



### MATRIX-003, SBR Operational Guidance #1

#### Operational Guidance Category:

- Clinical Procedures   
  Pharmacy   
  Laboratory   
  Other, specify: SBR

#### Brief Description: Capturing additional details on the EXP CRF; updating Visit Checklists

The purpose of this Operational Guidance document is to clarify use of the Expulsion Log CRF (EXP) and to clarify the order of SBR CRF administration during V5 and V9 in the Visit Checklists.

- 1) The EXP CRF should capture details of any experiences with the use of the study product that are not readily captured in regular visit CRFs. These may include experiences with ring removal, ring expulsion (partial or full), problems with ring reinsertion, or any other unusual experiences that are not otherwise captured. As an ongoing log, site staff can create new instances of the EXP CRF to note unusual occurrences, and should utilize the Notes field at the bottom of this form to provide further details.

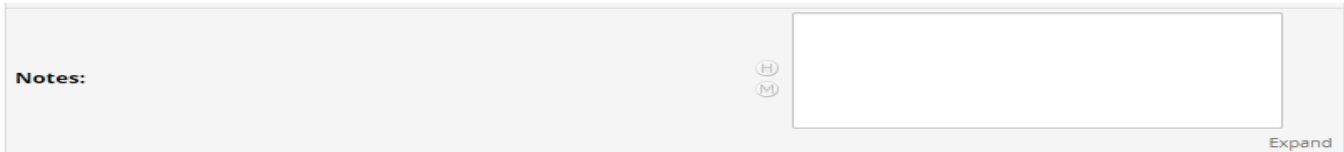



Figure 1. Example of Notes field in REDCap

- 2) Sites should update their Visit Checklists for Visit 5 and Visit 9 to move the administration of the FU4 CRF to after ring removal procedures. The FU4 CRF contains questions around participants' experiences of ring removal, so it is necessary for the removal to have been completed prior to administering this CRF; all SBR CRFs should continue to be administered prior to Product Use Counseling.

DocuSigned by:  
  
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 MATRIX D2D Pillar 2

5/1/2024  
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 Date

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.