

Promoting Semantic Interoperability of Laboratory Data: Public Workshop Update

Steven Gitterman, FDA

CLIAC Meeting

November 18, 2015

Agenda

- 8:15 – 8:45 **LOINC**: Introduction and use for interoperability: Dan Vreeman, Regenstrief Institute
- 8:45 – 10:15 Panel: Adopting LOINC: Industry, the Laboratory, and Others. Introductory comments: Rob Bush, Orchard Software
- 10:30 – 11:00 Reporting results: **SNOMED/UCUM** and laboratory results: Jim Case, National Library of Medicine, and Gunther Schadow, Pragmatic Data
- 11:00 – 12:15 Panel: Standardized Reporting: Implementation and Use
- 1:15 – 1:35 The Role of **UDI** in Laboratory Interoperability: Leslie Steen, CDRH
- 1:35 – 1:50 How SPL is Designed to Carry LOINC, SNOMED, and UCUM codes: Gunther Schadow, Pragmatic Data
- 1:50 – 2:10 Leveraging LOINC/SNOMED CT for Clinical Research/Drug Approval: Mitra Rocca, CDER
- 2:10 – 3:00 Open public session: A. Pitkus, A. Carter, S. Jones,
- 3:15 – 4:45 Panel: Moving forward. Introductory comments: Steve Posnack, Office of the National Coordinator, DHHS

General Info

- Participation by Clinicians, Electronic Health Record (EHR)/ Laboratory Information System (LIS) vendors, Informaticians, Academia, Public Health officials, Laboratorians, and Regulators (and non-regulators), to promote pathways to greater adoption of interoperable standardized codes and terminologies.
- From the Government: CDC, CMS, FDA, NLM, ONC
- > 250 participants in person or via web
- Video, slides, and transcript all available on the web
- Ongoing workgroup

Feedback

- “I would like to thank you and your team for putting this well thought out and informative workshop together. It is my hope that this is the first of many steps to come to move semantic interoperability forward, in the laboratory specifically and more broadly in health care.”
- “We concur that interoperability is important to advance the public health and support meaningful use of medical information. In that vein, consistent, harmonized terminology will be essential to successful implementation of electronic laboratory reporting.”

Comments

- Codes should not be considered promotional by FDA with the implications thereof
- Not an 'FDA' mandated activity
- Mechanism for distribution of codes should be other than through product labeling
- Industry-defined standardized publishing format
- Formation of a 'standard coding review' committee as a resource for IVD vendors, who desire to have their mappings verified
- Explore the role of vendor consortiums such as IICC and standards development organization (SDO) such as the Clinical Laboratory and Standards Institute

Standardized Coding: LOINC

- Mature characterization for most tests
- Substantial laboratory penetration
- Essential part of meaningful use
- Need to consider entire process:
 - Assigning codes
 - Template
 - Not a new concept
 - Consistency
 - ‘Availability’
- May not need to be complete
- Will be part of CDER data standards for clinical trials

Standardized Format: SPL

- “To further support the field, we also support an industry-defined publishing format to facilitate a standardized format to help promote consistency of coding. This could be used to guide the mapping. This will help reduce differences of coding between vendors for similar tests and align codes between laboratories using a comparable system class.”

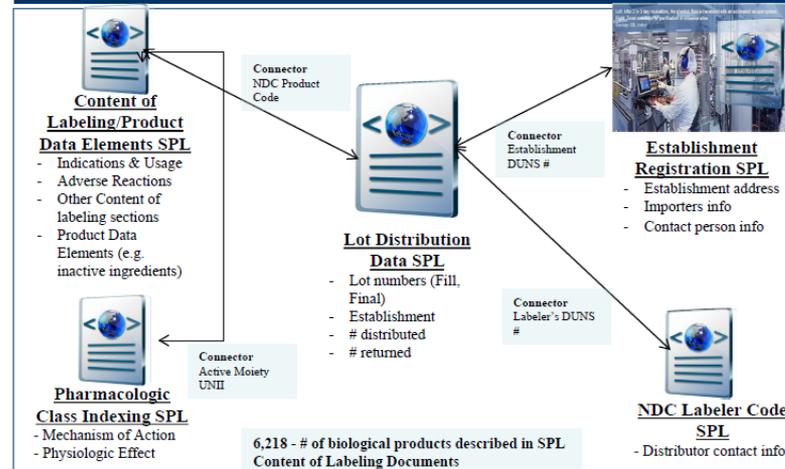
Standardized Distribution

Tracking and Linking Biological Product Lot Distribution Data Utilizing SPL - SPL Infographic

Collection of Lot Distribution Data in an Electronic and Standardized Format

Via the publication of the final *Guidance for Industry – Electronic Submission of Lot Distribution Reports* on June 10, 2015, CBER and CDER announced the commencement of the requirement for biological product application holders to submit lot distribution data (LDD) in Structured Product Labeling (SPL) format every six months. LDD SPL data may now be automatically linked to other types of data submitted in SPL files.

Linking Lot Distribution to Other SPL Documents



Content of Labeling/Product Data Elements SPL

Types of Biological Product Data in SPL Format	
Cellular Therapy	Licensed Minimally Manipulated Cells
Non-standardized Allergenic	Plasma Derivative
Standardized Allergenic	Therapeutic
Vaccine	

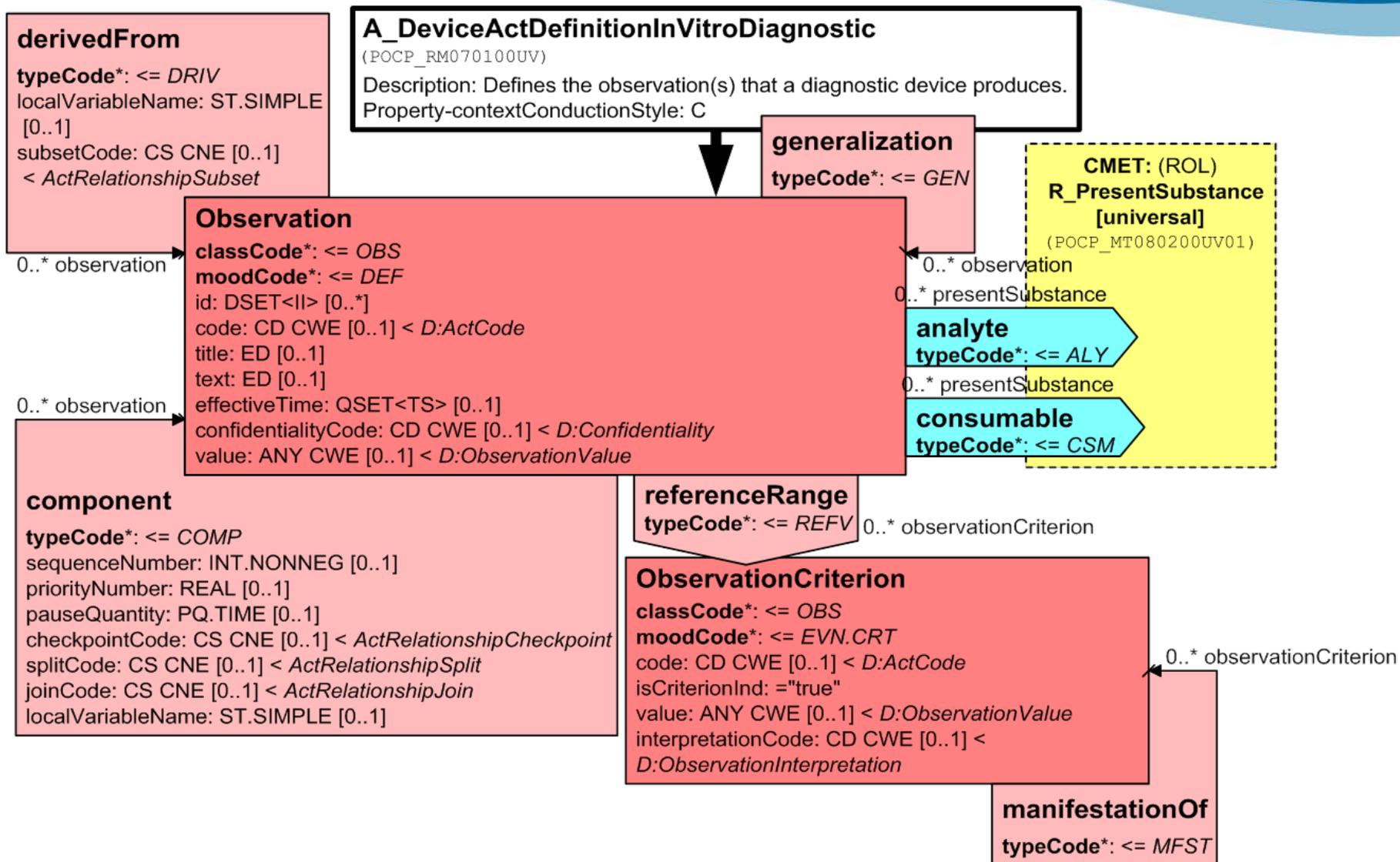


Public law
112-144 Sec 224
Electronic Drug Registration and Listing



Regulations
21 CFR 600.81 – Lot Distribution Data
21 601.14(b) (for BLAs) - Electronic Labeling Rule

Supporting Law & Regulations



Translatable to SPL Schema

```
<document>
  <section>
    <text>...</text>
    <subject>
      <manufacturedProduct>
        <code ... NHRIC, GS1, etc. item code .../>
        <deviceOf>
          <observation><!-- device act definition -->
            <code ... LOINC .../>
            <value ... SNOMED value code .../>
            <value ... SNOMED value code .../>
            <value ... SNOMED value code .../>
            <!-- ... all possible values ... -->
```

Standardized Results

- “As we have not seen a similar demand for manufacturer provision of SNOMED codes and have more limited experience with SNOMED (Systematized Nomenclature of Medicine), we concur with workshop discussants that focus should remain on LOINC at this time. Furthermore, we understand that efforts are already underway by groups to link LOINC codes to SNOMED codes, so LOINC appears to be most pivotal in supporting laboratory data interoperability at this time.”
- However:
 - May not reflect all participants
 - Excellent opportunity to make progress since integrates with SPL file
 - Still reflects important consideration

Ongoing Considerations:

- Workgroup continuing
- Pilot with Industry
- Integration of industry into workgroup
- FDA clarifications:
 - Cannot publish off-label uses although ‘alternative mechanisms’ to support laboratories exist
 - Formal discussions with industry
- Continue to work on SNOMED coding
- Guidance/Implementation Guide Development:
 - Flesh out technical solution

Questions?

- Thanks to:
 - Nancy Cornish
 - Maribeth Gagnon
 - Sandra Jones
 - Bill Mac Kenzie
 - Graylin Mitchell
 - Anne Pollack
 - Megan Sawchuk
 - Michael Waters