Clinical Research Informatics: Information Needs and Systems in the Clinical Research Environment

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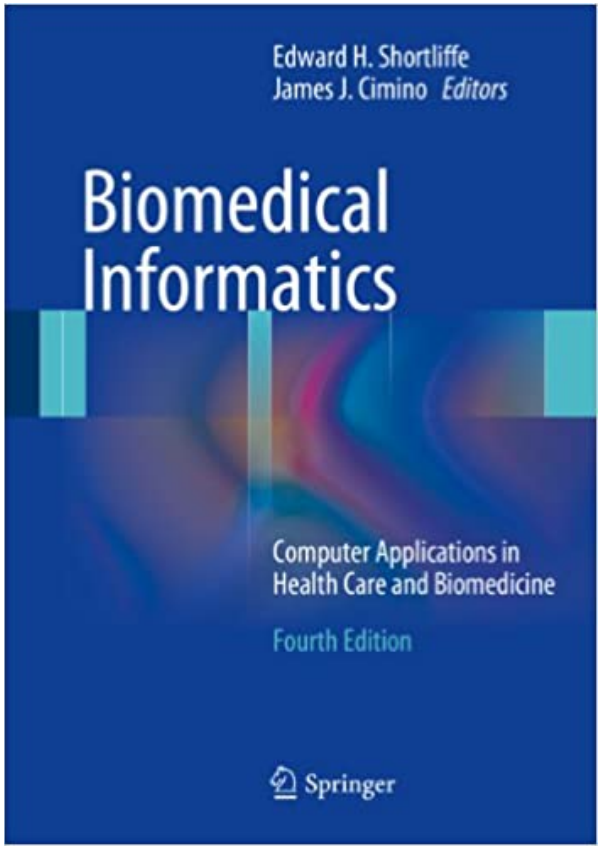


Textbook Material

Shortliffe and Cimino, Biomedical Informatics, V4
Chapter 26, Section 3

Roadmap for Discussion

1. Information systems supporting clinical research

2. Clinical research management systems

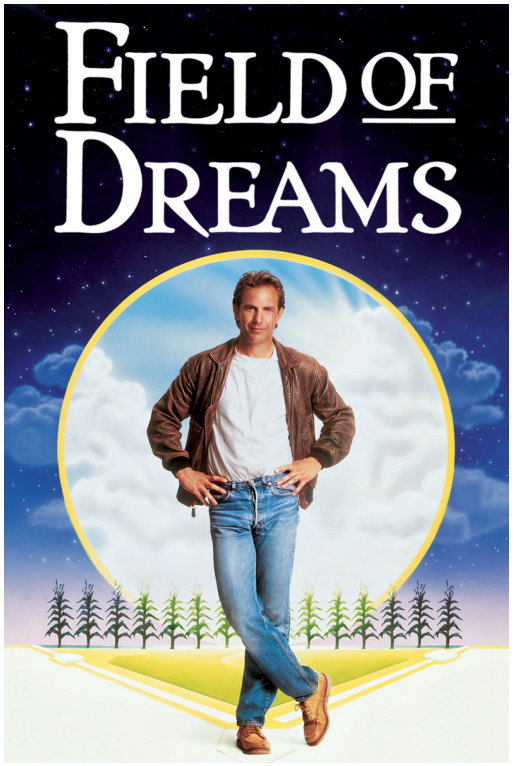
3. Using standard controlled terminologies for research data

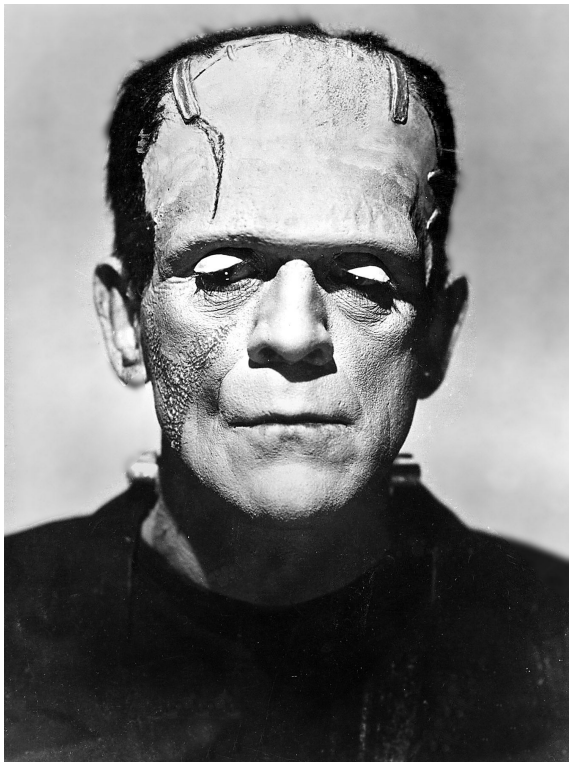
Disclosures

- Philip Payne is an expert
- Russ Waitman is also an expert
- Jeremy Provance has encountered a sampling of these topics and seen what works (and sometimes what doesn't)

Information Systems

Two Main Theories



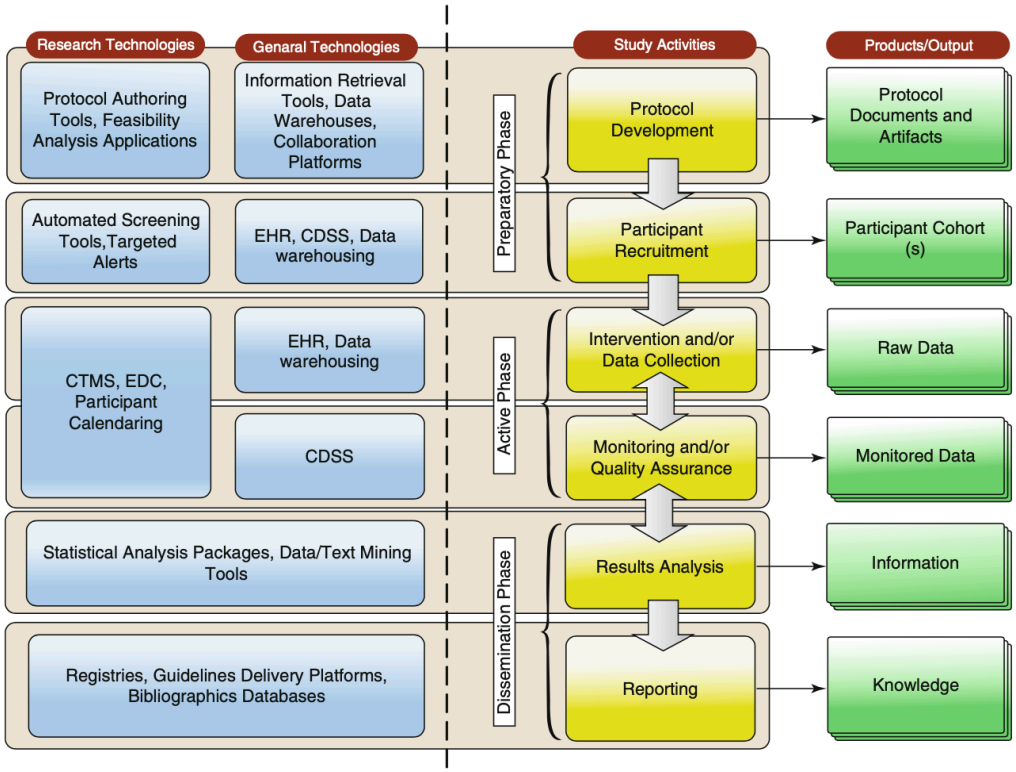


Two Main Practices

Central Questions

- What do you need to do? Want to do?
- What can you/could you already do?
- What kind of resources do you have to do it?

The General Idea



i2b2: a specific tool

Why i2b2?

- Big data—How do I quickly use it to make decisions?
- HIPAA—How do I circumvent red tape without causing harm?
- Python, R, SAS, SQL--What if I'm not a programmer?

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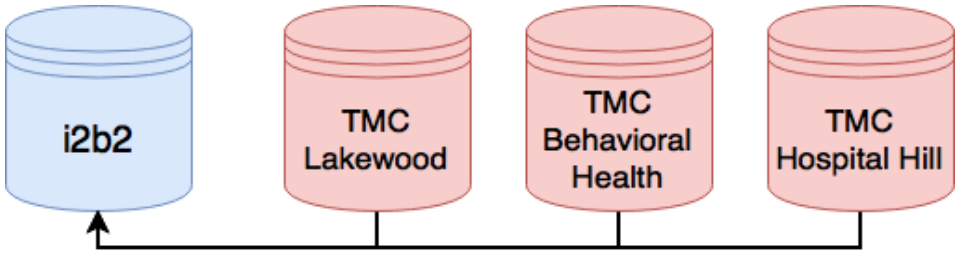
What is i2b2?

- Software for organizing clinical data so that it might be viewed for clinical research
- Locally: a de-identified repository for Truman Health Systems EHR data



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Key Use Cases

1. Cohort Discovery/Hypothesis Generation

- When a patient is seen at Truman with acute MI, what medications are they given?

2. Feasibility/Power Analysis

- How many patients have experienced sepsis at my location?

3. Retrospective/Quality Analysis

- What are the opioid prescription rates between the red clinic and blue clinic?

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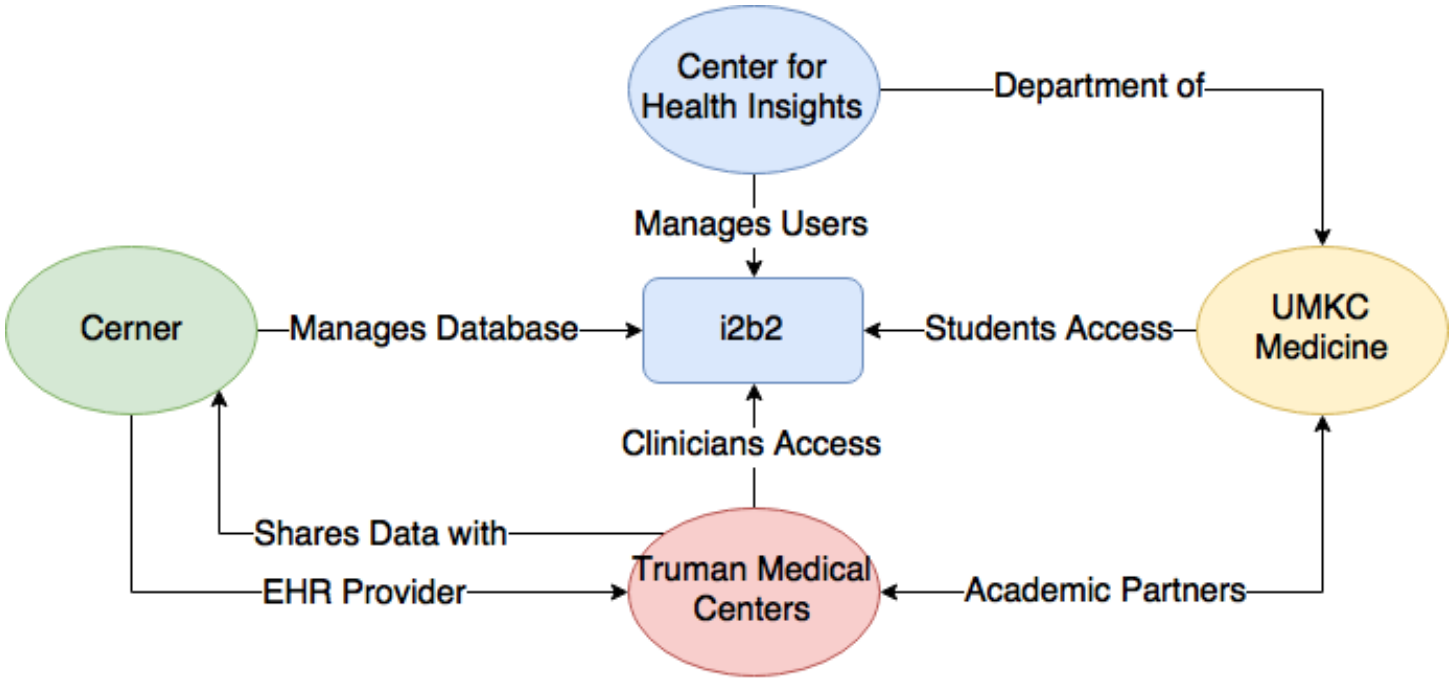
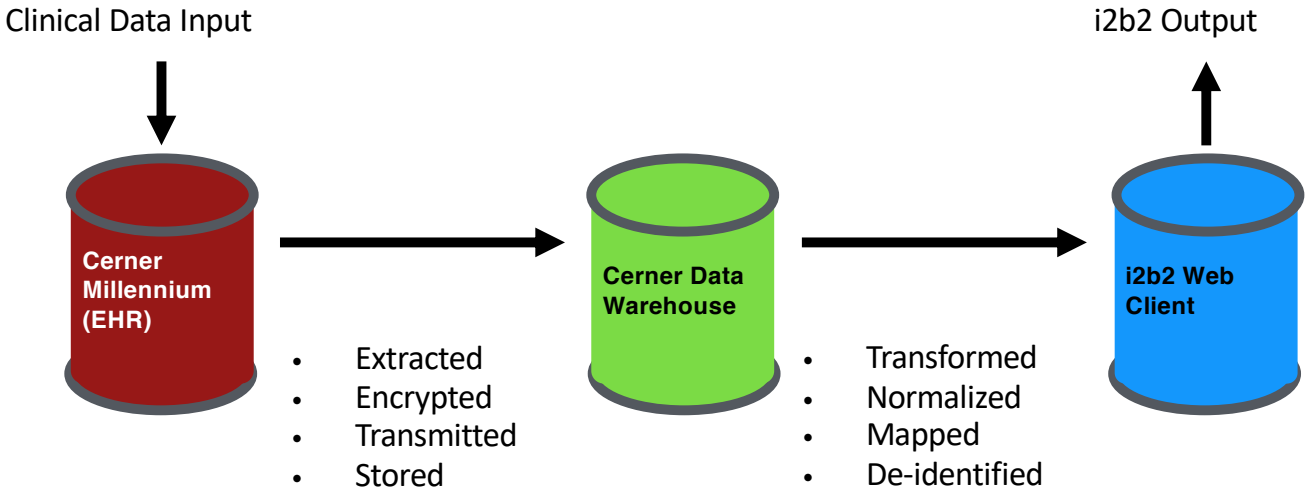
The Collaboration



How does i2b2 access data?



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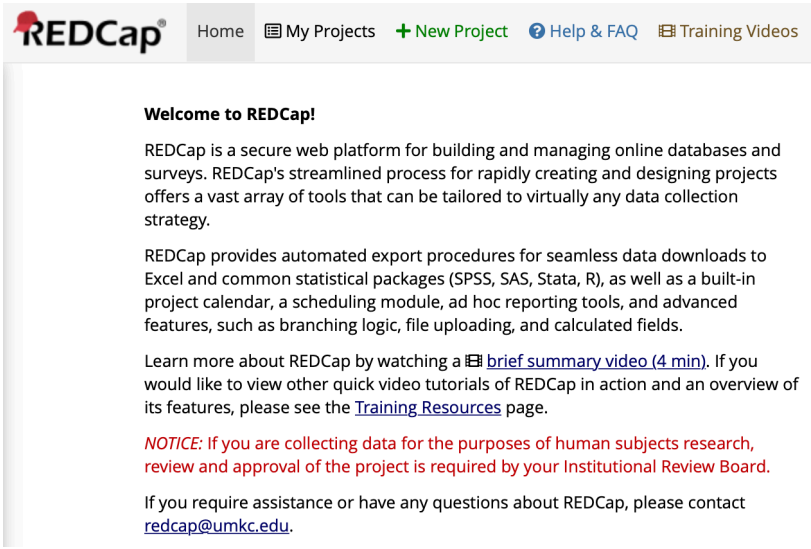
Problem

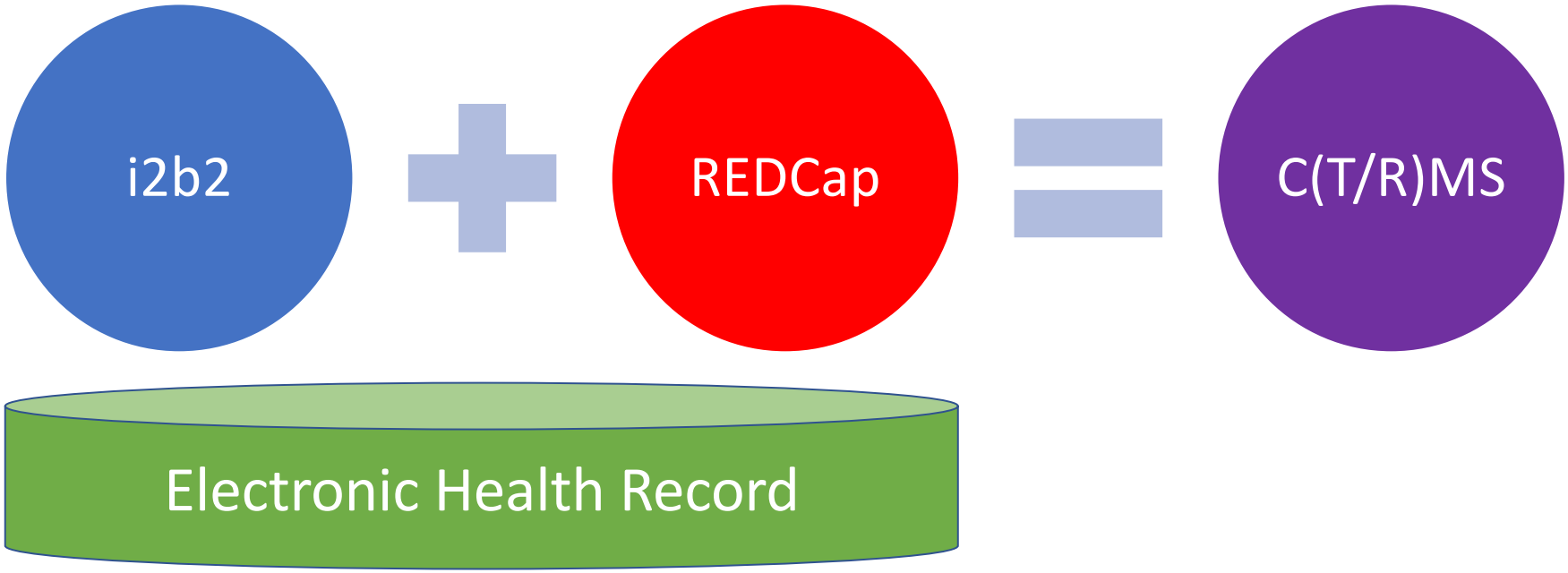
- Useful only in select circumstances
- When Cerner stops updating/supporting, you are out of luck

REDCap: a versatile tool

REDCap Features

- Collect, store, disseminate data
- Survey functionality
- Participant scheduling
- File storage
- Participant randomization
- Manage data collection tools
- Create data dictionaries
- Project manage
- Visualize/Export data
- More

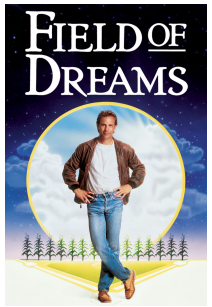
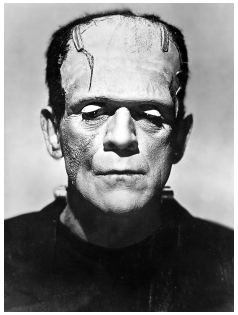



i2b2
REDCap
C(T/R)MS
Electronic Health Record

Clinical Research Management Systems

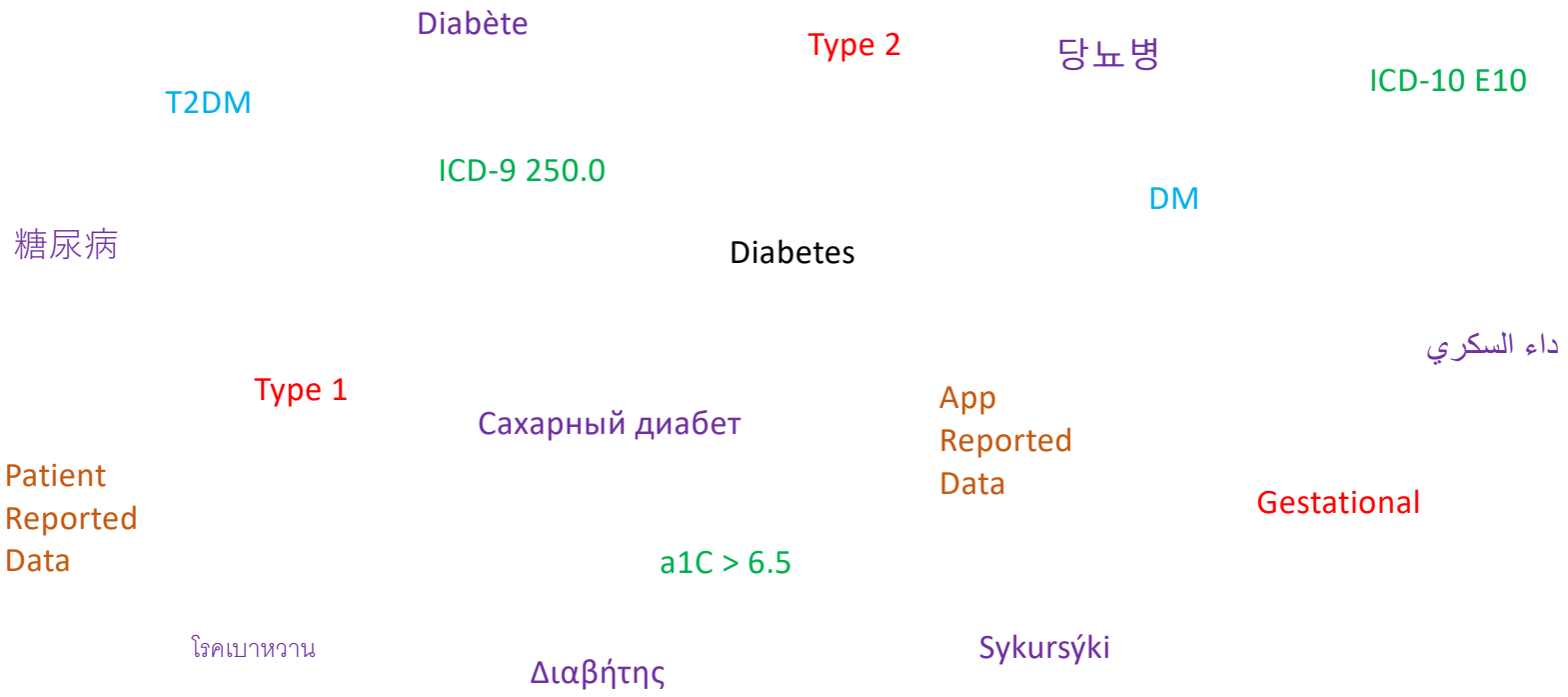
CRMS Functions

- Manage protocols (REDCap)
- Participant screening (i2b2)
- Participant calendaring (REDCap)
- Electronic Data Capture (REDCap)
- Monitoring Tools (REDCap/i2b2)
- Query and Reporting (REDcap/i2b2)
- Security and Auditing (REDCap/i2b2)

	CRMS	REDCap + i2b2
Theory		
Practice	 	 

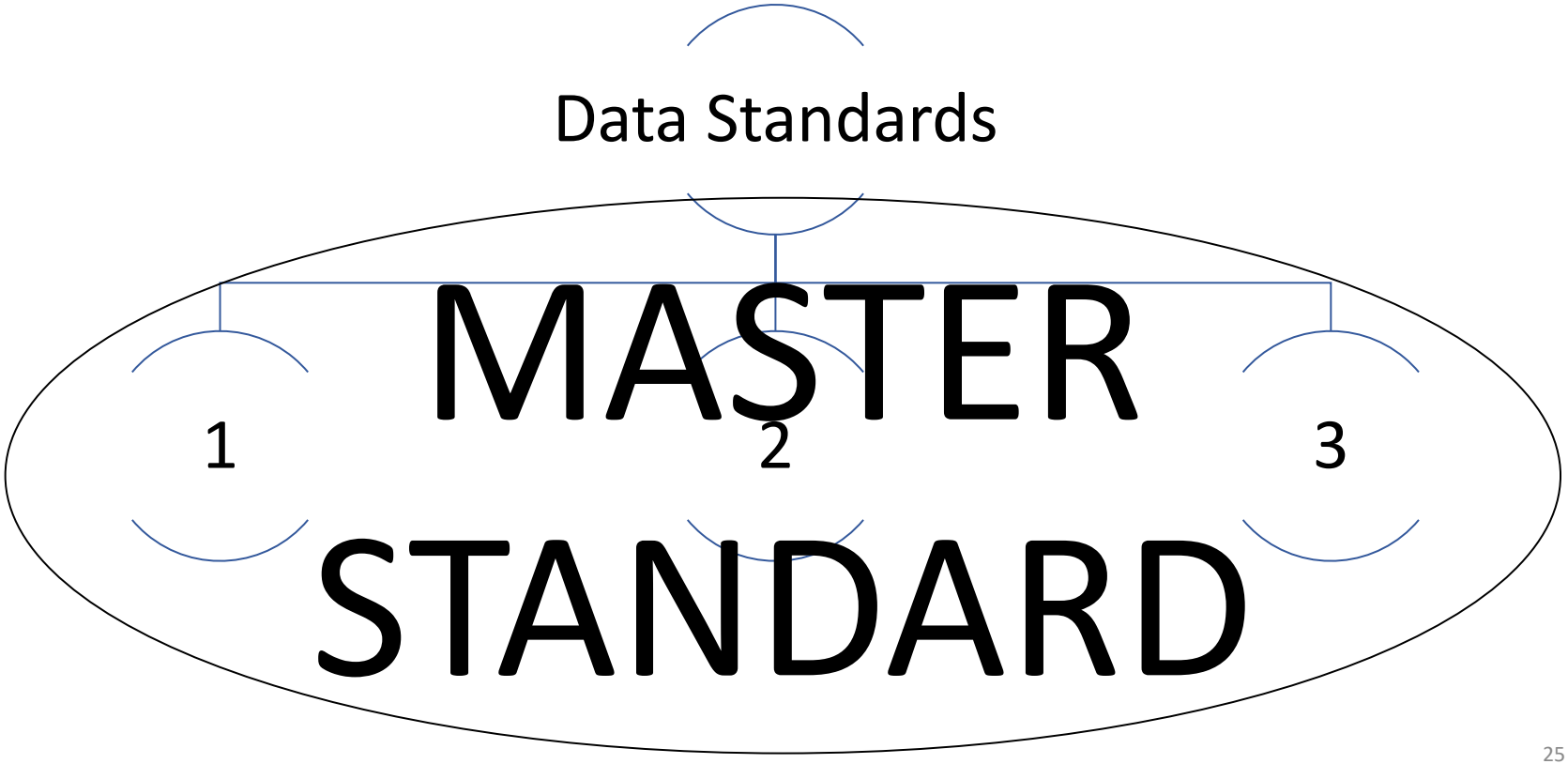
Standardized Terminologies

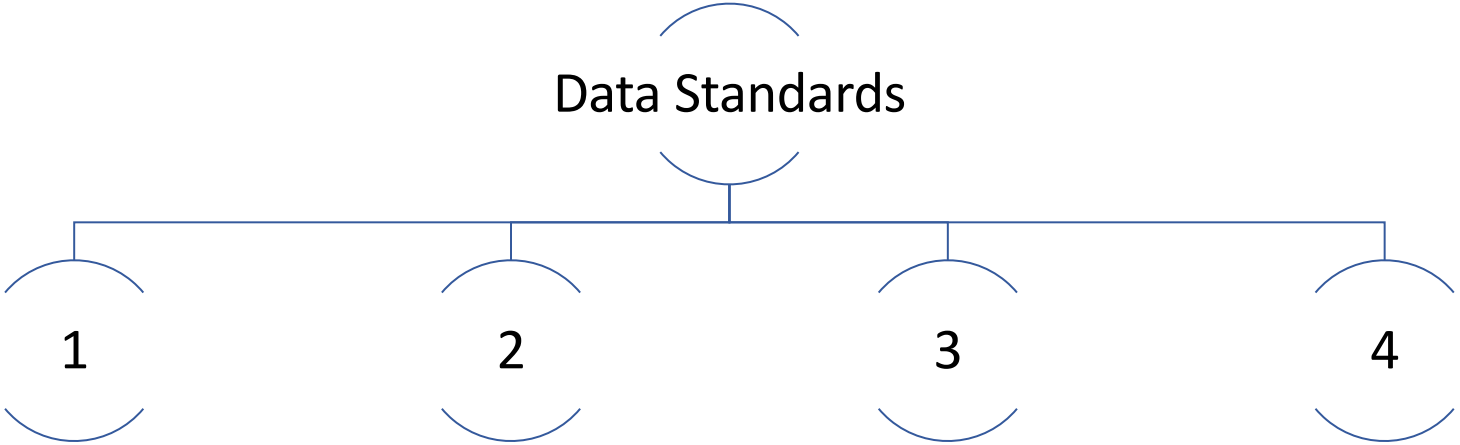
Why do I care? Tomato, tomato, right?



Reasons to use standard terms

1. Reuse data (AND YOUR CODE) for other purposes
2. Reduce rework
3. Interoperability: reporting sideways
4. Oversight: reporting upwards


Data Standards
MASTER
1
2
3
STANDARD


Data Standards
1
2
3
4

Standards are ~~improving~~ changing constantly

- ICD-10 → ICD-11 soon
- Common data models: OMOP, PCORNet
- Data interoperability: HL7 FHIR
- Data storage frameworks: XML

ICD-9 to ICD-10 Case Study

- ICD-9 V45.1: Postsurgical Renal Dialysis Status
- ICD-10 V45.1: Car passenger injured in collision with railway train or railway
- We haven't gotten it right yet

Data Sharing Soap Box

- We can have fancy tools (both broad and specific)
- We can have perfectly interoperable data standards and systems
- If we do not share data openly, it does not matter
- Need for:
  - Further work on sharing standards
  - Protection/compensation for individuals who shared
  - Liberation of data from hoarders

Questions?