Monthly Program Status Report – PROJECT

Reporting Period:	**May 2014**
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@jhsph.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	$188,989.39 (*$103,904.18) committed)	$801,671.43	$157,491.77	Salary, fringe, other expenses, and indirect costs

Activity Summary and Highlights

Over the last month, we have tested code for flexible sensitivity analysis methodology for monotone missing data. We solved the issue of under-coverage of standard confidence intervals by implementing a warp-speed double bootstrap procedure. The procedure is very computationally intensive. To execute in a reasonable timeframe, a computing cluster is required.

Key Accomplishments	
Current Reporting Period	***Planned for Next Period***
• Tested code for flexible sensitivity analysis methodology for monotone missing data. • Solved the issue of under-coverage of confidence intervals. • Invited to present 3 hour tutorial at Deming Conference in Atlantic City	• Initiate the Forum option on Website • Expand membership on Website • Post C code for flexible sensitivity analysis methodology for monotone missing data • Develop a less computationally intensive confidence interval procedure.

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	Open	5/21/14	Re-Distribution of Effort	Starting April 1, Aidan McDermott has reduced his percent effort by 20%. Chenguang Wang will join the project starting June 1.

Other Activities

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Attachments and References

- Simulation Results Table