JOHNS HOPKINS UNIVERSITY

Monthly Program Status Report – PROJECT

Reporting Period:	**March 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
FDA COTR:	Shaila Shaheed, Shaila.Shaheed@fda.hhs.gov
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	$127,201.33 (*$207,056.35 committed)	$760,307.32	$127,201.33	Salary, fringe, other expenses, and indirect costs

Activity Summary and Highlights

Over the last month, we have implemented and tested code for flexible sensitivity analysis methodology for monotone missing data. In a simulation study, we identified a major issue regarding the coverage properties of standard confidence intervals.

JOHNS HOPKINS UNIVERSITY

Key Accomplishments	
Current Reporting Period	*Planned for Next Period*
- Implemented and tested code for flexible sensitivity analysis methodology for monotone missing data. - Identified a major problem regarding the coverage properties of standard confidence intervals.	- Solve the confidence interval issue. - 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	Prior ity	Status	Opened	Issue	Description
Contract	1	Open	9/30/13	Intellectual Property	Revision to contract regarding intellectual property language.
Dissemination	2	Open	2/15/14	Website	FDA Personnel cannot connect to www.missingdatamatters.org from their office computers.
Software	1	Open	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.

Other Activities

Attachments and References