Name   Thurston Quarterly ARRA Report (7/1/10 – 9/30/10)

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 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 proposal to Iris Obrams (NIH) for permanent funding for the CTSpedia. The proposal will be submitted by UC Davis with Laurel Beckett as PI. The proposal is actually two proposals – one for minimal sustainable funding for UC Davis, Vanderbilt, and University of Rochester participants and one for enhanced funding for UC Davis, Vanderbilt, University of Rochester, and UCSF for additional initiatives and materials to foster good clinical practice.
- Redesign of the CTSpedia: The CTSpedia is being re-designed to make searching and finding support materials easier for users.   The Vanderbilt programmers have designed a very accessible web home where users will click on the type of support that they need, e.g. Help for Biostatisticians, Help for Clinical Researchers, Help for Consultants, etc. The Educational Materials web and Statistical Graphics materials that are ready for public display will be incorporated into the CTSpedia web.
- Technical support and site hosting: Vanderbilt continues to support the project. During this quarter, the programmers at Vanderbilt have added a number of plug ins, which enhance the wiki capabilities; re-designed the home page of the

CTSpedia; added tagging capabilities to all pages on the CTSpedia; and worked on assorted problems encountered by CTSpedia contributors.

- Contributors continue to update and link materials to the encyclopedic entries and research articles. These entries are cross referenced with embedded links to other research terms and include links to related tools and educational materials. In the re-design these entries will be more accessible with links to keywords in the Educational Materials.
- Rochester and UCSF biostatisticians have formed a working group with monthly conference calls to update templates and forms in Statistical Tools and to report on the latest collaborations in tool development. At the next meeting three Rochester biostatisticians will be reporting on the Pharmaceutical Users Software Exchange (PhUSE) Meeting in Boston. The PhUSE group is the European equivalent to our FDA working group. Our Statistical Tools group will discuss providing assistance and testing of SAS macros with the PhUSE and FDA participants.
- University of Rochester personnel wrote and uploaded the following five macros (program name, either SAS or R is indicated in parentheses):
  a. Matched sample (SAS): Given a file with two groups of observations, each with values for an arbitrary number of variables, this will match 2 groups of observations on the variables and output a file with only the matched observations on it.
  b. Boxplot (SAS): This is set of macros which creates side-by-side boxplots by grouping variables with similar ranges onto the same graph. This is useful as a quick way to check the distribution of several variables.
  c. StdErrPlot (SAS): This set of macros creates standard error plots for several variables over time and staggers the standard error bars by an optional grouping variable.
  d. ZipCheckFit (SAS): This tests for goodness of fit when modeling count data in the presence of a preponderance of zeros. It first checks the distribution for all variables (response and covariates) of interest and plots the distribution of response variable, and then compares the Zero-Inflated Poisson (ZIP) Model with the Poisson Model using the Vnong test. Finally, the final ZIP full and null models are fitted and tested using Chi-Squared test. The SAS PROC GENMOD is used to carry out the test and modeling.
  e. MWW_Longitudinal (R): This carries out a generalized Mann-Whitney-Wilcoxon test for detecting overall differences in two groups in a continuous longitudinal data setting with no missing values.

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 Educational Materials are open to public view. We now have over 117 individual pieces of course materials with slides, text materials, some video, and keywords for each presentation.

- Andy Cucchiera at the University of Pennsylvania has created a complete list of links to the CTSAs and their educational programs. This list is posted on Links & Resources on the CTSpedia. Andy compiled all the homesites and clinical research programs for the CTSA member sites. To this list we have added a link to any course materials on the CTSpedia from those sites. We will be adding a link to specific biostatistical training programs at the sites.
- At the last Educational Materials (the BERD Online Education working group) Meeting, plans were made for how to share, disseminate and evaluate educational materials in biostatistics and clinical research.

3. **Other collaborations:**
- BERD Evaluation Metrics: The BERD Evaluation Metrics have been posted on the CTSpedia. They are open for comment and suggestions.

- Statistical Graphics: Work with the FDA Center for Drug Evaluation and Research and Pharmaceutical Companies

  a. Mat Soukup from the FDA has designed the working space on the private Statistical Graphics web on the CTSpedia. There are four working groups: General Principles Subteam, ECG/Vitals Subteam, General Adverse Events Subteam, Labs/Liver Subteam. The participants are pharmaceutical company and FDA statisticians in the United States and Europe as well as CTSpedia support staff.
  b. The teams have monthly meetings discussing the design graphic template and code. The entire group has a monthly call to update everyone on activities, to announce meeting information, and to offer suggestions on different approaches to presenting the data.
  c. The teams have all agreed that when they have a production product they will upload it to the CTSpedia web to share with all users. Mat Soukup has five graphs and two datasets which will be posted for everyone to use.
  d. The General Principles Subteam took a step back and is presenting an overview document on how graphs are used to portray clinical trial safety data and what questions the statistician needs to ask as s/he is presenting the information. It will be a document that can be used by anyone thinking about graphical presentations of research data. Susan Duke (GSK), Fabrice Bancken (Novartis), and Richard Anziano (Pfizer) have taken the lead on this work. This subteam was not sure that we wanted such a document on the CTSpedia. They thought that they were just supposed to produce individual graphics. We pointed out that wiki collaborations allow us to realize that additional information will be extremely helpful in working with the data.

	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

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