
WHAT'S DIFFERENT ABOUT CLINICAL DATA?

AN RDAP TOWN HALL PANEL PRESENTATION

NINA EXNER, NEXNER@VCU.EDU,

RESEARCH DATA LIBRARIAN, VIRGINIA COMMONWEALTH UNIVERSITY LIBRARIES

LORI D SLOANE, LSLOANE@SALUD.UNM.EDU,

DATA MANAGER: HS LIBRARY AND INFORMATICS CTR., UNIVERSITY OF NEW MEXICO

CHRISTY E NAVARRO, CENAVARRO@UCDAVIS.EDU,

HEALTH LIBRARY INFORMATICIST, UC DAVIS BLAISDELL MEDICAL LIBRARY

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PRESENTERS IN ORDER OF PRESENTATION

Nina Exner, PhD

- Research data librarian
- Virginia Commonwealth University
- Serving data needs at both the medical and core campuses



Nina Exner (she/her pronouns)

Christy E. Navarro

- Health library informaticist
- UC Davis Blaisdell Medical Library
- Helps students, faculty and staff navigate the research data lifecycle, health data resources, and software tools for research and beyond



Lori D. Sloane

- Data manager
- University of New Mexico Health Sciences Library and Informatics Center
- Supports Health Sciences faculty, staff and students with research data management.



OUTLINE

- Nina: Terminology and overview of clinical data concepts
- Christy: Processes in clinical data
- Christy: Resources for working with clinical data
- Lori: Key infrastructure - REDCap

Terminology and Key Concepts in Clinical Research Data

Nina Exner, PhD

Research Data Librarian, [Virginia Commonwealth University Libraries](#)

nexner@vcu.edu

Just an overview

- Clinical data is its own complicated specialty
- The whole clinical research setting is very different than the nonclinical setting
 - Particularly at institutions with hospitals
- We're just giving a sense of what your roles might be and how to work with clinical research teams

What do we mean by “clinical” data?

- Clinical data is data that is collected mainly in clinical treatment settings
 - Clinical trials
 - Patient treatment (doctor’s offices are “the clinic”)
 - Health surveillance data from clinics and hospitals
 - Health studies collecting biobehavioral data on medical conditions

Clinical Trials

- NIH definition is about health interventions
 - Human participants
 - Prospectively assigned to a study arm
 - To evaluate the effect of the intervention on the participants
 - Evaluating a health-related biomedical or behavioral outcome
- FDA definition focuses on their regulatory roles
 - Drugs, pharmaceuticals, and biologic agents
 - Medical devices

Key role of regulation

- Highly regulated
 - Most clinical research is subject to at least human protections, HIPPA, and clinical trial regulations
 - Follow the money:
 - Additional regulations come into it if it is government funded
 - Alternatively, industry sponsors may fund clinical research at academic medical centers. These come with contracts about data.
- Highly private, often sensitive data

Privacy scrutiny

- Just because PIs have access to data, doesn't mean they can do research on it
- Typically expedited or full board IRB review
- Safe harbor de-identification by removing the HIPPA identifiers is a *minimum* expectation
 - Deidentified is not anonymized or anonymous
 - If deductive disclosure is likely, Safe Harbor probably isn't enough without a very clear consent for the risks



What do you
mean I can't
research it?
I have it right
here!

Team-based plus “core” supports

- PIs frequently are not solo researchers
 - Separate data collectors, or mediated data extraction
 - Clinical Research Administrators in their department
 - Biostatisticians, statisticians, or other analysts
- If they are funded, they also often chargeback (or recharge) parts of the study process to core services
- If the institution is too small for these services, the researcher probably trained somewhere larger

Make it so, number one!



Example

A nursing faculty member is studying diabetes disparities and wellness care across the lifespan.

Clinical data might include:

- Records from a hospital or community care center
- Pretest/posttest on attitudes or nutrition affected by health education sessions
- Samples, especially any collected in medical offices

Different culture of data

- Clinical setting has a totally different vibe
- Data management, data services, and data curation may all emphasize some things much more and skip other things compared to core campus data librarians
- Why should you care?
 - Talking to faculty with clinical or semi-clinical backgrounds
 - Working with groups (e.g. the NIH) that think clinically



TRANSITION TO CHRISTY

