CTSA BERD Program
Manisha Desai, Associate Dean of Research
Biostatistics Epidemiology Research Design (BERD) Program

• Each institution with a Clinical and Translational Science Award (CTSA; PI: Dr. Ruth O’Hara) has a BERD

• The mission of BERD Programs are to provide infrastructural support on study design, statistical analysis planning and data management guidance
Goal

Provide the necessary biostatistics and data science infrastructure to clinical and translational investigators in order to facilitate translational research.

Aims

1. Engage investigators in the design of studies and data management and analytic strategies.

   Educate and mentor investigators in knowledge and best practices of biostatistical principles and educate and mentor BERD members in modern data science methods and team science.

2. Develop new tools and establish best practices relevant to facilitate our engagement with the research community.
The BERD Team

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BERD’s Data Studios

- Panel of statistical experts advise on study design
- Offered 4 times per month for 9-month academic year
- Engages approximately 20 investigators per year
- Open to all investigators at no cost to them
New Initiative for All Junior Faculty
Data Science Navigation
Data Science Navigation
Proposal development
Design & analysis planning
Advice on team make-up and expertise

Weekly Clinic
Consistent & regular access to quantitative expertise

Enhanced BERD for Junior Faculty
• Pilot launched 11/1/2021
• Up to 100 hours subsidized by CTSA and SAD-R Office
• No cost to investigator
Details of New Initiative for Junior Faculty Data Science Navigation

• All SOM junior investigators eligible (5 projects/PI annually)
• 4 hours (subsidized by CTSA) + 16 hours (subsidized by SADR)
• **Pre-award:** 4 hours = high level advice on study design; up to 20 hours = proposal developed with statistical section; *We will advise on appropriate team structure and possible data science collaborators although BERD members may not be available for inclusion*
• **Non-sponsored:** 4 hours = high level advice on study design; up to 20 hours = Statistical Analysis Plan, Data Management Plan
• Effort devoted to educate on role of statistics and data science; on appropriate team make up and expertise and as mechanism to partnership
Data Science Navigation

- Study Design
- Full Proposal Development
- Education on role of data science
- Guidance on team make up
- Analysis and data management planning
- New Clinic offered weekly

Enhanced BERD

- Structure and access to Data Studios remain the same
- Data Science Navigation is geared toward junior faculty
  - Up to 100 hours subsidized by CTSA and SAD-R Office
  - No cost to investigator
For more information on BERD please visit
Questions?
OnCore

1. What is OnCore?

2. OnCore Enhancement Initiatives
What is OnCore?

The OnCore Enterprise Research system, or OnCore, is a vendor-supported Clinical Trials Management System (CTMS). OnCore benefits Principal Investigators, research teams, departments, administrators, and staff members involved in financial and regulatory functions to:

- **Effectively manage studies** – Gives research staff a single place for managing protocols and participants, and accessing up-to-date information.
- **Manage financials** – Price studies, track budgets, and generate financial management reports.
- **Streamline operations** – Single system that works seamlessly across the enterprise and reduces the need for disparate data environments and software infrastructures.
- **Simplify data management** – Collect, house, and track protocol, study, administrative, and financial data.
- **Create Custom reporting** – Generate reports that can support decision-making for individuals such as PIs, administrative leaders, and finance staff. Reports can be created for accrual, financials, participant safety, staff workload, and a wide range of other metrics.
OnCore Bulk Studies Registration (Non-Cancer)

**Objective:** Complete bulk registration of outstanding studies and all new studies registered with the IRB utilizing Application Programming Interfaces (API) via Advarra and OnCore Integration Services (OIS)

**Stakeholder Impact:** Reduce duplicate effort for registering a study; save days of coordinator time by eliminating individual study registration requests through the OnCore portal.

**Status:**
- Total Studies Already in OnCore - 1,881
- Total Studies Registered using API this month - 334
- Total to be entered - 775

**Completion:** August 2022 - 100% of all eligible studies entered into OnCore.
OnCore and REDCap Integration  
SAD-R & TDS Joint Initiative

**Objective:** Link REDCap and OnCore participant management systems.

- **Phase 1** - Participants registered for a study in REDCap will be linked and registered in OnCore, eliminating double entry into two different applications.

- **Phase 2** - Enable bidirectional linkage between REDCap and OnCore, and building a user interface that compares side by side the list of study participants in OnCore with the list of study participants in REDCap.

**Stakeholder Impact:** Studies registered in OnCore will contain up-to-date enrollment data. Participants’ data will be validated once only, when entered in REDCap. And with Phase 2 completed, we can now highlight any discrepancies between the two datasets on two separate systems in one place.

**Completion:** June 30, 2022 – Phase 1 & 2 completion.
Single Sign-On (SSO) for OnCore Access

**Objective:** To access OnCore Home Page via SUNet ID (SSO).

**Stakeholder Impact:** Eliminate the need to enter credentials when accessing OnCore; eliminate need to log in when timed out from OnCore; and eliminate “User Account Locked” messages.

**Completion** - April 30, 2022.
Next Steps and Discussion
COVID-19 Fund to Retain Early-Career Scientists Program
COVID-19 Fund to Retain Early-Career Scientists Program

- The overall goal of the program is to provide supplemental “extra hands” research funding to early-career faculty whose research productivity has been impacted by COVID-related caregiving responsibilities.

- Funding provided by the Doris Duke Foundation, Rita Allen Foundation, and Stanford School of Medicine

- Awardees will also receive mentoring, career coaching, professional development, grant development, networking resources, and biostatistical support.

- Program will complement and strengthen other initiatives designed to support early-career faculty at Stanford.
Eligibility

- School of Medicine assistant professors and new associate professors (within their first year of appointment) with UTL, UML, NTLR, or CE appointments.

- Compelling need for “extra hands” supplements that would boost productivity in light of increased pandemic-related caregiving.

- Must have an extant intra or extramural career development award or research project grant with annual direct costs sufficient to provide both research and salary support.
Funding

- Research supplements will be between $35,000-$50,000 depending on need and will have a duration of one year.
- Funding must be used to support “extra hands” (Admin Support, Research Associate/Technician, Clinical Research Coordinator effort), grant-writing support, or buy out of required clinical time so that more time can be spent on research.
- Because recipients are expected to have a main research grant, research costs are not allowable.
Application Requirements

- Research description (3 pages)
- Description of need (1 page)
- NIH biosketch
- Current and pending support
- Letter of support from Department Chair or Institute Director
Timeline

- RFA will be distributed soon!
- Applications due in late March
- Awards selection will be announced in April
Program Contacts

Program Director: Dr. Ruth O’Hara

Program Co-Director: Dr. Linda Boxer

Program Coordinator: Pooneh Fouladi

Questions? Please contact Pooneh Fouladi (pooneh.fouladi@stanford.edu)