



MATRIX-002 Operational Guidance # 01

Operational Guidance Category:

- Clinical Procedures Pharmacy Laboratory Other, specify:

Brief Description: Original Pharmacy Manual

The MATRIX-002 Pharmacy Manual version 1.0, 09 Jul 2023 stated the original MATRIX-002 Randomization Sheet was provided to the pharmacist and the certified copy was filed in the participant’s chart. However, this is discrepant from what is in the SSP Manual, Section 06: Study Product Considerations for Non-pharmacy Staff and what was decided across MATRIX studies. The Pharmacy Manual was updated to version 2.0, 28 Mar 2024 to be consistent with the SSP manual. The MATRIX-002 original Randomization Sheet is to be filed in the participant chart, and the certified copy of the Randomization Sheet is provided to the pharmacist and maintained in the pharmacy with the original MATRIX-002 prescription.

Operational Guidance 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. Operational Guidance 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 Operational Memo becomes effective the date it is signed.

DocuSigned by:

Cindy Jacobson

Signer Name: Cindy Jacobson
 Signing Reason: I am the author of this document
 Signing Time: 4/5/2024 | 1:46:47 PM PDT

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4/5/2024

Cindy Jacobson, PharmD
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Date