Monthly Program Status Report – PROJECT

Reporting Period:	**December 2013**
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	0	$1,094,565	0	

Activity Summary and Highlights

The project start date was 9/30/13. Since then we have

1. Created project website: see www.missingdatamatters.org
2. Presented shortcourse at FDA on 12/2/13
3. Submitted a manuscript on fully parametric sensitivity analysis for monotone missing data
4. Developed a more flexible sensitivity analysis methodology for monotone missing data that does not rely on fully parametric models for the distribution of the observed data

Key Accomplishments	
Current Reporting Period	***Planned for Next Period***
• Developed Website • Presented Short Course at FDA • Submitted manuscript on fully parametric sensitivity analysis for monotone missing data • Developed a more flexible sensitivity analysis methodology for monotone missing data that does not rely on fully parametric models for the distribution of the observed data	• Initiate the Forum option on Website • Expand membership on Website • Identify datasets for case studies • Implement code for the newly developed 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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