



MATRIX-003 Data Communique #1

Data Communique Category:

change to Clinical CRF change to SBR CRF change to CCG Other, specify: Addition of SBR Logs

Brief Description: Updates to clinical and SBR CRFs and addition of PRN Expulsion and PRN Sexual Partner Events Logs

The following provides instructions on the implementation of these changes:

1. Addition of PRN Expulsion Log

To better capture instances of expulsion and removal of the study product, a "PRN Expulsion Log" is being added to the data collection materials packet for MATRIX-003. This form is not participant facing and should be used if/when a participant reports removing the IVR or the IVR coming out partially or fully at any time other than a visit where the FU2, FU3 or FU4 CRF is administered (i.e., in between visits/interim visit). The goal is to capture details of the removal or expulsion to help understand the circumstances around these experiences.

2. Addition of PRN Sexual Partner Events Log

To better capture instances of sexual partner experiences, a "PRN Sexual Partner Events Log" (SPE) is being added to the data collection materials packet for MATRIX-003. This form is not participant facing and should be used if/when an event or complaint *for the sexual partner* related to the study participant's use of the IVR during the study is reported (by the participant or the sexual partner, as relevant).

3. Updates to clinical CRF

Additional questions about parity and mode of delivery have been added to the Baseline Medical and Menstrual CRF, to ascertain whether prior pregnancy history might be associated with an increased risk of ring expulsion.

4. Updates to SBR CRFs

Additional questions and minor edits have been added to three MATRIX-003 sociobehavioral CRFs, as specified in the bulleted list below. No additions or edits will affect participant-facing material, and therefore sites do not need to make changes to existing translations. Sites should submit these updates to their ethics committees/IRBs as appropriate.

The following sociobehavioral CRFs have been updated:

- Clinician observation for removal (COR) CRF (v2.1): 2 new questions about ring inspections after removal
- Brief acceptability (FU4) CRF (v2.1): Minor edit to correct skip pattern
- Sexual partner demographics (SPDEM) CRF (v2.1): Minor edit to correct skip pattern

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.

DocuSigned by:

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5/2/2024

Cecilia Milford, PhD
MATRIX D2D Pillar 2 Representative

Date