




Monthly Program Status Report – PROJECT

Reporting Period:	July 2016
Contracting Agency:	Food and Drug Administration (FDA)
FDA Project Manager:	Shaila Shaheed, Shaila.Shaheed@fda.hhs.gov , Thomas Permutt, thomas.permutt@fda.hhs.gov ,
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Contract / Order:	HHSF223201310230C
Contractor PI:	Daniel Scharfstein, dscharf@jhu.edu , 410-955-2420
Project Team:	Aidan McDermott (Computer Programmer)
Description of Activity:	A recent FDA-sponsored National Research Council Report recommended that "examining sensitivity to the assumptions about the missing data mechanism should be a mandatory component of reporting." While the Report outlines a framework for conducting sensitivity analysis, there are two major problems with existing methods: (1) they have not been implemented in software packages and (2) they do not adequately address non-monotone missing data patterns (i.e., patients provide data irregularly). The objective of this project is to address these gaps by: 1) creating unified and coherent methods for global sensitivity analysis of clinical trials with monotone and non-monotone missing data, 2) developing free, open source and reproducible software in SAS and R to implement the methods, and 3) demonstrating the methods and software using real clinical trial data.

Project Health Check							
Health ▶	Budget		Schedule		Resources		Deliverables
Notes ▶	Within Budget		On Schedule		Adequate		On Target

Budget Tracking – (TOTAL CONTRACT CEILING)							
POP	Ceiling Remaining	Cumulative Funding	Year Funding (Year 1)	Spent to Date	Year Funding Remaining	Month Invoice	Funding Covers
Base	\$1,094,565	\$1,094,565	\$1,094,565	\$963,261.96 (\$54,256.23 committed)	\$131,303.04	\$879,389.36	Salary, fringe, other expenses, and indirect costs

Activity Summary and Highlights
We completed R package and SAS procedure that extends SAMON to handle missing data prior to dropout. Gave short course at the University of Washington.

Key Accomplishments	
Current Reporting Period	Planned for Next Period
<ul style="list-style-type: none"> Gave short course at University of Washington Completed R package and SAS procedure that extends SAMON to handle missing data prior to dropout. 	<ul style="list-style-type: none"> Complete documentation for R package and SAS procedure. Submit <i>Clinical Trials</i> manuscript

Issues and Risks					
Category	Priority	Status	Opened	Issue	Description
Contract (FDA)	1	Closed	9/30/13	Intellectual Property	Revision to contract regarding intellectual property language.
Dissemination (FDA)	2	Closed	2/15/14	Website	FDA Personnel cannot connect to www.missingdatamatters.org from their office computers.
Software (JHU)	1	Closed	3/15/14	Coverage of Confidence Intervals	Simulations indicate that standard procedures for constructing confidence intervals are not providing adequate coverage with typical sample sizes.
Computing (JHU)	1	Closed	4/21/14	Periods of slow performance of computing cluster	A new computing cluster was installed at Johns Hopkins. We are experiencing periods of slow performance on the cluster.
Personnel (JHU)	1	Closed	5/21/14	Re-Distribution of Effort	Starting April 1, Aidan McDermott has reduced his percent effort by 20%. Chenguang Wang joined the project starting July 15.
Invoicing (FDA)	1	Closed	6/6/14	Payment of Invoices	Invoices have not been paid.
Computing (FDA)	1	Closed	6/6/14	Software on FDA Cluster	Investigate the steps needed to run software on FDA cluster
Personnel (JHU)	1	Closed	1/13/15	New Effort	Yi Lu joined the project to work on confidence intervals.
Software (JHU)	1	Open	6/15/16	Coverage of Confidence Intervals	Simulations indicate that standard procedures for constructing confidence intervals are not providing adequate coverage with typical sample sizes.

Other Activities

Attachments and References

Upcoming Short Courses/Webinars

- September 20 (12-3) ASA Webinar
- October 26-28 BASS Conference, Rockville, MD

Status of Milestones

- 4: Create Non-Monotone Missing Data Product (due 9/15/16, on schedule)
 - 4.3: SAS implementation (7/31/16)
 - 4.4: R Implementation (7/31/16)
 - 4.5: Two Case Studies (completed, need to write-up)