CTSpedia Final Report
PI: Thomas Pearson
Award number: 3UL1RR024160-04S2
October, 2011

Summary of accomplishments for each aim:

Aim 1: To continue generating site content in biostatistics, research design and epidemiology topics and find a sustainable home for CTSpedia.

- *Sep 2009- Dec 2009: Hire at least one graduate student intern to provide editing and light programming support on CTSpedia. (UCSF)*

Due to the transfer of UCSF effort to UC Davis, instead of hiring a graduate student intern we have hired Dr. Mary Banach to oversee the day to day operation of CTSpedia, which includes editing and programming support for CTSpedia.

Mary Banach works with all of the groups publishing data on CTSpedia. Fortunately, many of the groups have assigned managers (e.g. Mat Soukup of the FDA from the FDA/Industry/Academia Safety Graphics Group) to address, communicate, and test the group's ideas for display on the CTSpedia.

- *Sep 2009 – Dec 2009: Transfer technical support and site hosting to Vanderbilt to optimize site performance and sustainable site hosting. (Vanderbilt)*

Technical support and site hosting was transferred to Vanderbilt in year 1. We have changed from the TWiki that was used at UCSF to the Foswiki. This required Jeff Horner at Vanderbilt to initially expend an enormous effort to transfer and re-create all of the special screens and programming that Bloom Creative had done for UCSF. Jeff was able to capture all the changes that Bloom Creative had made and also lock the system from intruders. During the transfer of CTSpedia from UCSF to Vanderbilt someone was able to get into the system files and erase all the system programming. Jeff had to re-create all of the system programming before we could continue using the CTSpedia.

Jeff Horner and Dale Plummer are responsive to all IT needs and questions that have arisen on CTSpedia. When there are new plug-ins or better ways to organize the data, Jeff and Dale have installed and tested all the add-ons that help to organize the site. Jeff has also helped UCSF programmers with java script applications that they wished to upload to CTSpedia.

- *Sep 2009 – Sep 2011: Collect, generate and publish an additional 100 encyclopedic topic, multimedia tutorials and article entries within the purview of clinical and translational research. (UCSF)*

As we have collaborated with more groups and identified more ways to link the CTSpedia to our professional needs in clinical research, we have changed the focus from collecting, generating and publishing an additional encyclopedic, tutorials, and article entries to making our environment far more interactive and searchable. In all 242 research topics, 12 articles written by CTSpedia contributors including Interactive Tools, 28 links to biostatistics topics on the web, and 8 case studies can be found on CTSpedia. Our Statistical Tools Working Group (56 individual tools: SAS Macros and R-Scripts), Education Working Group (64 pieces of course materials), and our Clinical Trials Safety Graphics Working Group (65 individual and class safety graphs with background information, images, and code) are open to the public and provide users an entry point for their clinical research work.

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- *Sep 2009 – Sep 2011: Develop at an additional 30 statistical tools, utilities and macros including, but not limited to SAS and R applications. (Rochester/Davis)*

We have developed 56 statistical tools, utilities and macros in SAS, R, and Stata. These represent SAS macros, SAS utility macros, R-scripts, and Stata files. Some of our tools, e.g. Partial Least Squares, have both a SAS macros and R-script for the user to be able to run the program in either software. All the statistical tools are on forms, where new contributors can add code by software type to the individual tool.

Listing of All Statistical Tools

Title	Type of Tool
A U C G E E	SAS Macro
Boxplot	SAS Macro
Brief T-Test	SAS Macro
Calculates Residuals	SAS Utility Macro
Calculates Summary Statistics	SAS Utility Macro
Categorize	SAS Macro
Check Data	SAS Utility Macro
Check Number Exist	SAS Utility Macro
Check Numbers in List	SAS Utility Macro
Check Varables in List	SAS Utility Macro
Check for Specified Variable	SAS Utility Macro
Check for Words	SAS Utility Macro
Check for a Number	SAS Utility Macro
Checks for Variables	SAS Utility Macro
Chi-Square	SAS Macro
Combine Output	SAS Utility Macro
Counts Words	SAS Utility Macro
Create List	SAS Utility Macro
Create Next Word	SAS Utility Macro
Creates Deltas	SAS Utility Macro
Creates Dummy Variables	SAS Utility Macro
Creates Quartiles	SAS Utility Macro
Creates Reference Dummy Variables	SAS Utility Macro
Creates Variable Names	SAS Utility Macro
Cross Plots	SAS Macro
Effect Size Longitudinal	SAS Macro
Effect Size Mixed	SAS Macro
Example Testing SAS Formats	

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Title	Type of Tool
False Discovery Rate	SAS Macro
Generalized Linear Regression for Count Data	SAS Macro
Generalized Logistic Model	SAS Macro
Kappa R	R-Function
Least Squares Mean Plot GEE	SAS Macro
Least Squares Mean Plot for Mixed Models	SAS Macro
Linear Regression	SAS Macro
Logistc Regression	SAS Macro
Mann Whitney Wilcoxon R	R-Function
Matched Sample	SAS Macro
Mixed Effects Binary	SAS Macro
Multivariate Partial Least Squares (R)	R-Function
Nested Power Effect Size	SAS Macro
Partial Least Squares	SAS Macro
Pearson and Spearman Correlations	SAS Macro
Percent Change	SAS Macro
Power and Effect Size	SAS Macro
Proportional Odds Model	SAS Macro
ROC Cutoff	SAS Macro
Replay All Graphs	SAS Utility Macro
Run Programs	SAS Utility Macro
Standard Error Plot	SAS Macro
Summarize Continuous and Categorical Variables	SAS Macro
Summarize R Macro	R-Function
Transpose Variables	SAS Utility Macro
ZIP Check Fit	SAS Macro
ZIP GEE	SAS Macro
Zero Inflated Poisson R	R-Function

- *Sep 2009 – Sep 2011: Provide support to groups generating tertiary content on CTSpedia. (Vanderbilt/UCSF)*

Since taking over the system management of the CTSpedia, the Vanderbilt IT Department has been available for technical problems both small and large. Sometimes we cannot resolve an issue or link to a particular field (e.g. you cannot link plug-ins across forms) due to the limitations of the wiki mark-up language but Jeff and Dale always listen and provide guidance. As mentioned above they have helped with java script applications that were difficult to add to the CTSpedia. By far most of the time has been spent adding plug-ins (unique programming code that extends functionality of the Foswiki), testing the plug-ins, and determining the limits of the plug-ins, Within the last two years, Vanderbilt has added over 50 plug-ins, among them the tagging plug-in, rating plug-in, email notification plug-in, highlighting plug-in, etc. If a Foswiki

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plug-in is noted on another site, a simple email to Jeff Horner alerting Jeff to the new plug-in results in Jeff uploading and testing the new plug-in for CTSpedia.

- *Nov 2009, Nov 2010: Convene annual face to face meetings to discuss CTSpedia progress and plans.*

CTSpedia leaders met at face to face meetings in April 2010 and April 2011, in conjunction with the annual BERD fact to face meeting. We also met monthly via conference calls.

Aim 2: *To pilot a collection of workshop and short-course materials and slides related to statistical consulting and basic statistical concepts and tools.*
- *Sep 2009 – Dec 2009: Draft and disseminate a survey to CTSA BERD faculty to gather at least 30 articles of course materials (handouts, lecture slides, multimedia, etc.). (Rochester/Davis)*

We drafted and disseminated a survey to CTSA BERD faculty, which resulted in many articles of course materials, as described below.

- *Jan 2010 – Sep 2011: Initiate plan to systematically search, gather and publish course materials from CTSA institutions. (UCSF)*

- *Oct 2009 – Sep 2011: Publish at least 30 fully editable and freely shared articles of course materials within the purview of training in clinical and translational research. (UCSF)*

The following materials were contributed to CTSpedia and are available for download.

All Educational Materials

Title	CTSA	Format	Audience	Type of Course
A Brief Introduction to R	UCI	PDF	Graduate Student, Clinical Researcher	Instructional Material
A Conceptual Approach to Survival Analysis	NIH	PDF, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
Analysis of Categorical Data	Indiana		Graduate Student	Single Presentation
Basics of Clinical Data Management	Indiana	LaTeX	Graduate Student, Clinical Researcher	Single Presentation
Chapter 1 - Introduction to Stata	Utah	Word	Graduate Student, Clinical Researcher	Instructional Material
Chapter 2 - Stata Biostatistics	Utah	Word	Graduate Student	Instructional Material
Chapter 3 - Stata Epidemiology	Utah	Word	Graduate Student	Instructional

Title	CTSA	Format	Audience	Type of Course
				Material
Chapter 4-Specific Applications - Stata	Utah	Word	Graduate Student	Instructional Material
Chapter 5 - Regression Models - Stata	Utah	Word	Graduate Student	Instructional Material
Chapter 6 - Diagnostic Tests - Stata	Utah	Word	Graduate Student	Instructional Material
Cohort Study Design	UCSF	Topic Page	Graduate Student, Clinical Researcher	Single Presentation
Comparison of Means	Indiana	PDF	Clinical Researcher	Single Presentation
Correlation and Simple Linear Regression	Indiana	PDF	Clinical Researcher	Single Presentation
Design of Epidemiological Studies	NIH	PDF, Video	Graduate Student, Clinical Researcher	Instructional Material
Design of Genetic Studies	Indiana	PDF	Graduate Student	Single Presentation
Evaluation of Diagnostic Tests	Indiana	PDF	Clinical Researcher	Single Presentation
Evidence-Based Medicine Education Series	Duke	Links	Graduate Student, Clinical Researcher	Multi-presentation
Hypothesis Testing and Confidence Interval Estimation	Indiana	PDF	Clinical Researcher	Single Presentation
Introduction to Longitudinal Studies	Indiana	PDF	Graduate Student	Single Presentation
Introduction to Random Variables	Alabama	PPT slides	Clinical Researcher	Single Presentation
Introduction to Survival Analysis	Indiana	PDF	Graduate Student	Single Presentation
Issues in Clinical Trials	Indiana	PDF	Clinical Researcher	Single Presentation
Issues in Randomization	NIH	PDF	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
Lesson 1: Evidence-Based Medicine: The Basic Concepts	Duke	Links	Graduate Student, Clinical Researcher	Single Presentation
Lesson 2: Statistical Issues in the Design of a Trial, Part 1	Duke	Links	Graduate Student, Clinical Researcher	Single Presentation
Lesson 3: Statistical Issues in the Design of a Trial, Part 2	Duke	Links	Graduate Student, Clinical Researcher	Single Presentation
Lesson 4: Interpretation of	Duke	Links	Graduate Student,	Single

Title	CTSA	Format	Audience	Type of Course
Medical Literature Statistics and Statistical Terms			Clinical Researcher	Presentation
Lesson 5: Statistical Methods for Analyses	Duke	Links	Graduate Student, Clinical Researcher	Single Presentation
Lesson 6: The Role of Independent Data Monitoring	Duke	Links	Graduate Student, Clinical Researcher	Single Presentation
MCW Biostatistics Vimeo - Videos	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: Ahn_Analyzing Discrete Data	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
MCW: Bajorunaite_Paired Data	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: Institute for Health and Society Consulting Services	MCW	Links, Video	Graduate Student, Clinical Researcher	Single Presentation
MCW: Klein_Survival Analysis - Part I Univariate Statistics	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: Klein_Uses and Abuses of Non-parametric Statistics	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
MCW: Klein_Writing a Protocol	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: Laud_Concepts in Biostatistics	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: Logan_Designing Clinical Trials	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
MCW: Logan_Multiple Comparisons	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
MCW: Szabo_Simple Statistics in Excel	MCW	Links, Video	Graduate Student	Instructional Material, Single Presentation
MCW: Tarima_ANOVA: Comparing More Than Two	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
MCW: Tarima_Logistic regression	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: Wang_Logistic Regression	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation

Title	CTSA	Format	Audience	Type of Course
MCW: Zhang_Simple Linear Regression	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW: da Silva_Equivalence and Non-Inferiority Testing	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material
MCW:Le-Rademacher_Statistics, Probability and Diagnostic Medicine	MCW	Links, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
Multiple Linear Regression and Logistic Regression	Indiana	PDF	Clinical Researcher	Single Presentation
Multivariate Statistics	Alabama	PPT slides	Clinical Researcher	Single Presentation
Pletcher-introduction to Statistical Computing in Clinical Research - Stata Course	UCSF	PPT slides	Graduate Student	Instructional Material
Principles of Hypothesis Testing for Public Health	NIH	PDF, Video	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
Rochester: Thurston_Basic Statistics: MBI-540 (for Virologists)	Rochester	PDF	Graduate Student, Clinical Researcher	Single Presentation
Sampling Distributions	Alabama	PPT slides	Clinical Researcher	Single Presentation
Simple Descriptive Statistics	Alabama	PPT slides	Clinical Researcher	Single Presentation
Statistics for the Basic Sciences	Columbia		Graduate Student	Syllabus
Statistics in Clinical Research	Mayo	PDF	Graduate Student, Clinical Researcher	Syllabus
Study Design	Indiana	PDF	Clinical Researcher	Single Presentation
Teaching Methods - Biostatistics	Vanderbilt	Links	Graduate Student, Clinical Researcher, Professional Statistician	Instructional Material
UCLA: Online Biostatistics Courses and Seminars		Links	Graduate Student, Clinical Researcher	Instructional Material
UCSF: Glidden_Data Exploration	UCSF	PDF	Graduate Student, Clinical Researcher	Instructional Material
UCSF: Glidden_Multi-Predictor Linear Model	UCSF	Topic Page	Graduate Student, Clinical Researcher	Single Presentation
UCSF: Glidden_Simple Linear Regression	UCSF	PPT slides	Graduate Student, Clinical Researcher	Instructional Material

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Title	CTSA	Format	Audience	Type of Course
UCSF: Martin_Disease Association-Risk Ratio	UCSF	PPT slides	Graduate Student, Clinical Researcher	Instructional Material, Single Presentation
Vanderbilt: Dupont - Biostatistics II Lecture Notes for 2010	Vanderbilt	Links	Graduate Student, Clinical Researcher	Multi-presentation
Vocabulary of Uncertainty	Alabama	PPT slides	Graduate Student, Clinical Researcher	Single Presentation

- *Oct 2009: Draft, design and test presentation templates for disseminating course materials on CTSpedia. (All)*

Rather than testing individual templates, CTSpedia provides all the materials with scoring and feedback fields for users to tell us how the materials have worked for their audiences.

- *Sep 2009 – Sep 2011: Collaborate with the Education, Training and Career Development Key Function Committee and Strategic Goal Committee #2 to link BERD course materials to a national CTSA clinical and translational research education and training resource. (All)*

We approached leaders of the Strategic Goal Committee #2 about linking BERD course material to a national CTSA education and training resource. We provided them with all the links and said that we were available for any further discussions.

- *Sep 2009 – Sep 2011: Serve as the platform and editorial assistant to other CTSAs who want to publish and share educational materials. (UCSF/Vanderbilt)*

Currently, we are assisting many working groups with educational materials. Some of these groups are currently commencing activities on CTSpedia. Among these groups are:
- Reproducible Research – templates and materials are being collected on CTSpedia.
- Adaptive Design – templates and materials will be coming to CTSpedia.
- Clinical Research Management Program Excellence Group (CPEG) – templates and materials are being gathered to upload to CTSpedia.
- Patient Recruitment KFC – templates and materials will be coming to CTSpedia.

Further details regarding our accomplishments for CTSpedia

BERD Success Stories: At the 2011 Face-to-Face Meeting, many of the sites presented brief success stories of BERD activities at their CTSAs. At the same time the CTSA Online Newsletter needed more stories for the BERD Watch articles. To make all stories accessible to all users and to provide a database of stories for the BERD Watch articles, the Success Stories, with contributor's permission, were uploaded to the CTSpedia. Each month one is chosen to be expanded for the CTSA Online Newsletter. A form was created and any registered CTSpedia user can contribute a Success Story to CTSpedia.

Discussion Forum: Although we have had a rocky start with our attempts to add a discussion forum to CTSpedia, our current topics are viewed by many individuals. New discussion topics can be initiated either by using the CTSA BERD Listserv or on CTSpedia. Contributions emailed to the CTSA BERD Listserv are then transferred to the CTSpedia Discussion Forum.

Clinical Trials Safety Graphics: For the last two years the CTSpedia has served as the platform for the FDA/Industry/Academia Safety Graphics Group's work. As mentioned above there are currently 65 graphs open to the public. This group is composed of four sub-groups: General Principles, Labs and Liver, ECG and Vitals, and Adverse Events. Each group looks at the question of safety graphics according to their own particular lens with Labs and Liver, and Adverse Events detailing clinical questions that need to be answered by their graphics; and General Principles looking at the types of questions that need to be answered by a statistical graphic.

Links to datasets: All of our work benefits from good datasets to use for recreating and testing the statistical tools. Mat Soukup from the FDA has garnered permission for us to use the CDISC datasets, Vanderbilt has contributed an extensive list of datasets, other sources of data are given on CTSpedia, and users are encouraged to share their datasets on CTSpedia.

Other Contributions: An area on CTSpedia has been created for CTSpedia contributors to ask for assistance or to offer assistance on various projects. We are making plans to work with Felicity Enders on her assessment of biostatistical concepts in clinical research and to help Denise Babineau with her listing of commonly used surveys in clinical research. For Denise's work we would like to not only link to the surveys that are managed by REDCap but also to provide code and directions on using the surveys in CTSpedia.

Advertising: A CTSpedia advertising brochure was distributed at the JSM Meeting in Miami. The Clinical Trials Safety Graphics Group has presented the CTSpedia and the statistical graphics work at national and international meetings.