JOHNS HOPKINS UNIVERSITY

## Monthly Program Status Report – PROJECT

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| **Reporting Period:** | **January 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:** | Robyn Barringer, robyn.barringer@fda.hhs.gov, 301-796-8485 |
| **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

Over the last month, we have

1. Initiated implementation and testing of code for flexible sensitivity analysis methodology for monotone missing data.
2. Expanded membership on project website; 70 members as of 1/15/14
3. Identified members with open access to datasets that can be used as the basis of case studies
4. Submitted short course proposal

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| Key Accomplishments | |
|---|---|
| *Current Reporting Period* | *Planned for Next Period* |
| <ul><li>Initiated implementation and testing of code for flexible sensitivity analysis methodology for monotone missing data.</li><li>Expanded membership on project website; 70 members as of 1/14/14</li><li>Identified members with open access to datasets that can be used as the basis of case studies</li><li>Submitted short course proposal</li></ul> | <ul><li>Initiate the Forum option on Website</li><li>Expand membership on Website</li><li>Continue implementation and testing of code for flexible sensitivity analysis methodology for monotone missing data.</li></ul> |

| 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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