# Monthly Program Status Report – PROJECT

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|---|---|
| **Reporting Period:** | **December 2015** |
| **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@jhu.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 | $943,445.36 ($233,472.05) committed) | $151,119.64 | $685,781.43 | Salary, fringe, other expenses, and indirect costs |

**Activity Summary and Highlights**

We conducted extensive simulation studies to ensure that our confidence interval procedures are working properly. We worked on SAS implementation. We worked on a manuscript for *Clinical Trials*. We arranged for two new short courses: one at Johns Hopkins and one at the University of Washington.

## Key Accomplishments

| *Current Reporting Period* | *Planned for Next Period* |
|---|---|
| • Conducted extensive simulation studies<br>• Work on SAS implementation<br>• Work on *Clinical Trials* manuscript<br>• Arranged two new short courses | • Complete simulation studies<br>• Work on *Clinical Trials* manuscript<br>• Post SAS SAMON on website<br>• Continue implementation of intermittent missing data methods |

## 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 |
| Personnel (JHU) | 1 | Open | 1/13/15 | New Effort | Yi Lu joined the project to work on confidence intervals. |

## Other Activities

## Attachments and References