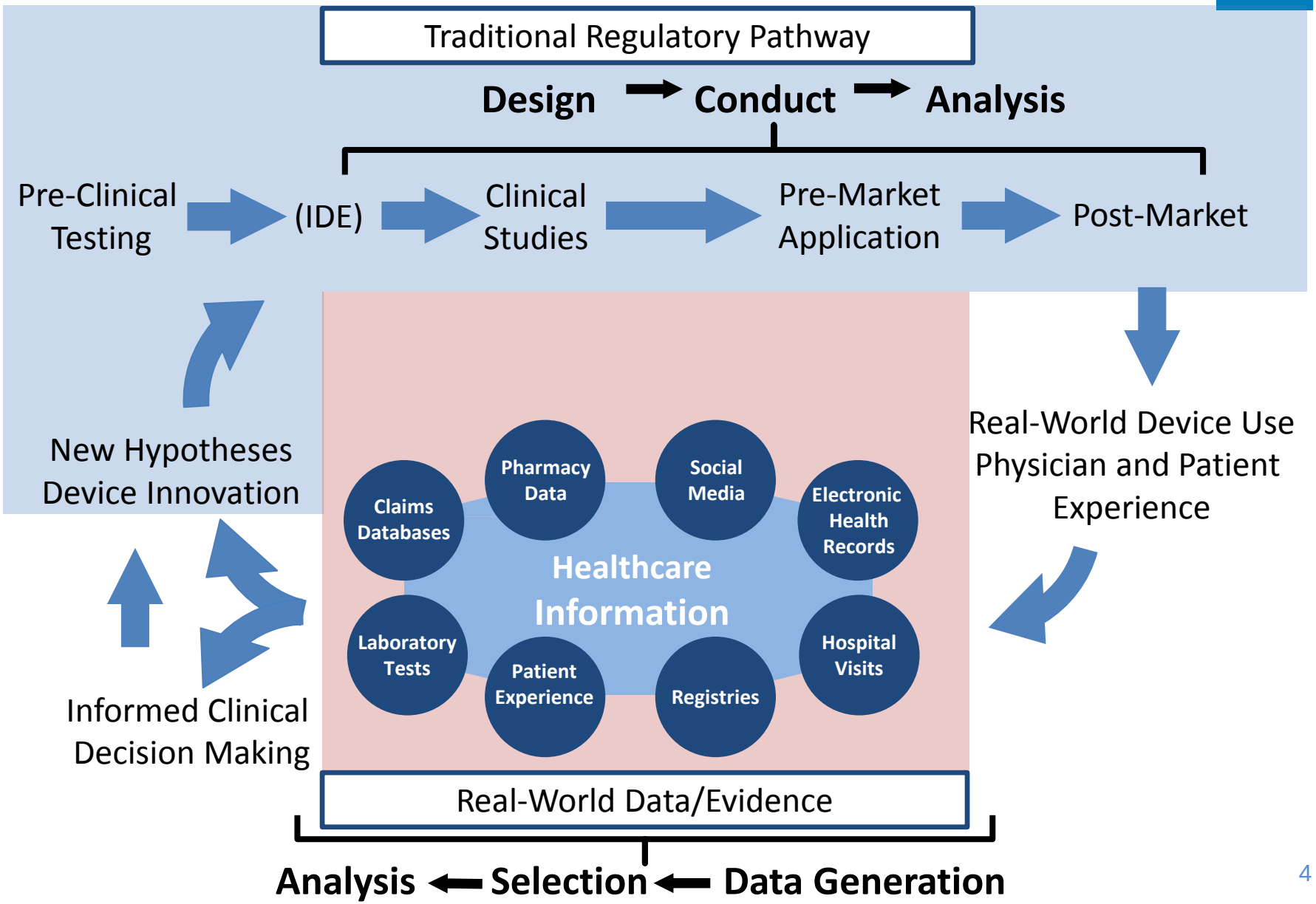
Interoperable Coded Message

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

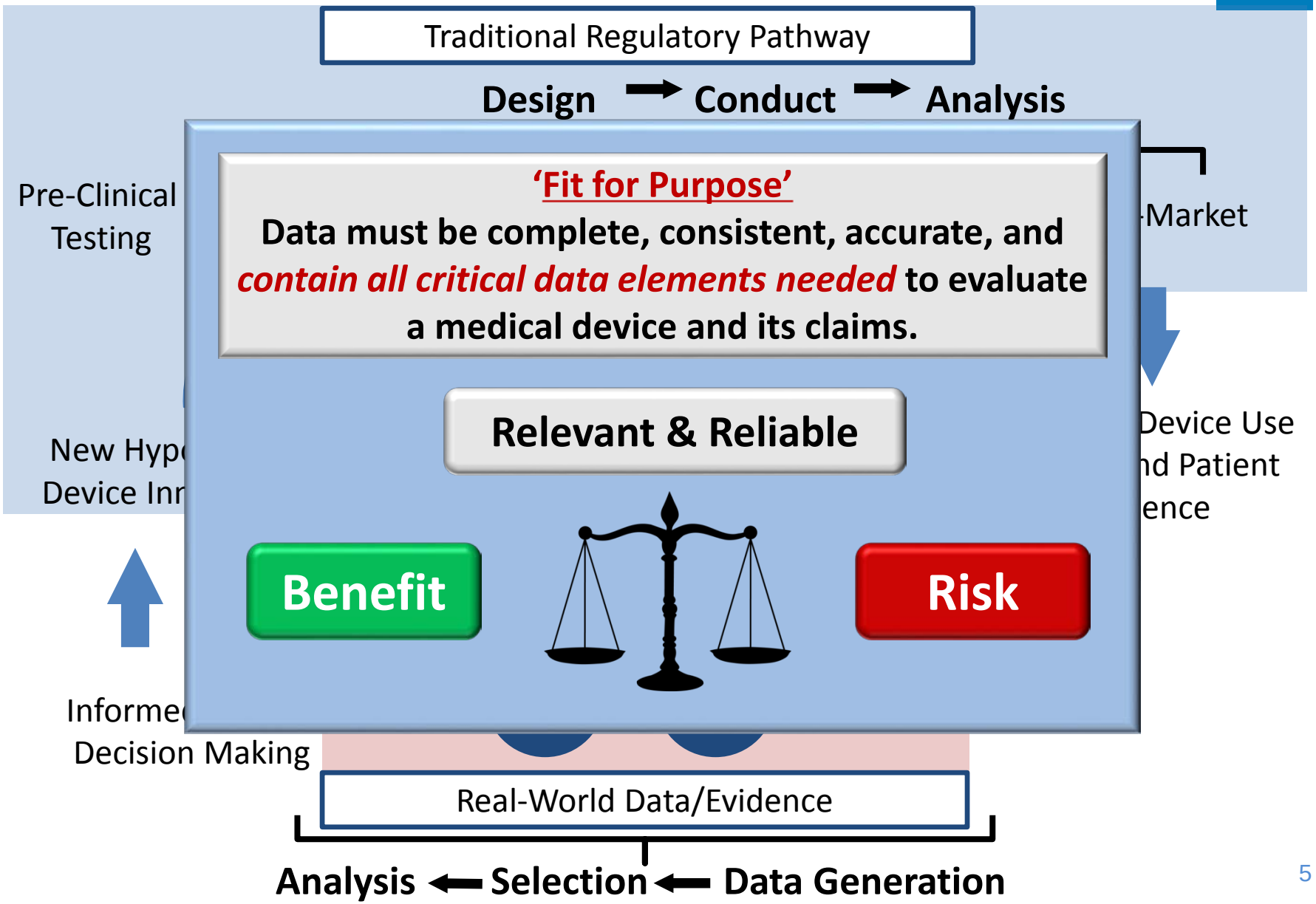
- A specific IVD…
- …'asks' a question of a specimen taken from a human body to…
- … get an 'answer' to that question.

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

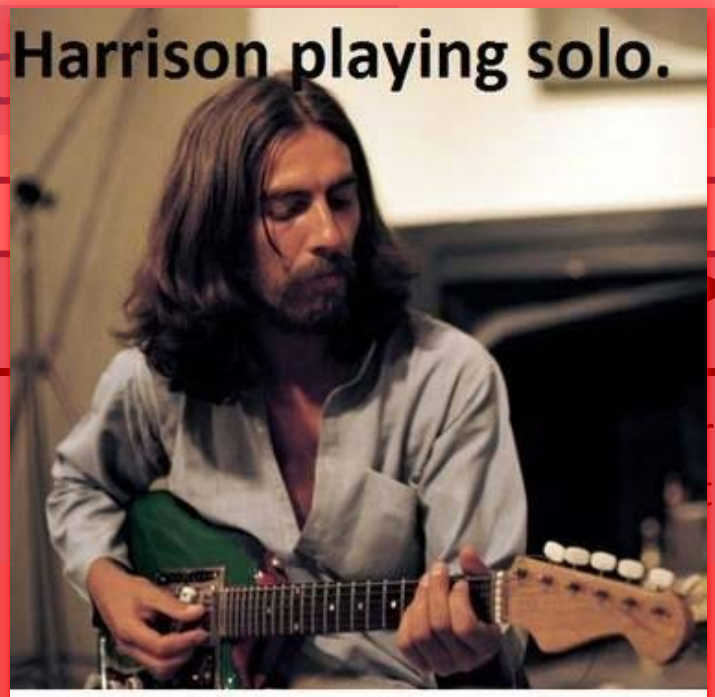
TPLC – Prospective/Retrospective



TPLC Data Requirements



TPLC – Pro pective



Pre-Clinical Testing → (IDE)

Analysis

rket ion → Post-Market

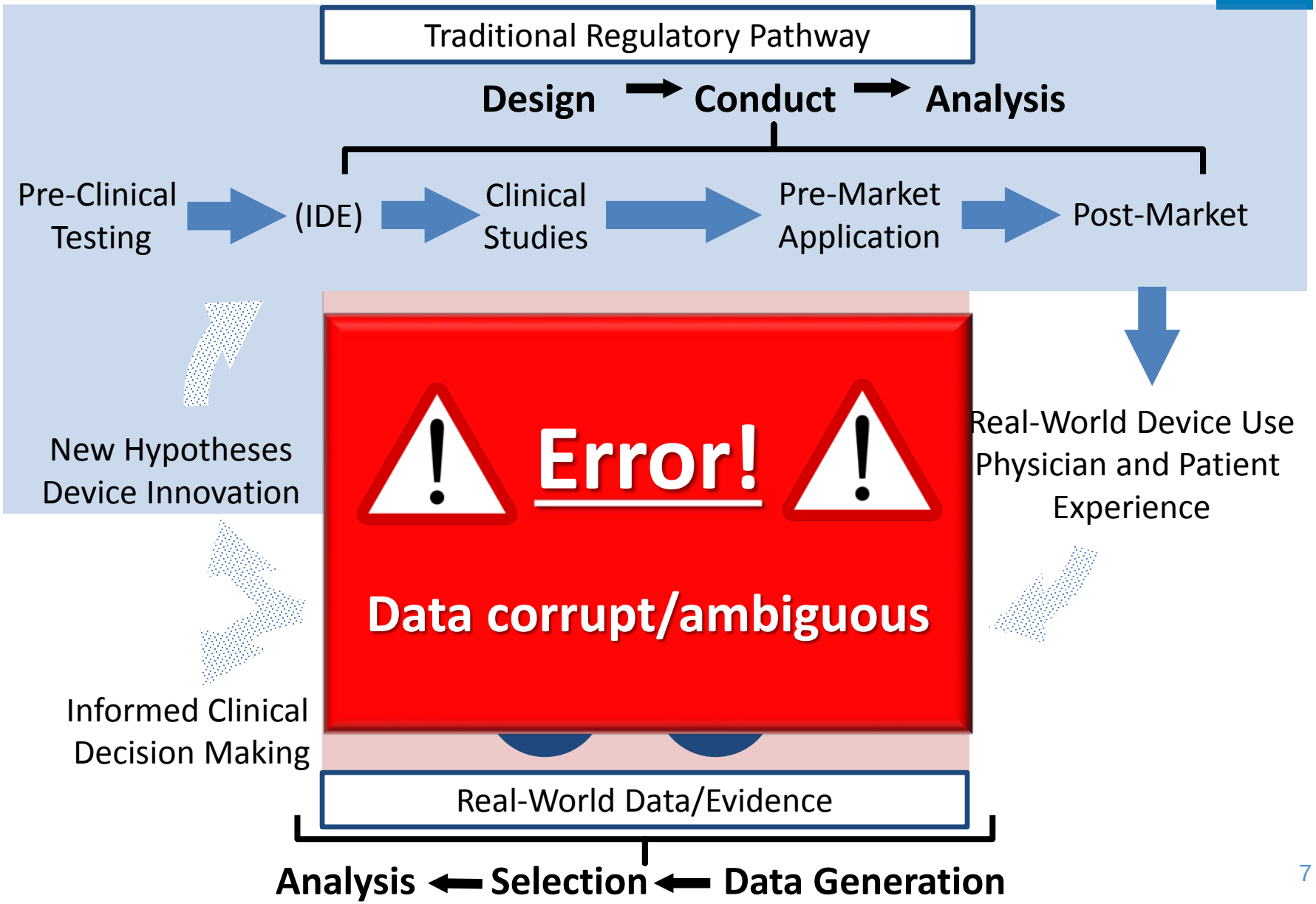
New Hypotheses
Device Innovation

Informed Clinical Decision Making

Data must be understood to be used

Analy eration

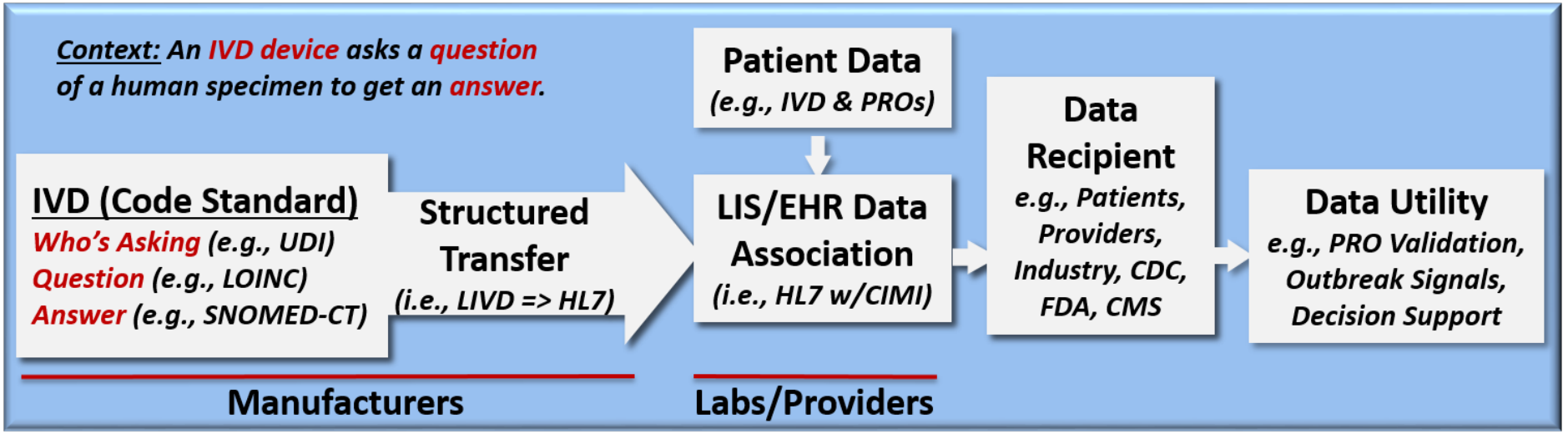
TPLC – Prospective/Retrospective



Standards Empower Lab Data Utility

W/Standards: ***Quality in – Quality out.***

W/O Standards: ***Garbage in – Garbage out***



SHIELD Stakeholders:

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

Infectious Disease IVD LOINC Mapping Manual

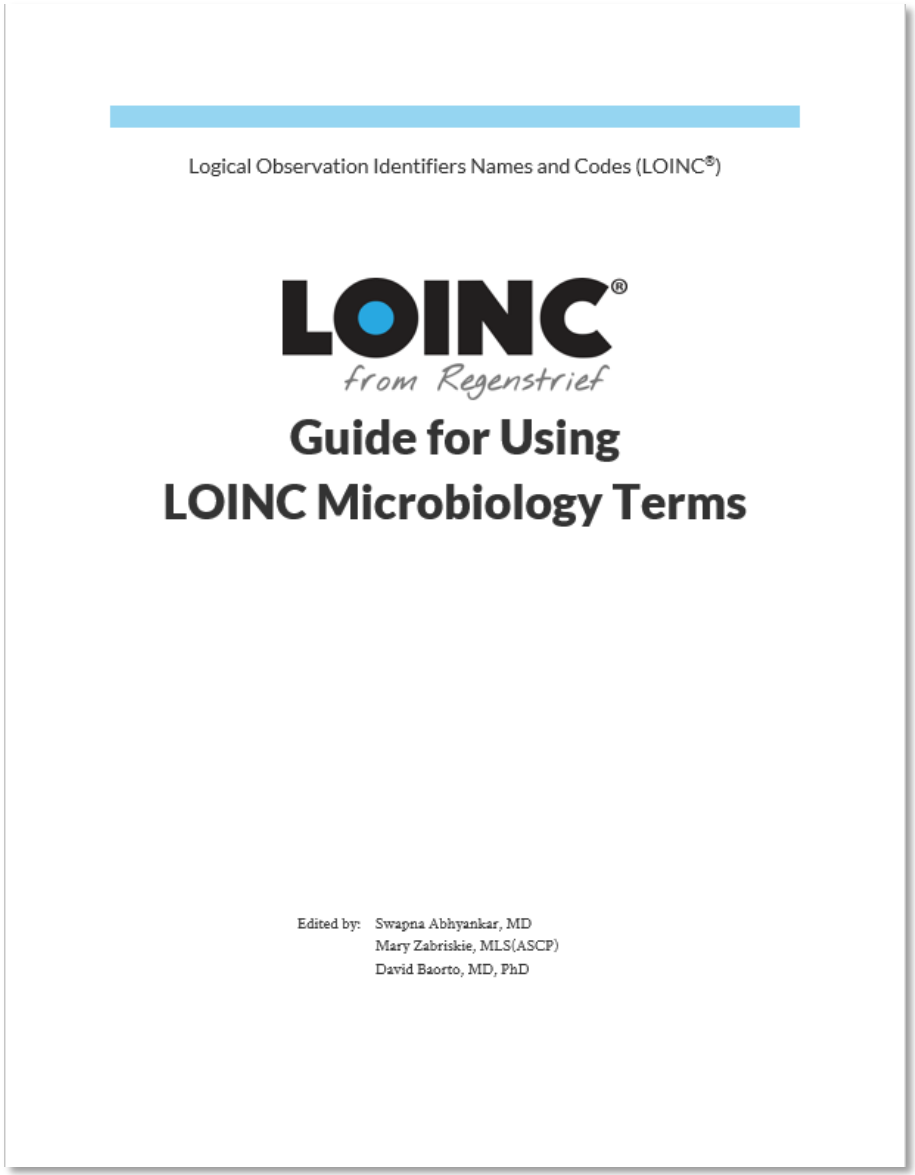
Components*:

- 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.

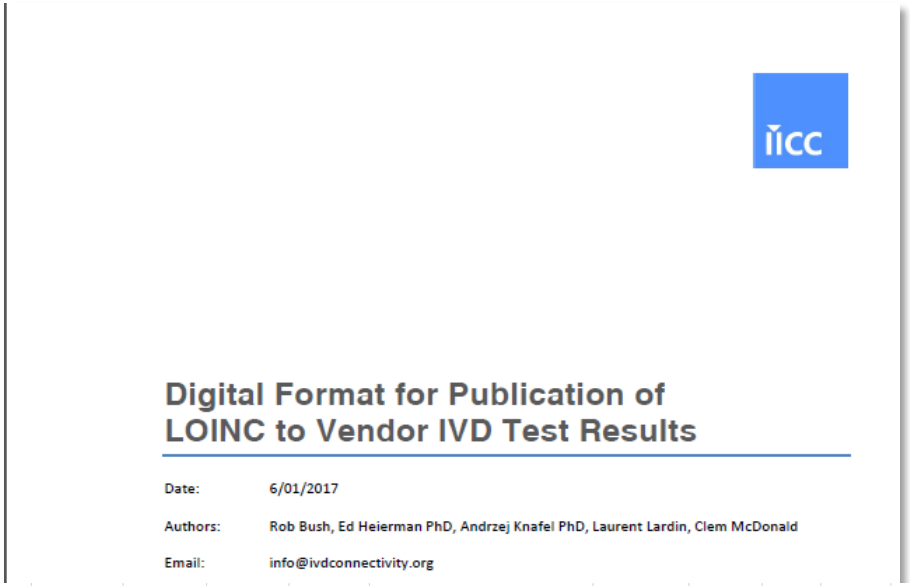


Digital Format for LOINC to IVD (LIVD)

IVD Industry Connectivity Consortium

IICC

FDA



DRAFT - Unofficial Content For LIVD Examples Only; Content does not represent actual manufacturer mappings

Publication	Equipment				IVD Test Result						LOINC							
Publication Version ID	Manufactur	Model	Equipment UID	Equipment UID Typ	Vendor Transmissio n Code	Vendor Analyte Name	Vendor Specimen Descriptior	Vendor Result Descripti	Vendor Reference ID	Vendor Comme	LOINC Code	LOINC Long Name	Compone	Proper	Tim	Syste	Scal	Method
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1069	GluC	Serum/Plasma	mg/dL	3L82		2345-7	Glucose [Mass/volume] in Serum or Plasma	Glucose	MCnc	Pt	Ser/Plas	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1069	GluC	Serum/Plasma	mmol/L	3L82		14749-6	Glucose [Moles/volume] in Serum or Plasma	Glucose	SCnc	Pt	Ser/Plas	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1095	GluC	Urine/CSF	mg/dL	3L82		2342-4	Glucose [Mass/volume] in Cerebral spinal fluid	Glucsose	MCnc	Pt	CSF	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1095	GluC	Urine/CSF	mmol/L	3L82		14744-7	Glucose [Moles/volume] in Cerebral spinal fluid	Glucose	SCnc	Pt	CSF	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1095	GluC	Urine/CSF	mg/dL	3L82		2350-7	Glucose [Mass/volume] in Urine	Glucose	MCnc	Pt	Urine	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1095	GluC	Urine/CSF	mmol/L	3L82		15076-3	Glucose [Moles/volume] in Urine	Glucose	SCnc	Pt	Urine	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1095	GluC	Urine/CSF	Ratio	3L82		2351-5	Glucose [Mass/time] in 24 hour Urine	Glucose	MRat	24H	Urine	Qn	Hexokinase/G-6-PDH
Abbott-TEST-v1	Abbott Diagnostics	ARCHITECT c8000	00380740 000509	FDA UDI	1095	GluC	Urine/CSF	Ratio	3L82		15077-1	Glucose [Moles/time] in 24 hour Urine	Glucose	SRat	24H	Urine	Qn	Hexokinase/G-6-PDH

https://ivdconnectivity.org/livd/

Digital Format for LOINC to IVD (LIVD)

IVD Industry Connectivity Consortium

IICC

FDA

September 29th, 2018

LIVD Connectathon

DRAFT - Un
Only; Co

Publication																		
Publication Version ID																		Method
Abbott-TEST-																		ase/G-6-PDH
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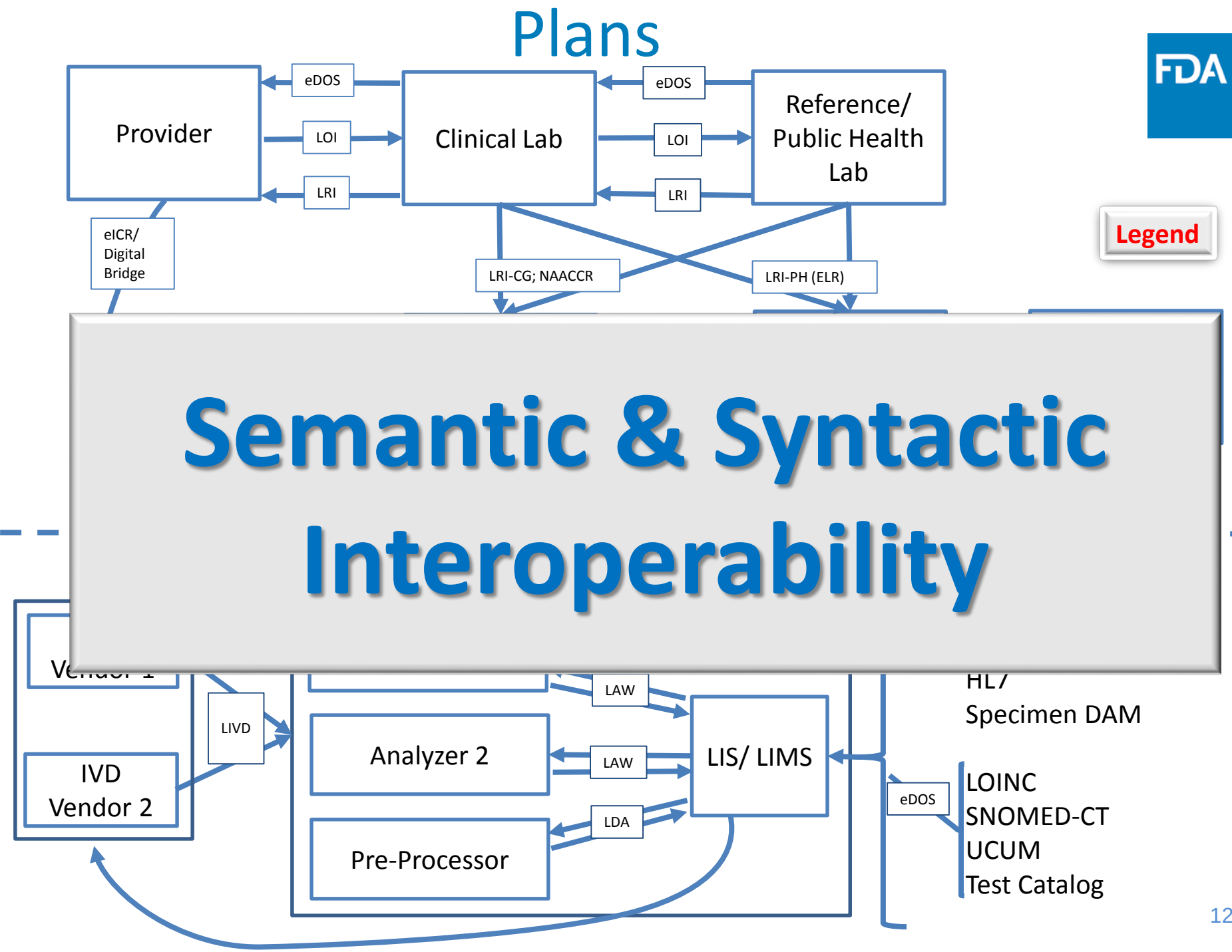
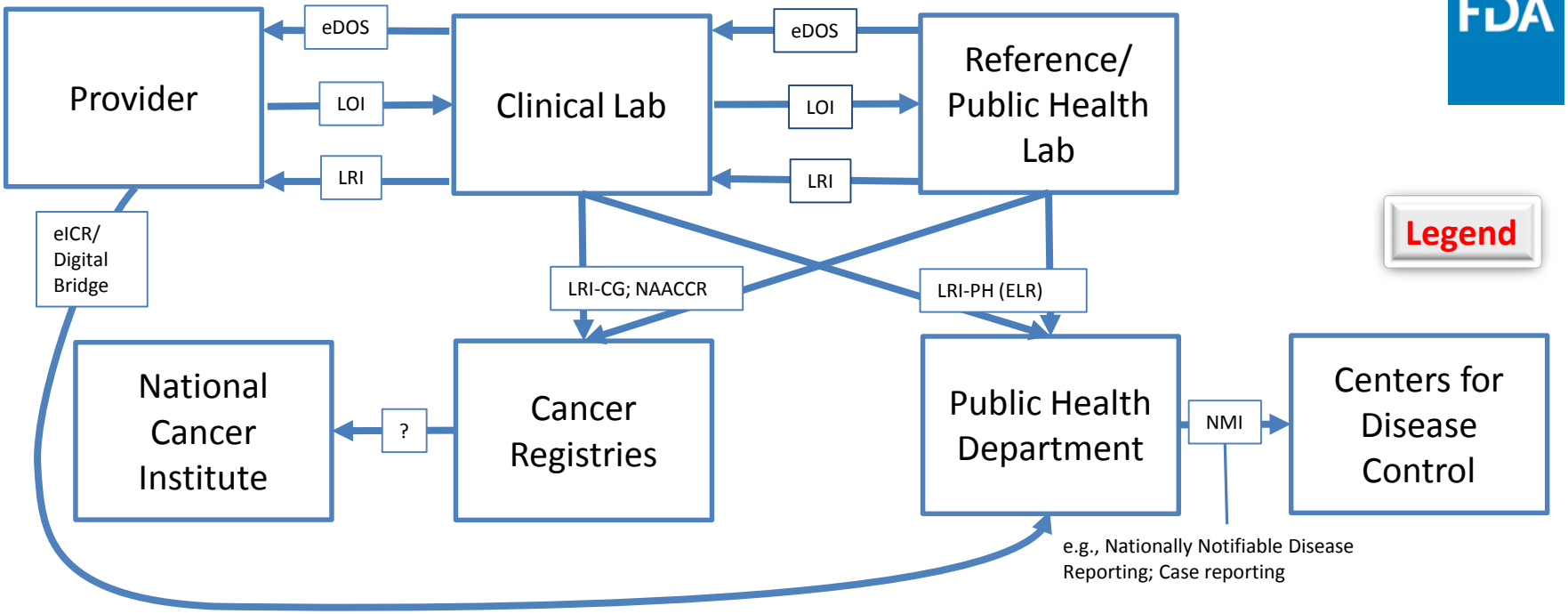
https://ivdconnectivity.org/livd/

Plans


Provider
eDOS
LOI
LRI
Clinical Lab
eDOS
LOI
LRI
Reference/ Public Health Lab
eICR/ Digital Bridge
LRI-CG; NAACCR
LRI-PH (ELR)
Legend
Semantic & Syntactic Interoperability
LIVD
IVD Vendor 2
LAW
Analyzer 2
LAW
LIS/ LIMS
LDA
Pre-Processor
eDOS
HL7
Specimen DAM
LOINC
SNOMED-CT
UCUM
Test Catalog

Plans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Clinical Lab
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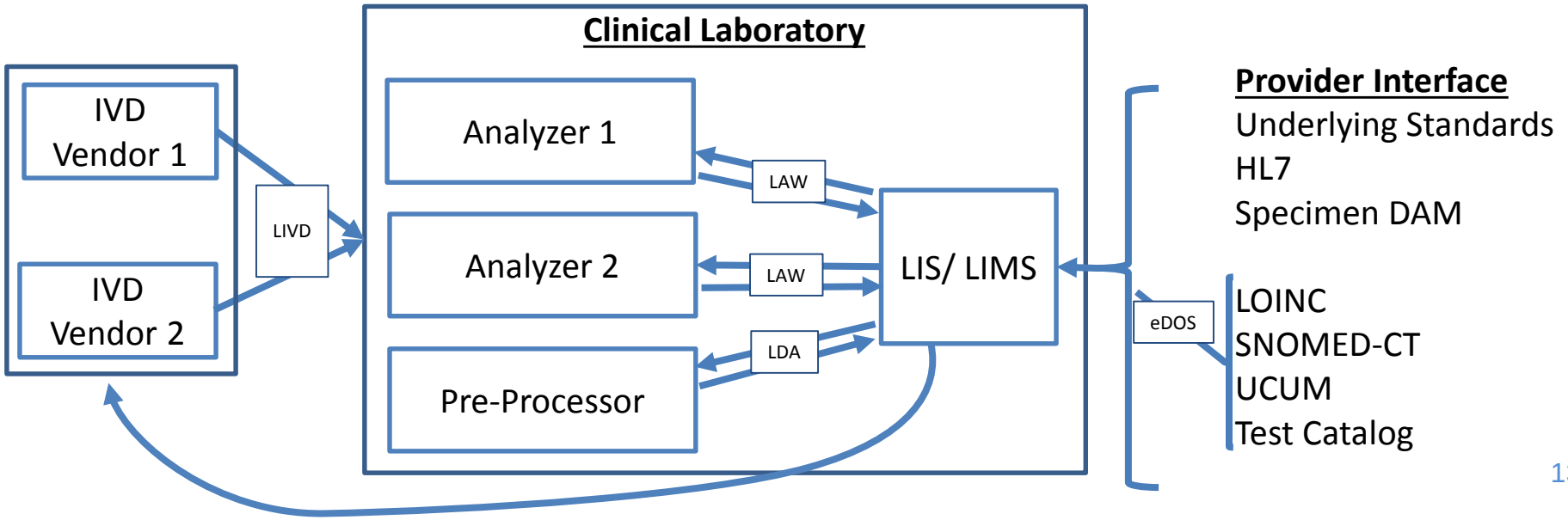
Reference/ Public Health Lab
eICR/ Digital Bridge
LRI-CG; NAACCR
LRI-PH (ELR)
National Cancer Institute
?
Cancer Registries
Public Health Department
NMI
Centers for Disease Control
e.g., Nationally Notifiable Disease Reporting; Case reporting


Clinical Laboratory
IVD Vendor 1
IVD Vendor 2
LIVD
Analyzer 1
Analyzer 2
Pre-Processor
LAW
LAW
LDA
LIS/ LIMS
eDOS
Provider Interface
Underlying Standards
HL7
Specimen DAM
LOINC
SNOMED-CT
UCUM
Test Catalog

Legend

CG – Clinical Genomics
DAM – Data Analysis Model
eDOS – Electronic Directory of Services
eICR – Electronic Initial Case Report
ELR – Electronic Laboratory Reporting
HL7 – Health Level 7
IVD – *in vitro* Diagnostic
LAW – Laboratory Analytical Workflow
LBL – Laboratory Barcode Labeling
LDA – Laboratory Device Automation
LIS – Laboratory Information System
LIMS – Laboratory Information Management System
LIVD – LOINC Transmission format for IVDs
LOI – Laboratory Orders Interface
LOINC – Logical Observations Identifiers Names and Codes
LRI – Laboratory Results Interface
LSH – Laboratory Specimen Handoff
LST – Laboratory Specimen Tracking
NAACR – North American Association of Central Cancer Registries
NMI – NNDSS Modernization Initiative
NNDSS - National Notifiable Diseases Surveillance System
PH – Public Health
SNOMED-CT – Systematized Nomenclature of Medicine – Clinical Terms
UCUM – Unified Codes for Units of Measure

SHIELD Demo Projects (Partial List)

1. *Infectious disease/antimicrobial resistance outbreak monitoring*

International Problem: Ambiguous lab data impedes surveillance & data transfer with patient

Solution: Implement SHIELD multi-agency/stakeholder standard infrastructure to improve accuracy and expediency infectious disease test data.

ROI: real-time outbreak monitoring; patient data transferable; RWE thru TPLC

2. *Standardize Lab Data to Enhance Patient-Centered Outcomes & Improve Value-Based Care*

National Problem: Poor lab data quality delays diagnosis/treatment & repeat testing/ billing

Solution: Link SHIELD-vetted lab data to diagnosis & claims codes in provider EHRs & MDEpiNet registries

ROI: 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

3. *Associate opioid diagnostics to patient reported outcomes & prescription data*

National Problem: Lack of reliable information leads to pain medication over-prescription, enabling substance abuse/addiction & illegal controlled substance distribution

Solution: Link SOC tests (w/SHIELD quality coding) for opioid overdose in emergency department to filled opioid prescriptions, patient diagnoses and PROs across institutions/states.

ROI: Portable data trifecta (IVD data, PDMP data, PROs) to support patient provided information & improve healthcare delivery that can follow a patient; RWE thru TPLC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U.S. FOOD & DRUG
ADMINISTRATION