



MATRIX-002 Data Communique # 2

Data Communique Category:

change to Clinical CRF change to SBR CRF change to CCG Other, specify:

Brief Description: Modification to Protocol Deviation Log CRF to include the category option of "Participant non-compliance" for type of deviation.

The purpose of this Data Communique document is to inform study staff of the additional category on the Protocol Deviation CRF.

The following provides instructions on the implementation of these changes:

The update to the paper CRF and REDCap eCRF will take effect 12APR2024. Please begin using the updated versions immediately. The Protocol Deviation Log CRF (v1.1 12APR2024) and the updated Data Collection Materials Table of Contents (v2.2, 12Apr2024) have been submitted for website publication.

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:

Leslie Meyn



Signer Name: Leslie Meyn

Signing Reason: I approve this document

Signing Time: 4/12/2024 | 2:01:29 PM EDT

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4/12/2024

Leslie Meyn, PhD
Protocol Statistician

Date