

Name Thurston Quarterly ARRA Report (3/31/11-6/30/11)

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

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: We have received the JIT letter for supplemental funding for one year. This supplement will be administered by UC Davis with sub-contracts to UCSF and University of Rochester. Vanderbilt University has been awarded the Coordinating Center contract for the CTSA, and CTSpedia programming staff and equipment at Vanderbilt will be funded through the Coordinating Center grant. The CTSpedia will work closely with the Vanderbilt Coordinating Center to develop any missing infrastructure.
 - Redesign of the CTSpedia: All statistical tools, statistical graphics, and educational materials have been moved to forms. This allows for database searches of all of the materials. All statistical coding on all of the forms is organized in an identical fashion – making it possible to find R-code, SAS macros, Stata code, or other code for all program and graphical submissions. Ratings and Comment boxes were added to each one of the forms. Users can rate the graphics and/or code. We are currently programming a calendar and “Help” area to let participants know the type of assistance that is needed, e.g. two of the statistical graphics need code developed for the graphical display.

- Technical support and site hosting: Vanderbilt continues to support the project. Mary Banach met with Jeff Horner and Dale Plummer at Vanderbilt. They reviewed the CTSpedia site and discussed easy fixes, not so easy fixes, and some fixes that cannot be made with this software. Jeff and Dale have great suggestions about improving communication. We will be adding a Tumblr link to CTSpedia to help with communication and reminders. Jeff has also added the Calendar plug-in. This will help us keep track of meetings and deadlines. Rochester and UCSF biostatisticians continue work on the Statistical Tools section of the CTSpedia. We now have 50 statistical tools: SAS macros, SAS utility macros and R-functions on the CTSpedia. These are hyperlinked to Statistical Graphics and other areas of the CTSpedia. Our goal is to have code to carry out common tasks in multiple languages for our users.

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.
- .The Educational Materials form was updated. We have received new material on teaching the basics of R from Babak Shahbaba at UC Irvine. He would also like to work with a group of individuals on developing course materials. Borko Jovanovic would also like to develop clinical trial educational materials. We are developing a plan for the development of these materials.
- 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 Adaptive Design Group have all contributed important publications for CTSpedia users. These listings are fully editable by CTSpedia registered users. Publications can be submitted without a DOI and we will make sure that all the articles are correctly cited.
- We will be starting an online journal club. Frank Harrell will choose the first paper. We will try to mirror some of the journal club work on StatExchange.com.

3. **Other collaborations:**

- **Statistical Graphics:** Work with the FDA Center for Drug Evaluation and Research and Pharmaceutical Companies continues. The Statistical Graphics area opened to public view for the DIA Annual Meeting on June 20th following Brenda Crowe's presentation.

- In preparation for opening the site, Mat Soukup and Rich Forshee from the FDA as well as Mac Gordon from J&J, Rich Anziano from Pfizer, and Janelle Charles from the FDA did a yeoman's job preparing the documents and working with their respective safety groups: General, Labs and Liver, ECG/Vitals, and Adverse Events. (We still need more code for some of the graphics and will be asking the Statistical Tools group for assistance.)
- One of the authors from SAS, Susan Schwartz, gave us permission to use her labs and liver graphics and told us that she was quite impressed with our work.
- We also need help with getting the CDISC data files formatted for use with R. Frank Harrell has started this work and we will follow-up with the Statistical Tools group.

Adaptive Clinical Trial Design:

- Chris Lindsell has received his JIT for the supplement on adaptive clinical trial design and he will be working with us on how best to use CTSpedia for his study.

Collaboration with PhUSE:

- Ben Szilagyi from PhUSE will be joining us on a Statistical Tools call.

Collaborations with REDCap

- Denise Babineau from Case Western has collected surveys that are important and relevant to clinical researchers. We will be meeting with Paul Harris at REDCap to determine how to use the REDCap survey tool for uploading these surveys. We will be using the CTSpedia to keep track of working group goals and building the instructional materials for survey users.
- Felicity Enders from Mayo Clinic has developed assessment tools to evaluate clinical researcher's understanding of biostatistical concepts. REDCap does not currently have assessment evaluations. We will see how we can upload her materials to REDCap. Again, we will be using the CTSpedia to keep track of working group goals and building the instructional materials for t users.

Collaborations with Statistical Ethics

- Shelley Hurwitz from Harvard, Jonathan Shuster from University of Florida, Liz Heitman from Vanderbilt, Brad Pollok from UT San Antonio, and Peter Bacchetti from UCSF would like to form a working group to look at ethics in statistical practice.

BERD and CTSpedia Recognition

- To improve BERD and CTSpedia recognition Madhu Mazumdar from Cornell and Mary Banach are helping NCRR with putting together the BERD Watch stories for the CTSA Online Newsletter. Chris Lindsell from University of Cincinnati collected BERD Success Stories before the April Face-to-Face Meeting. He provided Mary Banach with the list of success stories and she is

obtaining permission to post these stories on the CTSpedia. These success stories will be open to the public and used for the basis of BERD Watch articles. Again, a form is available for new registered users to contribute their success stories.

Andy Cucchiara, Bob Oster, and Sally Thurston prepared an announcement to be circulated to all CTSA BERD sites requesting assistance in raising awareness of the CTSpedia.

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.)

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

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) – 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