Name   Thurston Quarterly ARRA Report (12/31/10 – 3/31/11)

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

<mark>**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.**</mark>

In October of 2009, the University of Rochester, in collaboration with Vanderbilt University, UC Davis, and UCSF, received an administrative supplement from the NCRR 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: We have submitted a one year supplement with UC Davis taking the lead. NIH is awaiting the permanent budget from the federal government before making the awards. We are also talking to the FDA and pharmaceutical companies about administrative funding.
- Redesign of the CTSpedia: The redesign of the CTSpedia continues All the webs (Educational Materials, BERD Consortia, Statistical Graphics), except Research Ethics, are now included in the CTSpedia web. This makes searching and hyperlinking far more effective. In some of our earlier work we did not use forms to input the data and then manually attempted to hyperlink all the research topics and articles. We are in the process of bringing all materials on the CTSpedia into forms and then creating user reports. We are also in the process of determining the best way to provide evaluations for the CTSpedia. For the statistical graphics work we are using a rating plugin on each topic page and will determine whether this is the best approach to evaluate other pages on the CTSpedia.
- Reproducible Research: Standards and Definitions, Papers, and Methodology were added to this area. Activity continues in this area with CTSA sites, non-

CTSA sites, and industry participating in developing materials. Frank Harrell and Aniko Szabo have provided materials as well as examples of SAS weave. R2wd, and other methodology.

- Technical support and site hosting: Vanderbilt continues to support the project. The major focus this quarter was on registration issues; trash removal, which has accumulated since the beginning of the project making search and documentation run slowly; uploading the Vote Plugin and the Rating Contribution Plugin for collecting evaluation materials; and keeping up on general maintenance and support on the site..

Rochester and UCSF biostatisticians continue work on the Statistical Tools section of the CTSpedia. Over 100 updates to the Statistical Tools were made this quarter. As stated above, we are working on improving the forms and labeling the attachments for easy access and documentation. We received a thank you note for assistance on the AUCGEE macro from a biostatistician from Ecuador.

The following Statistical Tools were added since the previous quarterly report:

- R-script: ZIP.r: This fits a zero-inflated Poisson (ZIP) model to longitudinal data which contains measurements pre and post assessment, with possible missing values at the post assessment time point. The code uses a set of weighted generalized estimating equations to give distribution-free inference for the model parameters. Output includes estimates and standard errors for both the logistic and Poisson regression parts of the ZIP model.

- R-script: Kappa.u: This calculates kappa statistics (based on U-statistics) for comparing ratings from two raters within a longitudinal data setting.

The following Statistical Tools were updated since the previous quarterly report:

- Sas: MWW-longitudinal
- Sas: Effect Size Mixed
- Sas: Effect Size Longitudinal
- Sas: Count Regression SAS Macro
- Sas: Linear Regression SAS Macro
- There are also further examples of R, Sas, and Stata coding under Reproducible Research, Statistical Graphics, and Educational 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.**

- The BERD Education Working Group has defined the following goals:
Education working group. This working group was formed in spring 2010, and is a subgroup of the BERD Online Resources Task Force. Our focus is on creating,

organizing, linking, and managing educational materials primarily housed on CTSpedia.

As stated above we have moved all the Educational Materials to the CTSpedia web and are making sure that all the forms are updated. We are adding drop-down menus and keyword links to make searches easier. New this quarter:

- Dr. Sally Thurston's LaTeX slides on Basic Statistics for Virologists
- Links to The University of Washington Center on Outcomes Research in Rehabilitation from Dr. Laura Lee
- Links to 16 Videos from the Medical College of Wisconsin Biostatistics Center
- Updates on Dr. Greg Stoddard's Stata textbook.
- Work on study of the residency project materials to improve clinical research training programs for residents.

We are making a concerted effort to bring together new and important biostatistics and clinical research publications. Currently, the Statistical Graphics group, the Reproducible Research group, and others have contributed materials. We needed to work with librarians at UC to determine the best way to access these materials to avoid copyright conflicts. We are using the digital operator identifier (DOI) code to access these materials. Access to the articles will go through a proxy server thus avoiding copyright conflicts.

3. **Other collaborations:**

- **Statistical Graphics**: Work with the FDA Center for Drug Evaluation and Research and Pharmaceutical Companies continues. The Statistical Graphics section of CTSpedia will be open to the public in May 2011.
- A home page for the Statistical Graphics work was created within the CTSpedia Statistical Tools section. Links to the statistical graphics materials are given by evaluation rating, latest submitted graphics, random search, and targeted search as well as a site for statistical graphics contributions. Further information on noted publications, a glossary, and meeting schedules is also provided.
- Fabrice Banken from Novartis created a PDF flow chart of classes of statistical graphics. This chart is hyperlinked to descriptions, coding, and problems encountered in using these graphics. There are further hyperlinks to individual examples using these types of graphics.
- Numerous national and international meetings are planned for presentation of these materials.
- This quarter the Statistical Graphics were presented at the DIA Computational Science Meeting in Washington and the International Society for Biopharmaceutical Studies in Berlin. At both meetings there was interest in CTSpedia materials and further collaborations.
- The FDA/Industry/Academia working group is putting together an advertising plan for announcing the statistical graphics projects.

Adaptive Clinical Trial Design:

- Chris Lindsell has submitted a supplement on adaptive clinical trial design and he has requested that the educational materials be posted on the CTSpedia.
- Peter Bacchetti, Mary Banach, Laurel Beckett, Frank Harrell, Chris Lindsell, Sally Thurston, and Jim Ware had a conference call with Jerrry Schindler from Merck. Jerry has given a number of seminars on adaptive clinical trial design and is interested in working with the CTSpedia on establishing a repository for material on adaptive clinical trial design.

Collaboration with PhUSE:

- Last quarter programmers from Rochester attended the Pharmaceutical Users Software Exchange Meeting in Boston.
- At the DIA Computational Science Meeting attendees asked if the PhUSE wiki and CTSpedia could collaborate on providing materials for clinical research questions. We thought that that was an excellent idea. Ben Szilagyi from PhUSE will be talking with us about a joint collaboration.

<mark>**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.)**</mark>

    Not started
    Less than 50% complete
X   Completed 50% or more of the original goals
    Fully completed

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

<mark>**Question 7 JOB CREATION: List the individuals performing effort on this award. (Last Name, First Name; Last Name2, First Name2; etc…)**</mark>
Banach, Mary (UC DAVIS) – No new hires this quarter.

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