

## PREMIER Clinical Manual of Procedures

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**PREMIER Clinical Manual of Procedures**

**Summary of Edits**

## **PREMIER Clinical Manual of Procedures**

### **26. Trial Monitoring Reports**

#### *Introduction*

During the trial's course, the Coordinating Center produces a variety of reports summarizing the characteristics of the study as a whole and of individual clinical centers. These reports are distributed to the members of the Steering Committee, to appropriate subcommittees, and to the Data Safety Monitor Board to monitor the progress of the trial. Selected reports are also available on a daily basis on the site workstations and on the PREMIER Web site.

Additional reports, produced for the DSMB only, permit the DSMB to monitor the efficacy and safety of the interventions. These reports include not only standardized reports issued at regular intervals but also ad hoc reports as requested.

The reports prepared for the Steering Committee focus on the recruitment of participants into the trial. These reports allow the Steering Committee to ensure that recruitment is proceeding in a timely manner and to identify potential recruitment problems at an early enough stage that they can be corrected. In addition, the Steering Committee also receives reports summarizing the completeness and quality of the study database.

The other committees receive reports relevant to their areas of expertise.

Current versions of the standardized reports can also be generated on demand using the file servers and on the PREMIER web site. This allows individual sites to get up-to-the-minute reports, further enhancing data quality.

#### *Types of Reports*

##### *Recruitment/Follow-up Reports*

Recruitment and follow-up reports summarize recruitment activity and follow-up to date. These reports assist field sites in meeting recruiting needs and in scheduling eligible participants for upcoming screening visits.

##### *Baseline Data Reports*

These reports compare the baseline characteristics of the randomized participants. Data are presented both by site and by treatment status. All of the information reflects baseline, pre-intervention data, and therefore should be comparable across treatment groups.

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### *Quality Control Reports*

Quality control reports include a number of reports related to the integrity of the PREMIER database and adherence to trial protocol by both participants and sites. These include digit preference reports and blood pressure protocol reports.

### *Laboratory QC and Results Reports*

Laboratory quality control reports summarize lab tracking, including receipt, receipt status, and the collection of process measures such as start and stop times for 24-hour urine samples that will be used to establish the usability of data laboratory reports summarizing the results of laboratory analyses.

### *Side Effects Report*

The side effects report summarizes side effects reported by PREMIER participants during the course of the study.

### *Outcome Measures and Safety Issues Reports*

These reports are only sent to members of the DSMB. They comprise unblinded study data.

### *Data Management Reports*

These reports summarize the data completeness and data quality for single site

### *Distribution of Reports*

#### *Monthly Steering Committee/Measurement Committee Reports*

These reports are generally distributed 1-2 weeks prior to the meeting or conference call of each committee. Not every report is sent out in every mailing. The Coordinating Center reviews the available reports before each mailing and sends only those reports that have new and/or relevant data.

- Recruitment/Follow-up Reports
- Baseline Data Reports
- Quality Control Reports
- Laboratory QC and Results Reports
- Side Effects Report

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### *Monthly Recruitment Committee Reports*

The committee chair distributes these reports a week prior to the meeting or conference call.

- Recruitment/Follow-up Reports

### *Reports for DSMB Meetings*

These reports are prepared and distributed about 2-4 weeks prior to each DSMB meeting.

- Recruitment/Follow-up Reports
- Baseline Data Reports
- Quality Control Reports
- Laboratory QC and Results Reports
- Side Effects Report
- Outcome Measures and Safety Issues Reports

### *Reports Available on Site Computer Workstation*

These reports are available at all times and are run on the present 'live' data.

- Data Management Reports

### *Reports Available on the Project Web Site*

These reports are available at all times and are updated weekly (recruitment) or monthly (other reports). They include selected reports from the following categories.

- Recruitment/Follow-up Reports
- Baseline Data Reports
- Quality Control Reports
- Laboratory QC and Results Reports
- Side Effects Report