FDA – LOINC Implementation Guides

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Implementation Guides / Mapping Manuals

- Completed last year - 1st in series - Microbiology
- Current Project – 6 additional IVD mapping manuals:
  - Chemistry
  - Drug/Toxicology
  - Allergy
  - Serology/Hematology
  - Cell Markers
  - Molecular Pathology
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- **Phase 1: Initial Development of Manual**
  - Review (LOINC, lit, HL7), draft, feedback
- **Phase 2: Pilot Testing**
  - 3 labs or IVD manufacturers
- **Phase 3: Finalization of Manual Content**
  - Based on feedback
- **Phase 4: Manual Dissemination**
  - No cost worldwide
https://loinc.org/guides/ to sign up to be reviewer or pilot site
Guide Paradigms
Organizational Structure

• Analytical Techniques and Instrumentation
• Type of Analytes
• Pathophysiology
• LOINC – specific determinants (such as property and scale or type of specimen)
• Other suggested possibilities
Guide Paradigms

- The chapters in the original Microbiology guide were **method**-oriented
  1. Introduction
  2. Conventions
  3. Microscopic examination
  4. Cultures
  5. Susceptibility testing
  6. Antigen tests
  7. Nucleic Acid tests
  8. Serology testing
  9. Mapping qualitative result values
  10. Choosing the right LOINC term
  11. Putting it all together
  12. Mapping validation, maintenance, publication

Appendices. Resources, requesting new LOINCs, LOINC primer

- Other Guides will need to follow distinct organizational structure based on domain-specific paradigms

LOINC®

from Regenstrief
Term type variance

LOINC Property Comparison

- PrThr
- Titr
- AGnc
- Susc
- Prid
- MCnc
- SGnc
- MCnt
- Mass
- SRto

Legend:
- Micro
- Chem
- DrugTox
Common content / Unique content

• 7 Guides: Microbiology, Chemistry, Drug/Toxicology, Allergy, Serology/Hematology, Cell Markers, Molecular Pathology
• Possibly an 8th guide:
  • There are certain guiding principles to LOINC mapping that span all the domains
  • Proposal: Extract out common LOINC mapping principles common to all domains into a separate General guide or LOINC Quick start.
Suggestions for paradigms

Please sign up to be reviewer or pilot site

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