Monthly Program Status Report – PROJECT

Reporting Period:	**March 2015**
Contracting Agency:	Food and Drug Administration (FDA)
FDA Project Manager:	Jingyee Kou, jingyee.kou@fda.hhs.gov, 301-796-9495
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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	$612,145.13 (*$126,558.09) committed)	$482,419.87	$427,353.94	Salary, fringe, other expenses, and indirect costs

Activity Summary and Highlights

We completed the proof a key theorem for the monotone missing data manuscript and developed methodology for analyzing studies with intermittent missing data (see memo sent on 3/28/15). We continue to work on methodology for constructing fast and more accurate confidence intervals. We have re-written some of the code to improve its speed. We have also been implementing the intermittent missing data methodology. We purchased SAS/Toolkit so that we can convert SAMON to a PROC. We submitted a manuscript describing how to analyze randomized studies with death and missing data prior to death (shared with you on 3/16/2015). We submitted a poster abstract to the FDA 2015 ORSI Science Symposium.

Key Accomplishments	
Current Reporting Period	***Planned for Next Period***
• Completed proof of theorem • Developed methodology for intermittent missing data. • Worked on methodology for confidence intervals • Worked on speeding up software and implementing methods for intermittent missing data. • Completed purchase of SAS/Toolkit • Submitted manuscript on missing data in studies with death. • Submitted poster abstract to FDA symposium	• Initiate the Forum option on Website • Expand membership on Website • Develop SAS version of software • Work on methodology for confidence intervals • Implement intermittent missing data methods • Finish and submit 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	Open	6/6/14	Payment of Invoices	Invoices have not been paid.
Computing (FDA)	1	Open	6/6/14	Software on FDA Cluster	Investigate the steps needed to run software on FDA cluster
Personnel (JHU)	1	Open	1/13/14	New Effort	Yi Lu joined the project to work on confidence intervals.

Other Activities

Attachments and References