MATRIX-001 Data Communique #1

Data Communique Category:
☒ change to Clinical CRF ☒ change to SBR CRF ☐ change to CCG ☐ Other, specify:

Brief Description: MATRIX-001 Case Report Form Edits

The purpose of this Data Communique document is to inform sites about updates and edits to MATRIX-001 CRFs in OpenClinica and provide further guidance. The forms have been updated in OpenClinica as well as the in the updated CRF binder attached in the email and found on the MATRIX-001 Study Documents web page. Instructions on the implementation of these changes as follows:

1. Clinician Observation Form (CO)

An error was found in the skip pattern applied to Q6 of the Clinician Observation Form, erroneously ending the form, rather than skipping to Q8. This has been corrected on the CRF.

Please replace Clinician Observation Form Version 2.0 dated 14 October 2023 with Clinician Observation Form Version 3.0 dated 30Jan2024. Please review and update any translated forms to ensure that the skip pattern is corrected.

2. Concomitant Medication Form (CM)

The following edits were made to reduce queries associated with cross referencing of concomitant medications and medical conditions reported by participants in the MATRIX-001 trial.

Item 8 *Continuing at end of study* has had ***at end of study*** removed.

Item 9 *Related to AE or Medical History* has had ***MMH #*** removed.

Please replace CM form Version 2.0 dated 25Oct2023 with CM form Version 3.0 dated 01Mar2024.

3. Point of Care Form (POC)

To align with SSP guidance, item 4 *Urine Dipstick* now includes results for ***Blood: positive/negative***.

Please replace POC form Version 2.0 dated 25Oct2023 with POC form Version 3.0 dated 01Mar2024. No retrospective addition of data needs to be done for prior participant visits. Sites will include the new data on POC at participants' visits moving forward from date of this data communique.

Clarification for US site (EVMS CRC), HIV test results conducted at LabCorp are to be captured on the POC CRF for HIV test #1.

4. Specimen Storage Form (SPECST)

Item 1 *Plasma storage*: the word ***storage*** has been removed since the plasma is not specifically collected for storage.

Please replace SPECST form Version 2.0 dated 25Oct2023 with SPECST form Version 3.0 dated 01Mar2024.

5. Protocol Deviation Form (PD)

Item 4 *Type of deviation* had an option added for ***Clinically indicated prohibited medication***.

Please replace PD form Version 2.0 dated 25Oct2023 with PD form Version 3.0 dated 01Mar2024. **NOTE:** Sites will need to enter details of the concomitant medication and any other applicable information in the text box in item 5 *Description*.

6. Pre-existing Medical Conditions Form (PMC)

Item 3 *Is this condition being treated with medications* has had the ***specify CM#*** removed.

Please replace PMC form Version 2.0 dated 25Oct2023 with PMC form Version 3.0 dated 01Mar2024.

7. General Guidance for data collected on SBR forms

   Data collected through SBR forms is separate from clinical data that is collected. Discrepancies may occur between the SBR and clinical data and reconciliation is not needed. If a participant reports a social harm or safety issue, SBR staff should ensure this has been reported to the clinical team and documented in the participant record.

Anne Heath

Electronically signed by: Anne Heath
Reason: I have read this document and approved via Esignature
Date: Mar 13, 2024 14:13 EDT

03/13/2024

Name of Approver: Anne Heath
Title: FHI 360 Data Manager

Date

Data Communique memos, once signed, must be distributed to MATRIX sites via email. Sites are responsible for ensuring that appropriate staff review and understand the content of each memo and file the memo with their essential documents. Data Communique memos must also be posted to the appropriate MATRIX webpage. As per SSP section 13, the memos are official study documentation and will be considered an official part of the MATRIX SSP Manual. The Data Communique Memo becomes effective the date it is signed.

MATRIX-001 Data Communique 1_13Mar24

Final Audit Report 2024-03-13

Created:	2024-03-13
By:	Samantha McGohan (McGohaSF@evms.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAeqagfBcfLRlRIPuJ2kYmCHFJ6pba-alX

"MATRIX-001 Data Communique 1_13Mar24" History

Document created by Samantha McGohan (McGohaSF@evms.edu)
2024-03-13 - 2:50:04 PM GMT

Document emailed to aheath@fhi360.org for signature
2024-03-13 - 2:51:33 PM GMT

Email viewed by aheath@fhi360.org
2024-03-13 - 6:12:10 PM GMT

Signer aheath@fhi360.org entered name at signing as Anne Heath
2024-03-13 - 6:13:11 PM GMT

Document e-signed by Anne Heath (aheath@fhi360.org)
Signing reason: I have read this document and approved via Esignature
Signature Date: 2024-03-13 - 6:13:13 PM GMT - Time Source: server

Agreement completed.
2024-03-13 - 6:13:13 PM GMT