JAPAN ACADEMIC WORKSHOP

Use of CDISC Standards at an Academic Medical Center: a year later

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Last Year: One Researcher's Opinion About Why Academics in the United States Haven't Widely Used CDISC Standards and Recent Policy That May Prompt Change

Presented by Meredith Nahm Zozus, PhD

Meet the Speaker

Meredith Nahm Zozus, PhD

Title: Professor, Division Chief and Director of Clinical Research Informatics

Organization: Joe R. and Teresa Lozano Long School of Medicine

Dr. Zozus started her career at Duke University where she served as the Director for the data center at the Duke Clinical Research Institute and the Associate Director for Clinical Research Informatics in the Duke Translational Medicine Institute for 18 years. Her research career has focused on data quality in health care and health-related research including collection and management of data for clinical studies, and assessment and use of Electronic Health Record (EHR) data in clinical studies. Dr. Zozus is currently leading the **A**n**C**illiary Studies to **E**valuate **R**eal-**W**orld **D**ata Quality (*ACE-RWD* Program) assessing FHIR® data from EHRs. She is a Professor and Division Chief and Director of Clinical Research Informatics at the Joe R. and Teresa Lozano Long School of Medicine at University of Texas Health Science Center at San Antonio (United States).

In addition to over 100 published articles, she has led the development of six national/international data standards, and recently published The Data Book, covering fundamental principles behind the collection and management of research data. Dr. Zozus served as the Founding Editor in Chief of the Good Clinical Data Management Practices (GCDMP) and the Journal of the Society for Clinical Data Management (JSCDM).

Disclaimer and Disclosures

The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.

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Brief recap of last year's initial presentation

Two new policies in the United States required data sharing:

- National Institutes of Health (NIH) data management and sharing policy and
- National Institute on Aging (NIH-NIA) required monthly recruitment reporting for funded clinical trials

In 2022, the EDC system used by most academic institutions in the country, REDCap, had just release CDASH forms to the library

We reviewed current CDISC use at my institution:

- ~800 ongoing Investigator Initiated Studies
- Only 3 of them use CDISC (CDASH) standards, all three were using the Demographics form only

We talked about why …

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We talked about why …

Industry

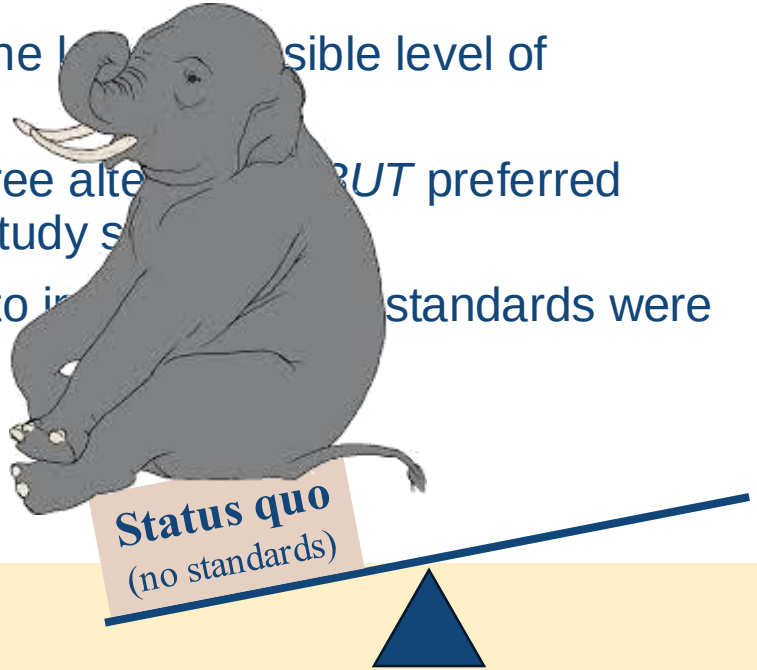
- Development programs for a compound with many similar studies (lots of chance for Return On Investment - ROI)
- Regulations in multiple regions require the standards
- Some software that leverages the standards (more chance for ROI)

Academia

- Pilot study + the real study
  (Little chance for ROI)
  (ROI accrues to those *other* than those who incurred cost)
- Standards historically not required
- Historically no software that leveraged the standards
- (mis-) Perception that very dollar spent on operations is a dollar that can't go toward statistical power (sample size)

The Research and the Results

- Whenever possible a researcher chose the l sible level of standards
- Researchers indicated preference for a free alte *BUT* preferred incurring cost over accepting a delay in study s
- Increased expenditure and time needed to i standards were seen as barriers to a study.



Conclusion

"Future studies should explore ways of creating mechanisms which decrease the time and cost associated with standardisation processes." (Cofiel et al. 2010)

Agenda

New use cases for CDISC standards in American academia

1. Sharing data from research funded with public money
2. Ongoing enrollment reporting to government funders (accountability for public money)
3. Desire for Registry Real-World Data (RDW) increasing
4. Other data that map

We will look at data for each use case.

Remember that research conclusion about decrease the time and cost associated with using standards ?

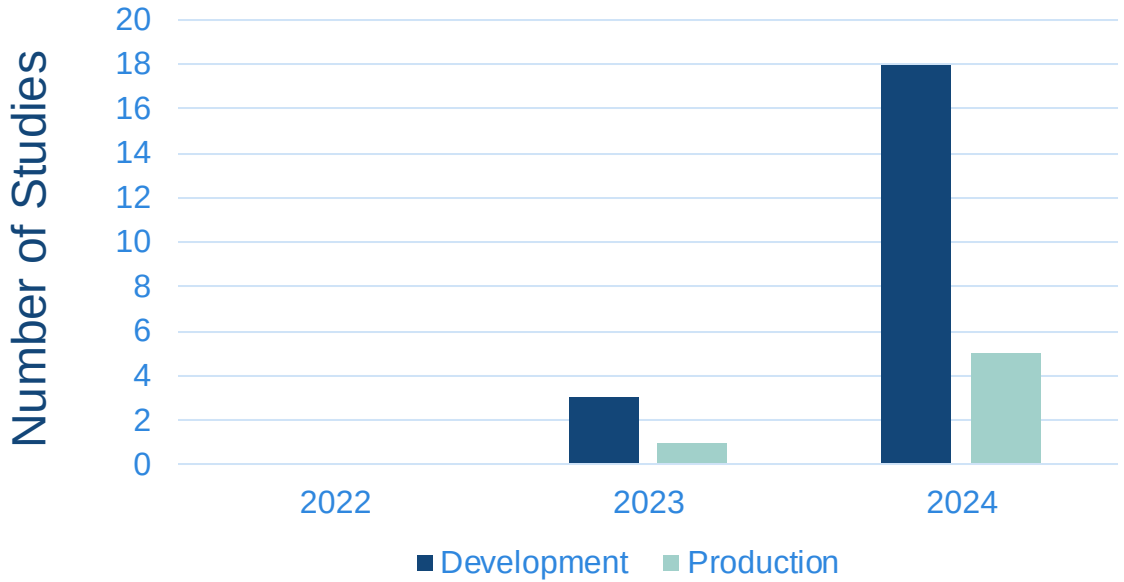
Journal of the Society for Clinical Data Management

Cheng AC, et al. Creating and Disseminating CDASH Harmonization Electronic Case Report Forms on the REDCap Shared Data Instrument Library. *Journal of the Society for Clinical Data Management*. 2022; 2(1): 7, pp.1–5. DOI: https://doi.org/10.47912/jscdm.172

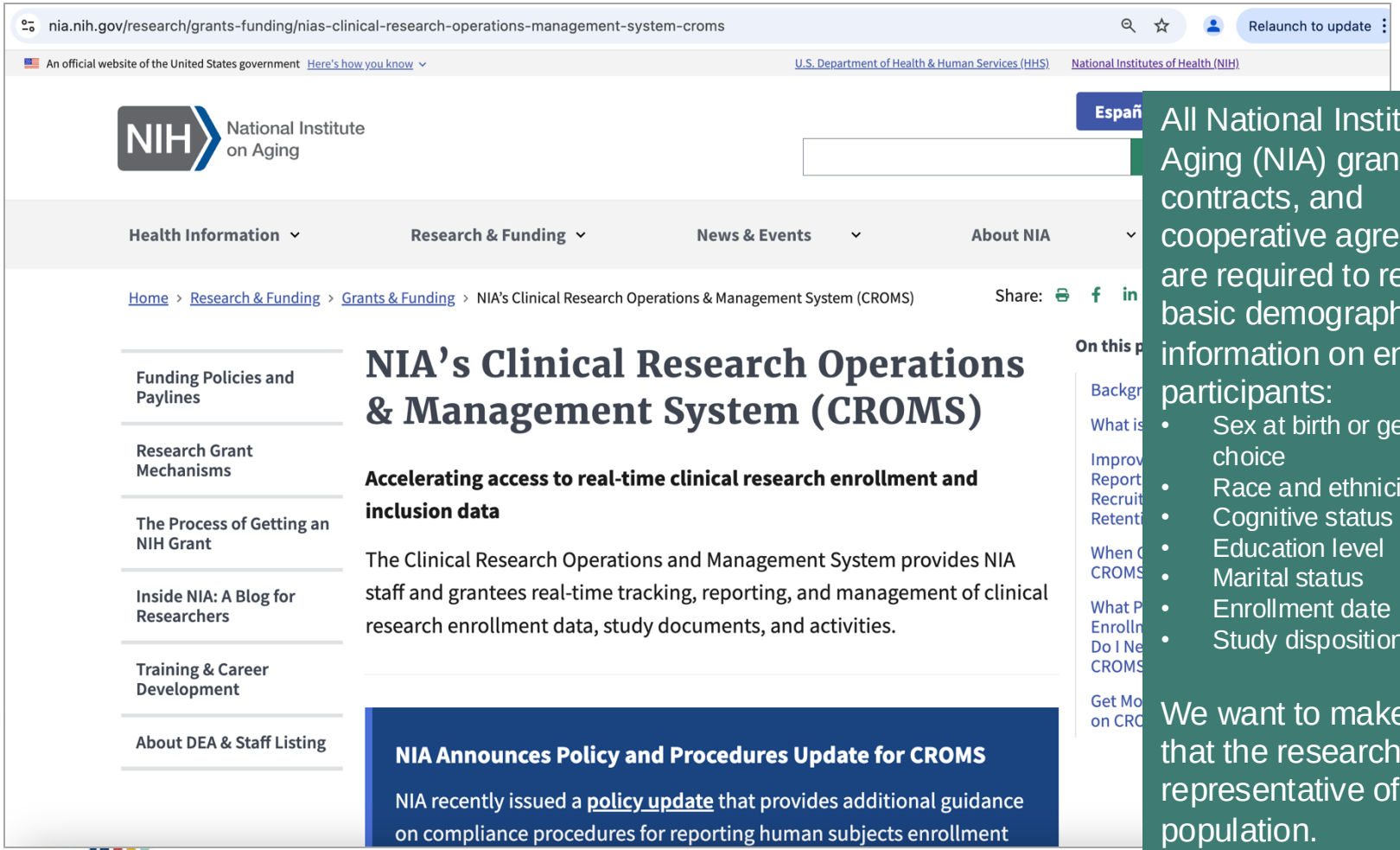
REDCap
Research Electronic Data Capture

- The REDCap Electronic Data Capture (EDC) system is used by 6890 institutions (the vast majority academic and other non-profits) in 155 countries around the world.
- In partnership with CDISC, the REDCap team recently translated metadata from 34 CDASH Foundational eCRFs and 20 CDASH Crohn's Disease eCRFs into REDCap eCRF metadata.
- These instruments are now available in the REDCap Shared Data Instrument Library for use.
- Researchers can import the standardized eCRFs directly into their REDCap projects for immediate use in clinical trial data collection.

Studies at My Institution Using the REDCap CDASH Modules



Forms Used:
Adverse Events
Concomitant medications
Demographics
Disposition
Medical history
Procedures
Protocol violations
Vital signs



All National Institute on Aging (NIA) grants, contracts, and cooperative agreements are required to report basic demographic information on enrolled participants:

- Sex at birth or gender choice
- Race and ethnicity
- Cognitive status
- Education level
- Marital status
- Enrollment date
- Study disposition

We want to make sure that the research is representative of the population.

Registry RWD and SDTM

	Number of Data Elements	Mapping rate after adjudication n (%)	Mapped to SUPPQUAL Datasets
Alzheimer's Uniform Data Set (UDS)*	837	814 (97%)	–
Frontotemporal Dementias (FTD)*	729	682 (94%)	–
Lewy Body Dementias (LBD)*	581	581 (100%)	–
North American Association of Central Cancer Registries (NAACCR Registry)	780	780 (100%)	320 (41%)
American Burn Association, Burn Care Quality Program (BCQP Registry)*	105	105 (100%)	7 (6.7%)

*Unpublished data from papers in review.

In collaboration with other organizations, we recently evaluated data quality of prospectively collected EHR data.

- Two oncology studies, conducted in the United States

  using Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR®) based EHR-to-EDC

- One oncology study conducted outside the U.S. using non-FHIR® based EHR-to-EDC

All three studies used an adapted **A**n**C**illary Studies to **E**valuate EHR and Claims **R**eal-**W**orld **D**ata Quality (*ACE-RWD*) program data quality assessment protocol.

Results

These data also map to the CDISC SDTM

Fields Evaluated	Traditional EDC (95% CI)		Extracted EHR Data (95% CI)
1,067*	1.22% (0.65%, 2.07%)	*vs.*	0.00% (0.00%, 0.35%)
1,878^	5.26% (4.17%, 6.61%)	*vs.*	0.00% (0.00%, 0.34%)

*Results published August 2024 at Medical Informatics Europe (MIE).
^Preliminary results presented at September 2024 ay DPHARM and CRAACO. The study is ongoing.

NOTE: non-overlapping 95% confidence intervals between data collected via traditional EDC and EHR-extracted data in both cases.

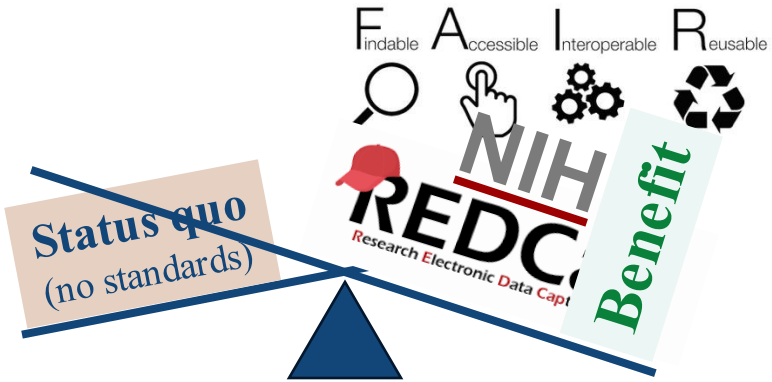
Main limitation: These are observational studies in which the traditional EDC data were captured first. Though there was significant delay between the two data captures.

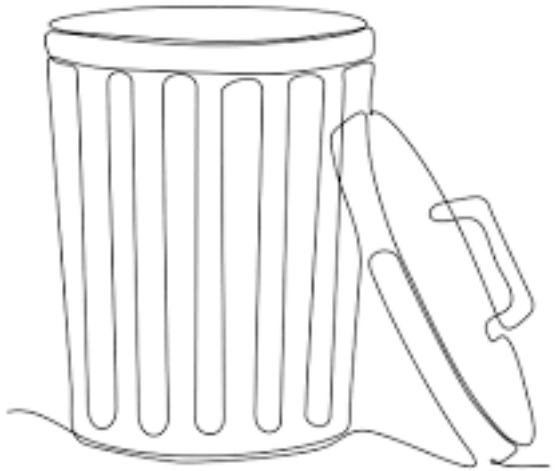
While more studies, sites, and therapeutic areas need to be evaluated, the data from two different EHR-to-EDC platforms reveal a significant difference.

The *ACE-RWD* program is ongoing with two years left. ***We'd Love a Japanese study !!***

Garza MY, Spencer C, Hamidi M, Liss M, Bikkanuri M, Syed M, Yadav S, Bhardwaj G, Chahal APS, Goodman K, Choi BY, Eisenstein EL, Zozus M. Comparing the Accuracy of Traditional vs. FHIR®-Based Extraction of Electronic Health Record Data for Two Clinical Trials. Stud Health Technol Inform. 2024 Aug 22;316:1368-1372. doi: 10.3233/SHTI240666. PMID: 39176635

If we are not yet tipping the balance, we will keep trying!





Thank You!

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