MATRIX-001 Study-Specific Procedures (SSP) Manual
Section 14 – Study Reporting Plan for Clinical Data

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14 Introduction

This reporting plan describes the routine reports that the FHI Data Management & Statistical Support team plans to generate for MATRIX-001. MATRIX-001 data will be collected in the OpenClinica database. All reports listed here will be derived from the data entered at the time the report is generated. OpenClinica is structured for direct-entry data capture, however, there are many circumstances which could lead to data entry lag time. Reports cannot accommodate or adjust for data that is not yet entered into OpenClinica.

Table 1: MATRIX-001 Data Management & Statistical Support Staff

Job Role	Name	Email Address
Protocol Statistician	Rachael Fuchs	RFuchs@fhi360.org
Clinical Data Manager	Michele Fanton	MFanton@fhi360.org

14.1 Purpose of Reporting Plan

This reporting plan was prepared by the MATRIX-001 Clinical Data Manager in collaboration with the Protocol Statistician. The purpose of this plan is to:

- Identify the content of each report
- Identify those responsible for the preparation and distribution of each report
- Identify who should review the reports, and indicate the process if follow-up is necessary (reports requiring a response are marked with *)

14.2 Study Reports

Data Quality Reports with specific parameters are developed by the Protocol Statistician and the Clinical Data Manager within OpenClinica. A Project Dashboard will be set up in OpenClinica to use as a quick reference for site Accrual and Screen-outs, which are updated in real time. Table 2 includes a listing of the reports available within OpenClinica in the Project Dashboard application. Table 3 shows the list of reports that will be available on the MATRIX Website. Table 4 includes reports to be sent via email; these are primarily safety-related reports. The Clinical Data Manager and Protocol Statistician have access to all of the reports listed in the tables below.

Table 2: MATRIX-001 Reports Available in OpenClinica

Report Title	Permissions List
Overall number of Screens, screens by site	Staff with access to the Study in OpenClinica
Overall number of Enrollments, enrollments by site	Staff with access to the Study in OpenClinica
Overall number of Screen Outs, screen outs by site	Staff with access to the Study in OpenClinica

Table 3: MATRIX-001 Reports Available on Website

Report Title	Update Frequency	Viewing Area
Overall and by site: Screening, Enrollment, and Screen outs	Weekly	secure
Recruitment/Accrual summary	Monthly	secure
Retention: Overall, by visit and by site	Monthly	secure
Evaluable participants by site	Monthly	secure
Missed Visit listing	Monthly	secure
Missed Visit Summary	Monthly	secure
Protocol Deviations and Enrollment Violations listing	Monthly	secure
Protocol Deviation and Enrollment Violations summary	Quarterly	secure
Adverse Event listing (blinded)	Monthly	secure
Adverse Event Summary (blinded)	Quarterly	secure
Social Harms summary	Quarterly	secure
Data Management Quality Report and summary	Quarterly	secure

Table 4: MATRIX-001 Reports Distributed via Email

Report Title	Distribution Frequency	Email Distribution List
*Site specific queries	No less than biweekly	Each site coordinator, separately
*Serious Adverse Event (SAE) or Grade 3 Related Adverse Event (AE) submission into OpenClinica	24-72 hours after entry into OpenClinica	Protocol Safety Review Team (PSRT)
Adverse Event listing	At Study Completion	Independent Safety Physician

Adverse Event summary	At Study Completion	Independent Safety Physician

*Report requires a response

Reports available in OpenClinica and updated weekly on the Matrix website:

1. Overall and by-site screening, enrollment, and screen-outs

Purpose: To provide a quick summary of the number of participants screened, enrolled, and screened-but-not-enrolled (screen outs) overall and by site, as reflected by data entered into the study database.
Components: Number screened, number enrolled, number screened out.

Reports available on the Matrix website:

1. Recruitment/Accrual Summary

Purpose: To provide a more detailed summary of the number of participants screened, enrolled and screened out, overall and by site, as reflected by data entered into the study database.
Components: Number screened, number enrolled, screen-to-enroll ratio, number screened out per protocol specific reason for ineligibility; also to include site activation date, date of first and last enrollments, and duration of accrual.

2. Retention Overall, by visit and by site

Purpose: To report on participant visit retention, as reflected by data entered into the study database.
Components: Overall, by site and by visit, the number of participants expected to have completed the visit, the number of participants who have completed the visit, the number of participants who have not completed the visit, the number of participants who missed the visit beyond window, adjusting for participants who have terminated early.

3. Evaluable Participants by site

Purpose: To provide the number of participants who are evaluable, as reflected by data entered into the study database.
Components: Overall and by site, documentation of completion of V6.

4. Missed Visit Listing

Purpose: To identify participants who have missed scheduled study visits, to help sites focus retention efforts.
Components: Site-specific listing of cumulative missed visits per the case report form (CRF) used to document missed visits; includes for each PTID, the enrollment date, visit name, start and end of visit window, and reason for missed visit if documented.

5. Missed Visit Summary

Purpose: To provide a cumulative summary of all missed visits for the study.
Components: Overall and by site, the number and percentages of missed visits reported for the study, as documented on the CRF tracking missed visits.

6. Protocol Deviations and Enrollment Violations Listing

Purpose: To provide a cumulative listing of all protocol deviations and enrollment violations reported for the study.
Components: Date of deviation, description of deviation and type of deviation, as recorded on the Protocol Deviation Log in the study database.

7. Protocol Deviation and Enrollment Violation Summary

Purpose: To summarize the reported Protocol Deviations and Enrollment Violations.
Components: Overall and by-site, the number and percentages of protocol deviations reported for the study.

8. Adverse Event Listing (blinded)

Purpose: To provide a listing of all reported AEs documented on the Adverse Event Log in the study database, excluding randomization group.
Components: Overall and by site, provides a cumulative line listing of all AEs reported including: AE Term, Date/Visit reported, onset, severity grade, whether the AE was a worsening of a baseline medical condition, action taken with study product, a determination of relatedness to study product, and status/outcome. SAEs will be included. New or updated AEs will be highlighted for easy reference.

9. Adverse Event Summary (blinded)

Purpose: To provide a summary of all reported AEs documented on the Adverse Event Log in the study database, excluding randomization group.
Components: Summary of AEs by term, severity grade, and relatedness.

10. Social Harms Summary

Purpose: To provide a summary of the Social Harms reported within the study database.
Components: Social Harm type, impact on quality of life, and physical harm assessment.

11. Data Management Quality Report and Summary

Purpose: To provide summary information on site performance regarding data management quality metrics.
Components: By site, number of queries submitted, queries per CRF completed, on-time query response rate; AEs entered on time (within 3 days of site awareness) based on dates entered into the study database.

Reports distributed through email:

1. Site specific Queries

Purpose: To provide each site with specific data management queries requiring data to be entered/updated within the study database.
Components: Missing values, incomplete or inconsistent data, lack of documenting missed visits and screen outs, and any other query identified by the CTH Data Management & Statistical Support team. Queries or questions found during a monitoring visit, or from a clinical review are not counted as data management queries. Site Coordinators should review the queries and make changes to the database as needed. If there is a concern that a query has been identified which they do not believe to be a query, the Clinical Data Manager should be contacted.

2. SAE or Grade 3 Related AE submission into OpenClinica

Purpose: To provide the PSRT with timely notification of an SAE or Grade 3 related AE.
Components: The entire submitted CRF is downloaded to pdf, saved by the CTH Data Management & Statistical Support team, and forwarded to the PSRT. The PSRT then reviews the submission, and if needed follows-up requesting the site provide additional information, otherwise acknowledges receipt of the SAE or Grade 3 related AE.

3. Adverse Event Listing

Purpose: To provide a listing of all reported AEs documented on the Adverse Event Log in the study database, may include randomization group.
Components: Overall and by site, provides a cumulative line listing of all AEs reported including: AE Term, Date/Visit reported, onset, severity grade, whether the AE was a worsening of a baseline medical condition, action taken with study product, a determination of relatedness to study product, and status/outcome. SAEs will be included.

4. Adverse Event Summary

Purpose: To provide a summary of all reported AEs documented on the Adverse Event Log in the study database, may include randomization group.
Components: Summary of AEs by term, severity grade, and relatedness.