Monthly Program Status Report – PROJECT

Reporting Period:	**September 2014**
Contracting Agency:	Food and Drug Administration (FDA)
FDA Project Manager:	Jingyee Kou, jingyee.kou@fda.hhs.gov, 301-796-9495
FDA Subject Matter Expert:	Thomas Permutt, thomas.permutt@fda.hhs.gov, 301-796-1271
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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	$330,156.18 (*$17,167.48) committed)	$764,408.82	$299,208.35	Salary, fringe, other expenses, and indirect costs

Activity Summary and Highlights

Over the last month, we presented the methodology underlying the software package at the University of Rochester (see website for slides) and we completed a full draft of the manuscript (see attached). We have made substantial progress in porting the software over Microsoft. We submitted a short course proposal to the Society of Clinical Trials (see attached). We worked on developing a methodology for analyzing studies with intermittent missing data. First paper accepted in *Statistics in Biopharmaceutical Research*.

Key Accomplishments

Current Reporting Period	*Planned for Next Period*
• Presentation at University of Rochester • Worked on porting to Microsoft • Completed full draft of manuscript • Submitted short course proposal to Society of Clinical Trials • Worked on methodology for intermittent missing data. • First paper accepted in *Statistics in Biopharmaceutical Research*.	• Initiate the Forum option on Website • Expand membership on Website • Develop Windows-based version of software • Develop a less computationally intensive confidence interval procedure. • Finish and submit manuscript • Work on methodology for intermittent missing data

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

Other Activities

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Attachments and References

- Draft of Manuscript, Short Course Proposal