

Name Thurston Quarterly ARRA Report (1/1/10 – 3/31/10)

Instructions Complete all fields below. If all required fields are not satisfactorily filled in you will be required to complete another survey.

Question 1 PI name (last name, first name): Pearson, Thomas

Question 2 Prime recipient award number: 3UL1RR024160-04S2

Question 3 QUARTERLY ACTIVITY UPDATE: Please provide an update to the project status, this is exclusive of the award completeness and should update employment, recruiting, purchasing, and or any and all pre-science processes.

In October of 2009, the University of Rochester, in collaboration with Vanderbilt University, UC Davis, and UCSF, received an administrative supplement from the NCCR to continue work begun by UCSF (in collaboration with the University of Rochester, Vanderbilt University, and UC Davis), to build a useful resource for clinical and translational researchers and consultants. In collaboration with members of the national Biostatistics, Epidemiology, Research Design (BERD) Online Resources and Education task force, we have subsequently made significant progress addressing the defined specific aims and fostering collaboration within the national consortia. Progress for this quarter is outlined by the specific aims in the grant application:

- 1. Aim 1: To continue generating site content in biostatistics, research design and epidemiology topics and find a sustainable home for the CTSpedia.**
 - Administrative update: Mary Banach received her appointment to UC Davis as program manager for CTSpedia. UC Davis is working on a logistical plan for interns and other support personnel.
 - Technical support and site hosting: Vanderbilt completed the move of the CTSpedia from UCSF. There were a number of unusual programming problems discovered in the move. All of the problems that affect day to day use of the CTSpedia have been addressed. A new registration form, capturing institutional affiliation, type of institution, and primary expertise, was uploaded and is working well. With the new registration form all spam registrations have ceased.
 - At Rochester the three macros or functions that were ready or almost ready to be uploaded in the first quarter (but could not be uploaded due to CTSpedia problems) were uploaded. These macros are
 - 1) SAS macro “EFDPowlongitud”: power analysis for nested and longitudinal continuous data – computes detectable effect size for a pre-specified power or effect size between two treatment conditions in a longitudinal setting, assuming equal sample sizes but unequal standard deviations.
 - 2) SAS macro: power analysis for longitudinal binary data – computes detectable effect size for a pre-specified power or effect size between two treatment

conditions in a longitudinal setting, assuming equal group sizes.

3) R function "summarize": displays a concise summary of variables in a dataframe, where the user can show results on the screen, or save in a plain text or LaTeX file.

- At Rochester the following new macros were written and uploaded:
 - 1) SAS macro "LSMPlotMIXED": computes and plots covariate-adjusted least squares means of two groups over time from models fit using proc mixed, where the user can choose any of the available working correlation matrices and methods of inference (ML or REML).
 - 2) SAS macro "LSMPlotGEE": computes and plots covariate-adjusted least squares means to compare two groups over time from models fit using proc genmod, where the response can be continuous or binary, and the user can choose any of the available working correlation matrices.
 - 3) SAS macro "ROCcutoff": finds a cutoff for a continuous predictor which maximizes the linear combination of specificity and sensitivity when the response variable is binary, and fit a final logistic regression using the resulting cutoff.

 - A new Help Guide for the Statistical Tools section is being designed by the Rochester contributors to the CTSpedia.
 - UC Davis added a new section to the Articles – Mouse Studies providing case study materials for sample size planning and study design issues. The site was presented to the FDA/DIA Computational Science Meeting and well-received by the audience.
 - With the assistance of the CTSpedia administration the ResearchEthics Web (Dr. Alex Kon and Debi Schilling, both at UC Davis) are working on restructuring the presentation of the materials and adding more CTSA site input.
 - With the help of Knut Wittkowski (Rockefeller University) we are working on a way to present the biographical materials of all CTSpedia collaborators. Our intention is to not only include clinical research and biostatistical papers but also other clinical research activities, such as FDA submissions.
 - We are looking at re-design issues throughout the CTSpedia for the best presentation of the materials.
- 2. Aim 2: To pilot a collection of workshop and short-course materials and slides related to statistical consulting and basic statistical concepts and tools.**
- On Survey 1, we collected 94 names of individuals who teach biostatistics courses for non-statisticians. Fourteen individuals sent in their course materials and/or syllabi. These courses spanned a large array of formats and audiences from small workshops for practicing professionals to entire semester courses.
 - Rather than send out Survey 2 at this time, we elected to start by uploading all the course materials from the 14 individuals providing their materials into a new web on CTSpedia called Educational Materials.

- We also formed a working group of individuals who are interested in Educational Materials. They will meet at the April BERD Meeting. The primary focus of this group will be to discuss how to provide all CTSA sites with good educational materials and what are the best formats for presenting these materials: online, face to face, etc.

3. Other collaborations:

- FDA Work with CDER: Mat Soukup and Joan Buonconsejo from the FDA made arrangements for us to share the CTSpedia and our view of collaborative work efforts at the DIA Meetings in March, April, and June. Mat Soukup and Laurel Beckett presented at the March DIA Meeting. The participants were very impressed and will be registering and using the CTSpedia. There is a possibility of much wider use of CTSpedia within FDA, allowing sharing of biostatistical and clinical trials methodology, teaching materials, and software among FDA and academic biostatisticians.

Question 4 Provide an evaluation as to the completeness of the project. (If a subaward has been issued, this must include the status of the prime and subaward.)

Less than 50% complete

Question 5 SUBAWARD: Is any amount of this award passed through to a Subrecipient? If you answer “Yes” to this question, please answer the next question. If you answer “No”, please proceed to Question 7. Yes

Question 6 SUBAWARD: Legal Name of the Subrecipient (ie: Rochester Institute of Technology)

University of California, Davis
Vanderbilt University

Question 7 JOB CREATION: List the individuals performing effort on this award. (Last Name, First Name; Last Name2, First Name2; etc...)

Banach, Mary (UC DAVIS)

Question 8 VENDOR: Have you purchased anything for this project from a vendor individually greater than or equal to \$25,000? No

Question 9 VENDOR: Do you anticipate purchasing anything for this project from a vendor greater than or equal to \$25,000? No

Question 10 VENDOR: If you answered “Yes” to either Question 8 or Question 9, please provide the name of the vendor. No