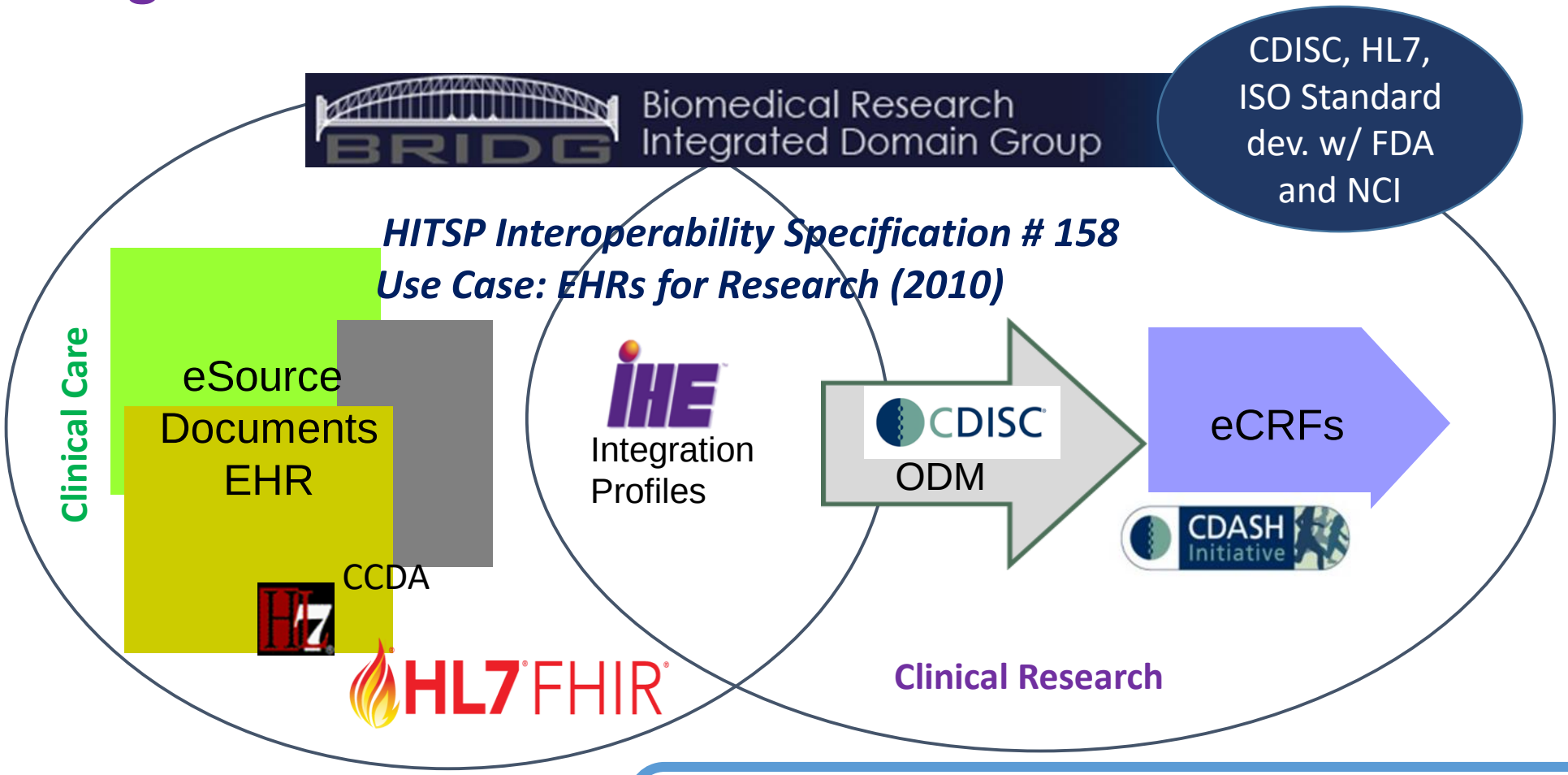
Optimizing Clinical Research



As of 2016, FDA and PMDA require CDISC SDTM, ADaM, define.xml and Therapeutic Area Specific Standards
www.fda.gov/ForIndustry/DataStandards/StudyDataStandards

Initial "Optimizing Research" Slide from 1997; CenterWatch Book published 2003, *eClinical Trials: Planning and Implementation*

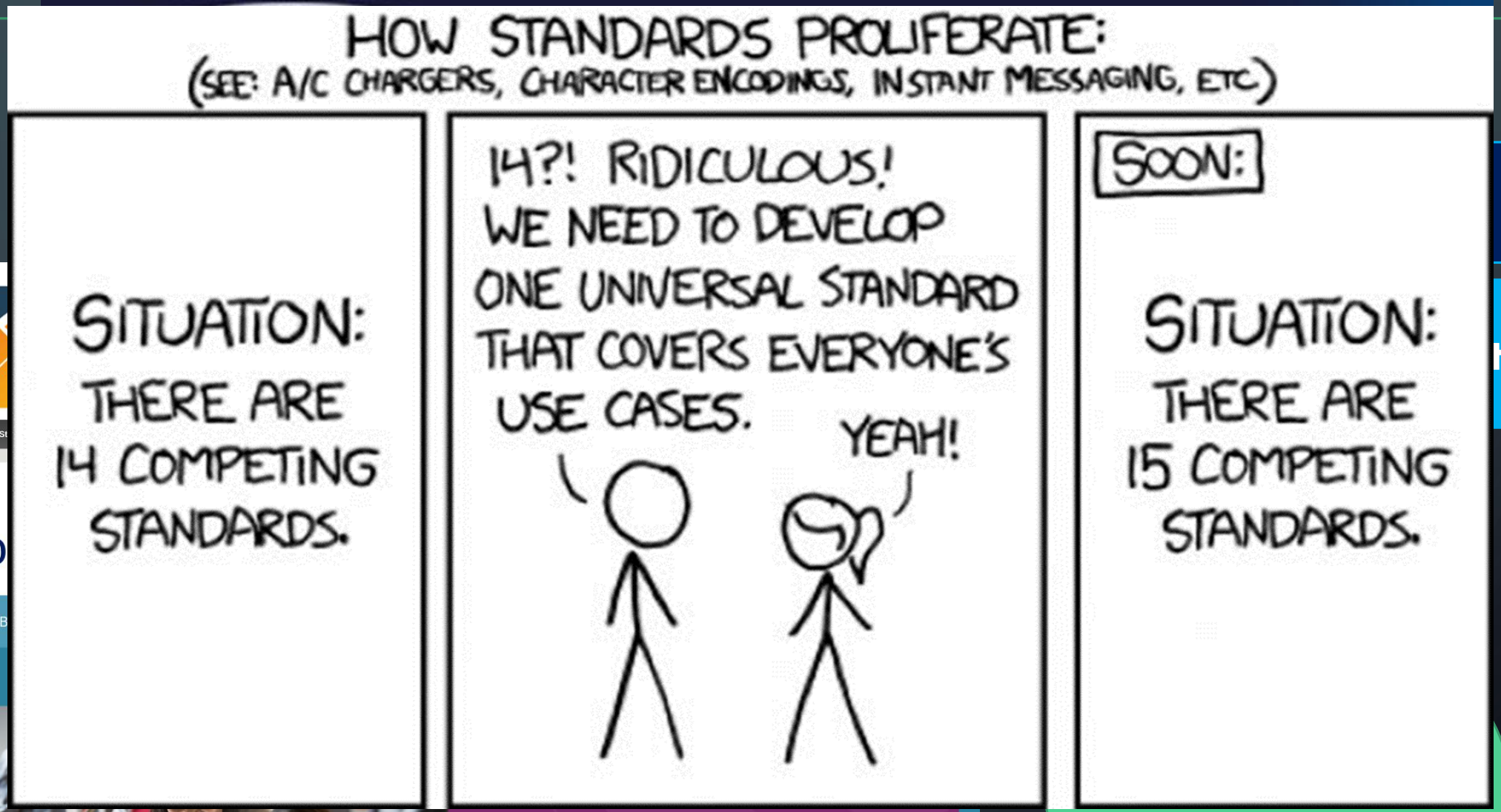
Relevant References

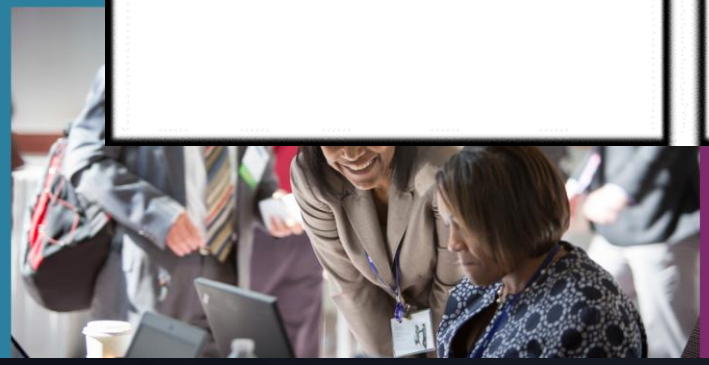
ECRIN CORBEL Consensus Report – 10 Principles

- ***P1:*** *The provision of individual-participant data should be* ***promoted, incentivised and resourced so that it becomes the norm in clinical research****. Plans for data sharing should be described prospectively, and be part of study development from the earliest stages.*
- ***P4:*** *To promote inter-operability and retain meaning within interpretation and analysis, shared data should, as far as possible,* ***be structured, described and formatted using widely recognised data and metadata standards.***
- ***P10:*** *Any dataset or document made available for sharing should be associated with* ***concise, public and consistently structured discovery metadata,*** *describing not just the data object itself but also how it can be accessed. This is to maximise its discoverability by both humans and machines.*

Ohmann, C. et al. "Sharing and reuse of individual participant data from clinical trials: principles and recommendations", **British Medical Journal Open**, 2017:7:e018647, doi: 10.1126/bmjopen-2017-018647

Case Study: Common Data Models and "Common" Data Elements





Research Done Differently

PCORI was established to fund research that can help patients and those who care for them make better-informed decisions about the healthcare choices they face every day, guided by those who will use that information.

ELEMENTS (CDEs)

PCOR TRUST FUND CDMH PROJECT LED BY FDA (M. ROCCA)

PARTICIPANTS: HHS/FDA, HHS/NIH/NCATS, NIH/NCI, NIH/NLM, HHS/ONC

Problems to Solve

- Networks currently use different CDMs (Sentinel, i2b2, OHDSI, PCORNet)
- Open, consensus-based standards may not be leveraged in these CDMs
- It is desirable to facilitate interoperability among these networks and reduce requirements for CIOs to accommodate all to accommodate research
- Federal agencies in the U.S. currently have different requirements for data 'submission'
- eSource data can improve efficiency and quality of clinical research, but it is currently quite disparate

Progress and Lessons

- ✓ Four CDMs mapped to BRIDG Model (Common Data Model Harmonization)
- ✓ BRIDG mappings registered by NCI and balloted through HL7
- ✓ Terminologies harmonized across data models (NCI EVS) and with CDEs, CDISC and HL7 FHIR
- ✓ Query for pharmacovigilance use case revealed that barriers were largely cultural, political and legal
- ✓ Mappings, harmonization products and lessons learned will be leveraged (along with FHIR) in the CDMH project Phase II

21st Century Cures Funding: Use Case testing by Mayo/Yale and Elligo Health Research with Data Partners

RDK Key Messages

- The technical ability to share meaningful data should be ‘platform-independent’; data standards enable this.
- Standards (used at the start of a research study) and eSource can create efficiencies in data sharing and research processes; they should be addressed in the planning stages.
- Standards and data models are most effective when they include appropriate metadata and are broadly adopted.
- Researchers should leverage existing robust/global standards and data models before creating new ones.
- If the above recommendations are followed, the barriers to data sharing are primarily legal, political and cultural.