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
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