



Leveraging National Data Models & Terminologies for Medical Device Evaluation



DukeHealth

The great thing about standards is that there are so many to choose from.

common quote (author unknown)



Data Models

- Data modeling is a process used to define and analyze data requirements needed to support business processes
 - Conceptual: identification of data required
 - Logical: translation of data specifications into database specifications (data elements, data tables, structures and relationships)
 - Physical: the actual database (tables, rows, columns, etc.)
- Healthcare Common Data Models
 - OMOP, SENTINEL, PCORnet, i2b2



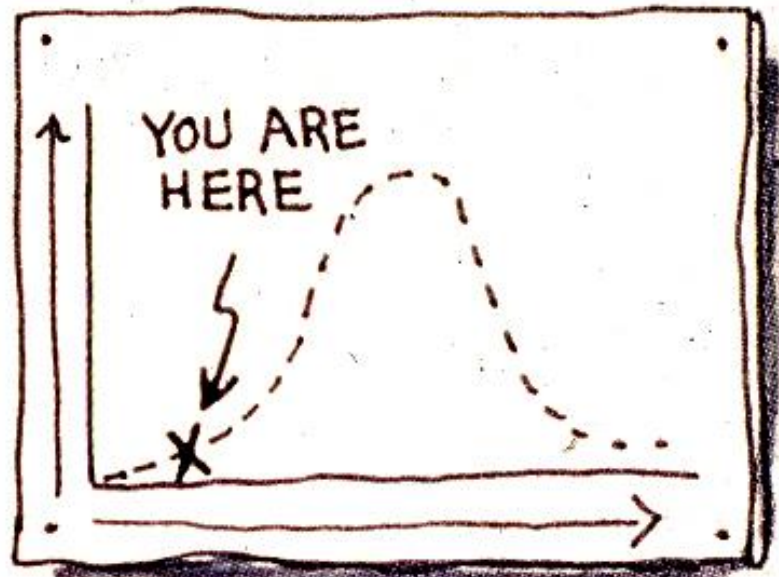
Terminology Standards

- Multiple levels of rigor
 - Ad hoc – Informal agreement and use
 - De facto – large number choose to adopt so it becomes a standard
 - Government-developed and mandated
 - Formal process /consensus – role of SDOs
- Greater rigor requires resources and expertise
- Not just “interoperability”
 - Without data standards, semantic harmonization required between every two interface points (exponential number of harmonization tasks)
- Common Data Element modeling
 - ISO 11179, NCI EVS, CIMI



Healthcare SDOs

- American Standards and Testing Materials (ASTM)
- American Standards Committee X12 (ASC X12)
- American Collage of Radiology (ACR)
- National Electrical Manufacturer's Association (NEMA)
- Health Level Seven (HL7)
- International Health Terminology Standards Development Organization (IHTSDO)
- Logical Observation Identifiers, Names, and Codes (LOINC)
- World Health Organization (WHO)
- National Library of Medicine (NLM)
- Object Management Group (OMG)
- National Council for Prescription Drug Programs (NCPDP)



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