

MTN-016

Source Documentation



Chart Notes

- Explain why procedures in addition to those listed on a checklist were performed
- Explain why procedures listed on a checklist were not performed
- Document procedures performed at interim visits
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements)

Source Documentation

- Informed Consent forms/ comprehension checklists/ coversheets
- Medical Chart
- Lab Results Forms
- Non-CRF Trial Forms
 - Visit Checklist/ Flow Sheet Notes
- Parent Protocol CRFs as Source
- MTN-016 CRFs as Source

Wild Card Question

- EMBRACE and VOICE have some similar CRFs...how many can you name?

Source Documentation

- VOICE and 016 have some similar CRFs
 - Woman Con Med Log
 - Woman Social Harms Assessment Log
 - Woman Medical History Log
 - Pregnancy Report & History
 - Pregnancy Outcome

Source Documents

Can you name the method the MTN-016 SSP suggests for note-taking during participant visits?

Hint: The answer is in the SSP, Section 3:
Documentation

Hint #2: The answer is on page 3-10