

Monthly Program Status Report – PROJECT

Reporting Period:	February 2014
Contracting Agency:	Food and Drug Administration (FDA)
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Contract / Order:	HHSF223201310230C
Contractor PI:	Daniel Scharfstein, dscharf@jhsp.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	\$70,991.10 (*\$138,377.22 committed)	\$885,086.28	\$44,248.62	Salary, fringe, and indirect costs

Activity Summary and Highlights
<p>Over the last month, we have</p> <ol style="list-style-type: none"> 1. Implemented and tested code for flexible sensitivity analysis methodology for monotone missing data. 2. Expanded membership on project website; 173 members as of 2/15/14

Key Accomplishments	
<i>Current Reporting Period</i>	<i>Planned for Next Period</i>
<ul style="list-style-type: none"> Implemented and tested code for flexible sensitivity analysis methodology for monotone missing data. Expanded membership on project website; 173 members as of 2/15/14 	<ul style="list-style-type: none"> Initiate the Forum option on Website Expand membership on Website Post C code for flexible sensitivity analysis methodology for monotone missing data

Issues and Risks					
Category	Priority	Status	Opened	Issue	Description
Contract	1	Open	9/30/13	Intellectual Property	Revision to contract regarding intellectual property language.

Other Activities
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Attachments and References
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