JOHNS HOPKINS UNIVERSITY

## Monthly Program Status Report – PROJECT

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| **Reporting Period:** | August 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 | $325,516.31 (*$42,316.63 committed) | $769,048.69 | $244,087 | Salary, fringe, other expenses, and indirect costs |

### Activity Summary and Highlights

Over the last month, we posted the software (titled SAMON) on our website.  The software runs in a Linux/Unix environment running GSL and SAS. Ted Peterson (CDRH) has successfully beta tested the software. We presented the methodology underlying the software package at a JSM invited session (see website for slides). We continued to work on adding data analysis and simulation sections to the manuscript. We scheduled a short course for January 2015. We have made progress on speeding up the code.  We are working on porting the package to Microsoft and building an R interface.  We are developing a methodology for analyzing studies with intermittent missing data.

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| Key Accomplishments | |
|---|---|
| *Current Reporting Period* | *Planned for Next Period* |
| • Posted and beta tested C code.<br>• Presentation at JSM<br>• Worked on speeding up code<br>• Worked on porting to Microsoft<br>• Continued work on manuscript<br>• Scheduled short course for January 2015<br>• Worked on methodology for intermittent missing data. | • Initiate the Forum option on Website<br>• Expand membership on Website<br>• Develop Windows-based version of software<br>• Develop a less computationally intensive confidence interval procedure.<br>• Finish draft of manuscript<br>• Work on methodology for intermittent missing data<br>• Submit short course proposal to SCT. |

## 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 |

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**Other Activities**

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**Attachments and References**

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