OFFICE OF CLINICAL TRIAL DEVELOPMENT AND IMPLEMENTATION (AND RELATED RESOURCES)

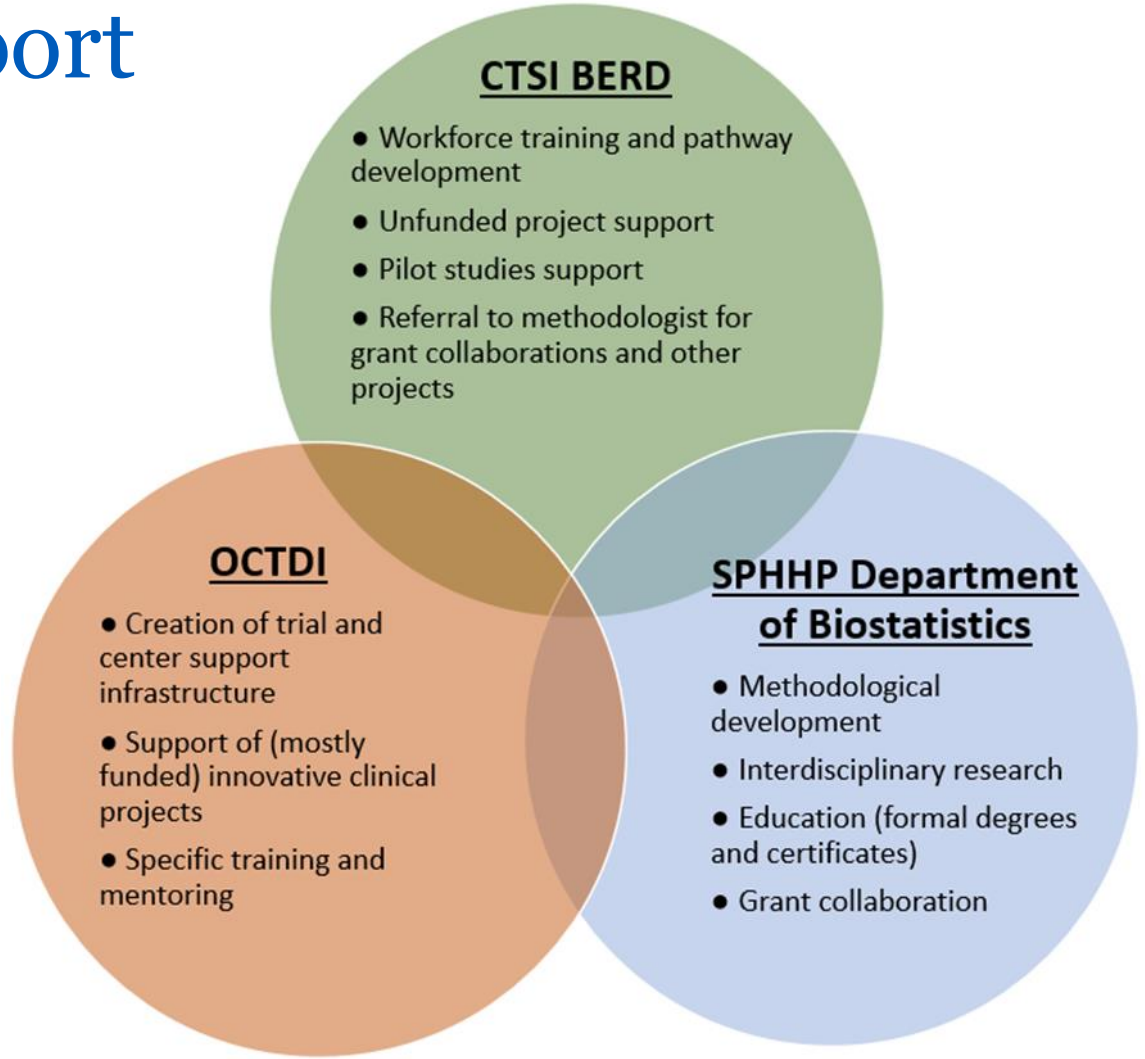
Gregory E. Wilding, Ph.D.
Professor, Department of Biostatistics
Director, OCTDI
Director, CTSI BERD Core

University at Buffalo The State University of New York

Statistical Expertise and Support Units at UB

The statistical expertise at UB is vast!

- UB Department of Biostatistics, with faculty affiliated with
  - All UB Health Science schools
  - UB Institute for Artificial Intelligence and Data Science
- UB Clinical and Translational Science (CTSI) Biostatistics, Epidemiology, and Research Design (BERD) Core, which spans the
  - Departments of Biostatistics and Epidemiology & Environmental Health
  - Roswell Park Department of Biostatistics and Bioinformatics
- UB Office of Clinical Trial Development and Implementation (OCTDI)
  - Supported and housed with Office of the Vice President for Health Sciences
  - Integrated statistical and data management support for trials



The UB Department of Biostatistics, VPHS, SPHHP, and BERD faculty are committed to supporting the growth of research endeavors

CTSI Biostatistics, Epidemiology, and Research Design (BERD) Core

The BERD provides clinical and translational researchers access to a coordinated and collaborative resource for study design and statistical analysis needed to further advance scientific initiatives at all levels of clinical and translational research

Diverse Expertise

- All stages of translational research, T1-T4
- From pilot to definitive studies
- Cell line studies, animal studies, clinical studies
- Simple to complex data structures (ex., -omic)

Team Science

- Members of the BERD have a wealth of practical experience working in the Team Science context
- Working with other data analysts / data scientists is not uncommon

BERD Core Aim

Aim 1. Support novel interdisciplinary research through consultation and collaboration to advance clinical and translational science and research, and establish support systems required for impactful large-scale initiatives.

Aim 2. Provide mentoring and career pathway development in biostatistics, epidemiology, and research design, to BTC researchers and trainees, expand educational components to the SUNY system, and offer innovative programs to expand and increase diversity in the pool of future data scientists and biostatisticians.

BERD Core Personnel

Gregory E. Wilding, PhD, BERD Core Director, Professor, Department of Biostatistics

Jeffrey Miecznikowski, PhD, BERD Core Co-Director, Professor, Department of Biostatistics

Saptarshi Chakraborty, PhD, Assistant Professor, Department of Biostatistics

Yi Xiong, PhD, Head of the BERD Consulting Lab, Assistant Professor, Department of Biostatistics

Michael J. LaMonte, PhD, MPH, Research Professor, Epidemiology and Environmental Health

Austin Miller, PhD, Clinical Trial Development Division, Department of Biostatistics and Bioinformatics, Roswell Park

Research Assistants:

Jingtao Zhu, MA
Zhaoqi Zhang, MA








BERD scientists have

- Formal and comprehensive training (i.e., advanced degrees) in BERD appropriate fields (e.g., Statistics, Biostatistics, and Epidemiology)
- A wealth of diverse and practical experience (e.g., > 600 combined publications referenced on pubmed)

BERD Core Activities: Interdisciplinary Science

The BERD serves a critical role in unfunded research efforts at UB!

BERD Consulting Lab

BERD Consulting Lab offers limited free consulting services including assistance with study design, hypothesis formulation, sample-size and power calculations, statistical analyses, preparation of abstracts and manuscripts for publication, and statistical review.

Largely support by BERD research assistants

Research on a Napkin

CTSA Pilot Program applicants invited to submit full proposals are offer feedback from BERD Core members during a 30-minute session

Interdisciplinary Grant Development

BERD faculty assist in the planning of extramural grant applications in the role of Co-I or Co-PI to sponsors

Assistance with identification of quantitative expertise

BERD Core Activities: Training and Mentoring

BERD faculty provide user-friendly training in statistical and epidemiologic principles tailored to the changing needs of researchers, staff, and students

	Target Audience	Initiative
Core competencies	Clinical and translational research workforce	• BERD Workshop Series • Degree/certificate Programs
Profession development and skill refinement	Graduate students	• Mentorship • Internship opportunities
Pathway development	Undergraduate students	• BERD Winter Institute • Internship opportunities
	High school students	• BERD High School Poster Contest

In order to be responsive to the heterogeneous backgrounds and learning styles of our workforce, we will deliver a vast array of educational products in cooperation with local partners!

Many activities are provided SUNY-wide for boarder impact!

Office of Clinical Trial Development and Implementation (OCTDI)

The OCTDI serves as a centralized hub for interdisciplinary clinical trial research collaboration for UB investigators and our regional and industry partners support by experience personnel

- Funded by and existing within the **Vice President for Health Sciences Office**, with a physical location on UB South campus

Mission: Improve the planning and conduct of clinical trials by providing high quality statistical and data management support and workforce training.

Goals:

1. Support clinical trial efforts by establishing the statistical and data management support systems required for the proper planning, oversight, and implementation of high-level clinical trials and clinical trial-oriented research centers
2. Provide protocol development, study objective formation, study design, data management, interim and final statistical analysis, and reporting support to specific investigators initiated and industry-sponsored clinical trials projects
3. Provide skill-set building opportunities to novice and more advanced trialists in a variety of formats

The OCTDI will better position UB to obtain external funding and enhance the reputation of UB and the SUNY system

OCTDI Personnel

Gregory E. Wilding, PhD, OCTDI Director, Professor, Department of Biostatistics

- 25+ year in clinical trial research within academia and industry
- Involved in the planning/analysis 200+ trials, across many scientific area and phases

Austin Glick, MPH, Clinical Data Manager

- 5+ years of experience in clinical trial research working at the industry level
- Direct experience working on all phases of large, multicenter, NIH funded clinical trials across many scientific areas

Jingtao Zhu, MA, Statistical Programmer

- Graduate Research Assistant with expertise in trial design and analysis

TBD, Senior Statistician (hire expected by the end of September 2024)

OCTDI personnel

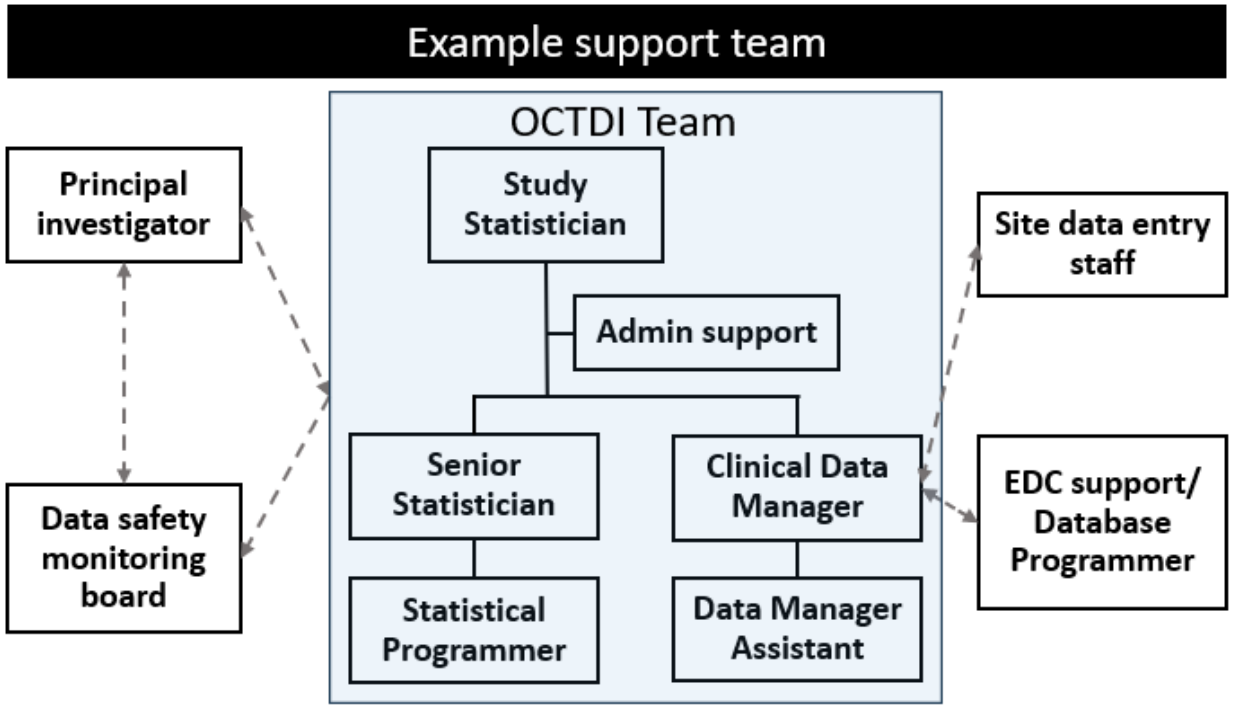
- Have immense experience
- Operate according to the highest statistical and data management standards

Some key University partners

- Department of Biostatistics (Faculty serving the role of Study Statistician)
- CTSI (Team building and resource access)
- Research Information Systems (REDCap and database programming support)
- Clinical Research Office

OCTDI Activities: Trial support

OCTDI infrastructure allows for professional and efficient trial conduct with timely reporting



Example study tasks

Stage	Statistical support	Data management support
Design	• Study design (sample size, randomization scheme selection, outcome selection, etc.) • Design evaluation via simulation • Grant application/protocol development assistance	• Data management plan (DMP) development • Design data collection instruments (CRFs) • Define the clinical database structure
Start-up	• Randomization procedure development and validation • Statistical analysis plan (SAP) development and review • Specialized software development • Prepare DSMB documentation and data reporting format	• Configure and test CRFs and the electronic data capture system (EDC) • Train personnel on data entry and management • Establish review, monitoring, and quality assurance processes for data quality and validation
Execution	• Statistical oversight • Accrual modelling • Tables, Figures and Listing (TFLs) programming • Interim analyses • DSMB analysis and reporting • Regulatory reporting assistance	• Post-production changes • Data review and cleaning • Issue and resolve queries • Prepare the data for DSMB review • Report generation • Data entry • Maintaining audit readiness
Close-out	• Statistical results production and interpretation • Clinical study report (CRS) production • Publication preparation • Clinicaltrials.gov reporting assistance	• Resolve all queries and outstanding data issues • Final data cleaning, database lock, and archive • Create datasets and documentation for sharing

* For grant-support projects where the OCTDI personnel are written into the budget, limited design stage tasks are covered in-kind.

**All tasks will proceed based on established SOPs and workflows

OCTDI Activities: Training

Clinical Trial Minicourse

Sponsored by:

- *UB OCTDI*
- *UB CTSI BERD Core*
- *UB CTSI Workforce Development Core*

Goal: Provide a series of online workshops in Fall 2024 designed to turn attendees into more educated consumers of statistics, epidemiology, and research design methodology as applied to clinical trials.

Target audience: SUNY-based personnel currently or planning to perform clinical trial research activities, including, but not limited to new and established researchers within academia and industry

Part 1: Introduction to clinical trials (Fall 2024, Tuesdays 4-6)

Date	Title	Instructor
10/22	Clinical trial basics I	LaMonte
	Clinical trial basics II	LaMonte
11/12	Clinical trial outcomes and analysis concepts I	Miller
	Clinical trial outcomes and analysis concepts II	Miller
11/19	Randomization techniques	Wilding
	Designing pilot trials	LaMonte
11/26	Clinical trial data management I	Glick
	Clinical trial data management II	Glick

Part 2: Advanced clinical trials (Spring 2025)

Title	Instructor
Parallel group design I	Wilding
Parallel group design II	Wilding
Cross-over trials	Wilding
Stepped-wedge designs	Markatou
Pragmatic trials	Landsittel
Adaptive designs I	Wilding
Adaptive designs II	Sill
Trials based on time-to-event outcomes	Yu

Working with the OCTDI and Contact

- Although the OCTDI focus is collaboration on grant funded large trials and trial-based centers, it may be seen as a contact point for all trial-based research
- Request for OCTDI collaborations should include
  - Requests for applications (RFA) be responded to
  - Timeline for submission
  - Tentative aims, outcomes, and eligibility criteria
  - Information on feasibility constraint (maximum number of sites, patient pool size, etc.)
- As demand is already high and is expected to increase, please contact 2 months in advance
- Contact info: **Gregory E. Wilding, PhD**, Professor and OCTDI/BERD Director, gwilding@buffalo.edu
  - For BERD service requests, use the CTSI portal
- Other key contact for support: **Douglas Landsittel, PhD**, Professor and Chair, Department of Biostatistics, dplansit@buffalo.edu
  - Can assist in finding potential collaborators
  - Working on other plans to expand research collaborations at UB through the creation of centralized more resources

THANK YOU

Contact: Gregory E. Wilding, Ph.D.
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