



MATRIX-002 Data Communique #1

Data Communique Category:

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

Brief Description: Updates to sociobehavioral CRFs, addition of PRN Expulsion Log, distribution of CRFs as posted to website

The following provides instructions on the implementation of these changes:

1. Updates to sociobehavioral CRFs

Additional questions and response options have been added to three MATRIX-002 sociobehavioral CRFs, as specified in the bulleted list below. Sites have been instructed to translate and submit these changes to their ethics committees/IRBs as appropriate. Sites will start/continue to collect data using the currently approved sociobehavioral CRFs (v2.1) on REDCap or paper forms (as needed) until their IRBs have approved the new data collection instruments. Sites will only use the new versions (v2.2 for FU3 and FU4, v3.0 for FU2) of these forms once they have received IRB approval. Upon receiving IRB approval, each site should immediately inform Enyonam Odoom and Tracy Zamborsky to facilitate access to the updated forms on REDCap.

The following sociobehavioral CRFs have been updated:

- Brief acceptability (FU2) CRF (v3.0)
 - 7 new questions about film expulsions
 - Minor edits to question wordings
- Follow-up behavioral and acceptability (FU3) CRF (v2.2)
 - Additional *N/A* response options added
 - Additional interviewer instructions added
- Final behavioral and acceptability (FU4) CRF (v2.2)
 - Additional *N/A* response options added
 - Additional interviewer instructions added

2. Addition of PRN Expulsion Log

To better capture instances of expulsions of the study product, a "PRN Expulsion Log" is being added to the data collection materials packet for MATRIX-002. This form is not participant facing and should be used if/when a participant reports film coming out partially or fully at any time other than a visit where the FU2 CRF is administered (i.e., in between visits/interim visit or at V6/V9). The goal is to capture details of the partial/full expulsion to help understand the circumstances around the expulsion.

3. SBR CRFs in format as posted to website

Please note that alongside this Data Communique, a zip file has been attached that includes all updated SBR CRFs as described above, with additional header/footer information that matches the forms as posted to the website for use in situations where direct entry into REDCap is not possible. As always, please download forms for printing from the website when possible.

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:

Alexandra Minnis

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Alexandra Minnis, PhD, MPH
MATRIX-002 Protocol Co-Chair

2/22/2024

Date