SHIELD\textsubscript{x} - Harmonizing Standards Application to Accelerate Innovation

Michael Waters, Ph.D.

\textit{SHIELD}\textsubscript{x} Team Lead/OIR RWE Representative

OHT 7: Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiologic Health (CDRH)
Food and Drug Administration (FDA)
Goal

Describe the same test data the same way.
SHIELD\textsubscript{x} is a public-private partnership focused on the adoption/development, harmonized application and implementation of diagnostic data standards to advance innovation.

**SHIELD Stakeholders (>70 institutions engaged):**

FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, VA, CAP, IVD Manufacturers, EHR Vendors, Laboratories, Standards Developers, PEW Charitable Trusts, NEST/MDIC, Academia
in vitro diagnostics (IVDs) utility:

1° *in vitro* diagnostics (IVDs) products are... intended for use in diagnosis of disease or other conditions... 21 CFR 809.3

2° generate data used to drive:
   - Epidemiology/outbreak monitoring
   - Healthcare research and innovation
   - Regulatory decisions
   - Clinical Decision Support (CDS)
   - Artificial Intelligence (AI)
   - Public health reporting
   - Signal detection
   - more
What IVDs Do?

Each IVD asks a ‘question’ of a specimen to get an ‘answer’.

1) Collect and process specimen (e.g., blood specimen collection).

2) Ask Question:
   Does the venous blood specimen have:
   Ebola Virus Antigens (by immunoassay)?

3) Provide Answer:
   Ebola Virus Antigens Detected

Report
   __________
   __________
   __________
Currently: Same Test Represented Different Ways

Data must be understood and reliable to be useful.
Describing the Same Test the Same Way

Each IVD asks a ‘question’ of a specimen to get an ‘answer’.

1) Collect and process specimen (e.g., blood specimen collection).
2) Ask Question: Does the venous blood specimen have: Ebola Virus Antigens (by immunoassay)?
3) Provide Answer: Ebola Virus Antigens Detected

IVD Test

Report

Ebola Virus Antigens Detected
Plan:
Ecosystem supports manufacturers/industry to provide vetted and harmonized descriptive IVD codes (*vetted through a sole authoritative source*) to labs to improve utility for consumers.

Goals: Semantic Interoperability
*(Describing the same test the same way)*

Feedback Loop

Test Manufacturers
- Manufacturer 1
- Manufacturer 2
- Manufacturer 3
- ...

Test Site
- Test 1
- Test 2
- Test 3
- ...

Test Report

Seamless Transmission

End Users
- WHO
- CDC
- Registries

U.S. Pilots beginning now!
Goals: Semantic Interoperability

(Describing the same test the same way)

FREE! INTERNATIONALLY AVAILABLE NOW!

Ecosystem supports manufacturers/industry to provide vetted and harmonized descriptive IVD codes (vetted through a sole authoritative source) to labs to improve utility for consumers.


https://loinc.org/guides/micro/

http://ivdconnectivity.org/livd/

PI

Regulatory Framework

Authoritative Sole Source

Harmonized and Structured Transmission

CDC

WHO

Seamless Transmission

Test Sites

Test 1

Test 2

Test 3

Manufacturer 1

Manufacturer 2

Manufacturer 3
Simplified Process for IVD Code Assignment

Same IVD Type

Mapping for ~12,000 Micro Codes

Helpdesk Support

Example List

Mapping Tool

Unambiguous Descriptive Codes

80618-2
Zika virus IgM Antibody in Cerebral Spinal Fluid by Immunoassay

https://loinc.org/guides/micro/
Empowering Future Possibilities: Simplified Data Collection/Transmission

IVD Test

Ebola Vir Ag
NCBI 1570291
ICD-9-CM 078.89
SCTID 424206003
LOINC 71768-6
SCTID 709374001
ICD-10-CM A98.4
CPT A984
SCTID 424206003
LOINC 41637-0
Antigen, Ebola Virus
L-300C8
EBOV Ag

Report

End Users

WHO

CDC

Registries

Empowering Future Possibilities:
Simplified Data Collection/Transmission
Empowering Future Possibilities: Simplified Data Collection/Transmission

- IVD Test
- Ebola Vir Ag
- NCBI 1570291
- ICD-9-CM 078.89
- SCTID 424206003
- LOINC 71768-6
- SCTID 709374001
- ICD-10-CM A98.4
- CPT A984
- SCTID 424206003
- LOINC 41637-0
- Antigen, Ebola Virus L-300C8
- EBOV Ag
Empowering Future Possibilities: Simplified Data Collection/Transmission

Simplified Data Collection/Transmission

Harmonized Codes

LOINC 71768-6
SCTID 709374001

Real-Time Transmission

End Users

WHO

CDC

Registries

IVD Test

Case Report Date: Tap to enter date

Patient Information

Patient ID: ______ Age: ______
Occupation: ______ Location: ______
Alive/Dead Choose one Consent: ______

Clinical Signs & Symptoms

Symptoms: Check all that apply
Unexplained Bleeding: Check all that apply

Hospitalization Information

Admission Date: Tap to enter date
Checkout Date: Tap to enter date
Location: Choose one Isolation?

Laboratory Testing

Test Date: Tap to enter date
Test Results: Choose one
Test Type: Choose one
Specimen: Choose one

Epidemiological Risk/Exposures

Patient Information

Case Report Date: Tap to enter date

Patient ID: ______ Age: ______
Occupation: ______ Location: ______
Alive/Dead Choose one Consent: ______

Clinical Signs & Symptoms

Symptoms: Check all that apply
Unexplained Bleeding: Check all that apply

Hospitalization Information

Admission Date: Tap to enter date
Checkout Date: Tap to enter date
Location: Choose one Isolation?

Laboratory Testing

Test Date: Tap to enter date
Test Results: Choose one
Test Type: Choose one
Specimen: Choose one

Epidemiological Risk/Exposures
To get involved/learn more, contact: Michael.Waters@fda.hhs.gov

THANK YOU!

SUPPORT

- HHS Patient-Centered Outcome Research Trust Fund (PCORTF)
- Medical Countermeasures Initiative (MCMi)
- Presidential Advisory Council for Combatting Antimicrobial Resistant Bacteria (PACCARB)
- DEDICATED VOLUNTEERS WHO HAVE INVESTED COUNTLESS HOURS AND CONSIDERABLE EXPERTISE