Interoperability of Lab Data and LOINC: Industry Perspective

FDA-Industry IVD Roundtable

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Importance of Interoperability

- Advances the public health
- Allows exchange and pooling of clinical data for clinical as well as research purposes
- Facilitates meaningful use of real world medical information and data

Purpose of LOINC

- Logical Observation Identifiers Names and Codes (“LOINC”) can bring consistent, harmonized terminology to labs and manufacturers – a step toward interoperability

Key Issues and Challenges

- Technical
  - Volume and complexity of codes, variation in coding, levels of granularity possible– one test can have multiple codes
  - Codes can continually change, raising issues of sustainability. Maintaining codes can be time consuming and costly
  - Codes are owned and housed by Regenstrief Institute, a non-profit medical research organization – not manufacturers

Progress on technical effort amongst industry (as reported in 11/8 Semantic Interoperability Workshop), but must be coupled with address of regulatory issues.

Key Issues and Challenges

- Regulatory
  - FDA recognition as non-regulated activity
    - Otherwise, could slow innovation, potentially freeze design, and would require rulemaking.
  - Provision of accurate codes is a necessity to ensuring interoperability, but might be viewed as off-label product promotion if provided by manufacturers.
    - Even if FDA exercised enforcement discretion, manufacturers could be open to liability from authorities. There has to be another solution.

Collaborations

- FDA Public Workshops
  - September 28, 2015: *FDA, CDC, NLM Workshop on Promoting Semantic Interoperability of Laboratory Data*
  - November 8, 2016: *Workshop on Promoting Semantic Interoperability of Laboratory Data*

Technical Resolution

- IVD Industry Connectivity Consortium ("IICC") proposal for digital format of LOINC codes
  - Easily transformed into human readable format to allow manual selection of LOINC codes by labs
  - Electronic format for use by IVD systems to allow mapping of IVD vendor tests to LOINC codes based on inbound test orders
  - Uses JSON (JavaScript Object Notation), industry standard for describing digital content
- Third party (Regenstrief) involvement – but needs to be sustainable in the long-term
- Standardization through standards setting organization (e.g., CLSI)
- Focus now on LOINC, not link to SNOMED
- Importance of continued overall harmonization for long-term success (e.g., GMDN)

Regulatory Recommendations

- Support provision of LOINC codes; industry supports voluntary efforts
  - First step should be a mapping of LOINC to existing tests
  - Required programming of LOINC into software or instruments would freeze design, slow innovation and acceptance.
  - Other appropriate venues than product labeling (which would present unsurmountable challenge and excessive regulatory /administrative burden).
  - LOINC is not an appropriate addition to GUDID or any other regulatory-required data set
- Encourage alignment of interests and resolutions within FDA (regulatory/legal coordination) and cross-office/Center collaboration
- Recognize in regulation or guidance that good faith provision of LOINC codes is not misbranding or adulteration;
  - Provide specific disclaimer(s) that establish a safe harbor, e.g., provision of LOINC codes is a recognized or supported public health activity by FDA and it may not nor should be viewed as product promotion or evidence of inappropriate product promotion by manufacturers