

FOLLOW-UP CONSIDERATIONS

MTN-017 Study-Specific Training



FOLLOW-UP VISITS

- Initiate Period Visits (Visits 5 and 8)
- Mid-Period Visits (Visits 3, 6 and 9)
- Period End Visits (Visits 4, 7 and 10)
- Phone calls (48-72 hours and 2-Weeks)
- Interim Visits
- Missed Visits

PROCEDURES COMPLETED AT EVERY SCHEDULE CLINIC FOLLOW-UP VISITS

Administrative/ Regulatory:

- Review/update locator information
- Provide reimbursement
- Schedule next visit/contact
- Provide available test results
- Provide condoms

Clinical:

- Review/update medical history
- Perform rectal exam
- Record/update adverse events
- Review/update concomitant medications
- Offer Hepatitis B vaccination
- Provide STI/RTI treatment if needed

INITIATE PERIOD 2 AND 3 VISITS

- Protocol Adherence
- Product Use Instructions
- Product Adherence
- SMS Training

Behavioral



- Sponge for Adherence PK
- Sponge for PD

Lab



- Provide study product (new regimen) and study lubricant if in a gel use regimen
- Observe/simulate product use
- Provide male condoms

Study Product



MID-PERIOD VISITS

- HIV pre- and post-test
- HIV/STI risk reduction
- Protocol Adherence
- Product Use
- Product Adherence
- Conduct Data Convergence Interview

Behavioral/Counseling



- Rectal Sponge for Adherence PK
- Rectal Sponge for PD
- Blood for HIV Serology
- Blood for PK

Lab



- Provide study product (resupply) and study lubricant if in the gel use period
- Collect unused study product
- Provide male condoms

Study Product



PERIOD 1 AND 2 END VISITS

- HIV pre- and post-test
- HIV/STI risk reduction
- Administer Follow Up CASI Behavioral Questionnaire
- Conduct PK Data and Data Convergence Interviews
- Conduct In-Depth Interview (Selected subset at Period 1 End Only)

Behavioral/Counseling



- Rectal Sponge for Adherence PK
- Rectal Sponge for PD
- Rectal swab for GC/CT
- Blood for HIV Serology
- Blood for PK
- Blood for Plasma Storage
- Blood for Creatinine

Lab



- Collect unused product
- Provide male condoms

Study Product



PERIOD 3 END/FINAL CLINIC VISIT

- HIV pre- and post-test
- HIV/STI risk reduction
- Administer Follow Up CASI Behavioral Questionnaire
- Conduct PK Data and Data Convergence Interviews

Behavioral/Counseling



- Rectal Sponge for Adherence PK
- Rectal Sponge for PD
- Rectal swab for GC/CT
- Blood for HIV Serology
- Blood for PK
- Blood for Plasma Storage
- Blood for Serum Chemistries, CBC with platelets and diff
- Urine NAAT for GC/CT

Lab



- Collect unused product
- Provide male condoms

Study Product



- Provide AE Dial-In Instructions

Administrative



Triv?a



INITIATE PERIOD VISITS

Which procedure is required at every follow-up visits but is not required at the Enrollment/Initiate Period 1 visit?

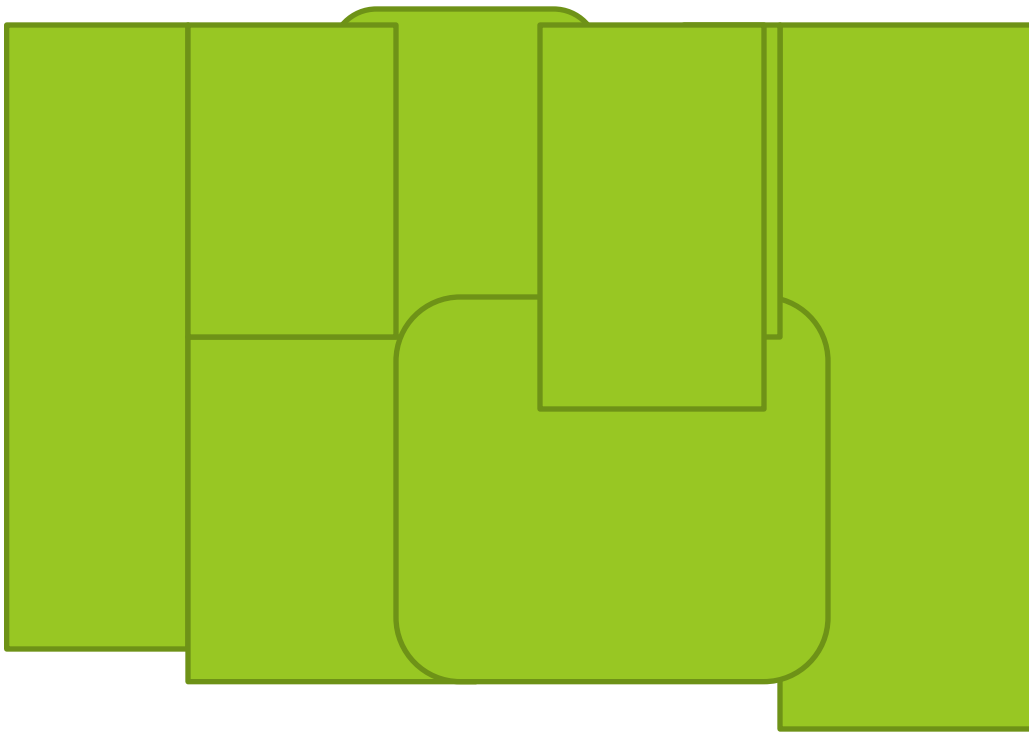
Could you tell me why?

INITIATE PERIOD VISITS

Which procedures are required at every visit with the exception of the Initiate Period Visit 2 and 3?

In which case would these procedures be done at the Initiate Period Visit 2 and 3?

CAN YOU GUESS THE PICTURE?



END PERIOD VISIT

Which procedures are required at every follow-up visits, with the exception of the End Period Visits?

END PERIOD VISIT

Which procedures are done only at the
End Period Visits?

Which procedure is only done at the
End Period 1 Visit (Visit 4)?

END PERIOD VISIT

Which follow-up procedures are only required at the Period 3 End Visit (Visit 10/Final Clinic visit)?

1. Provision of AE dial-in instruction
2. Physical Exam
3. Urine collection
4. Blood collection
5. All the above
6. 1 and 2
7. 2 and 4
8. 1, 2 and 3

END PERIOD VISIT

What follow-up laboratory blood samples are only done at the Period 3 End Visit (Visit 10/Final Clinic visit)?

- a. CBC with differential and platelets
- b. AST/ALT
- c. Creatinine
- d. a and c
- e. b and d
- f. a and b

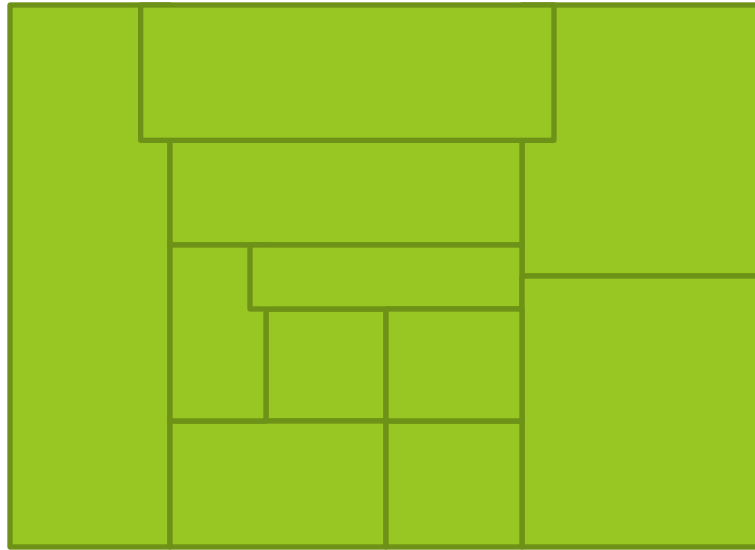
EARLY TERMINATION VISIT

If a participant terminates early from the study, which procedures should be done at the participant's last study visit?

PHONE CALLS

- Two phone calls following the Initiate Period Visit (Period 1, 2, and 3)
 - 48-72 hours following the expected date of study product initiation for each period.
 - Two weeks following the expected date of study product initiation for each period.
- All participants will be instructed to call-in to the clinic to report any new or worsening AEs within 7 days following the Final Clinic Visit 10 (Week 26).

CAN YOU GUESS THE PICTURE?



INTERIM VISITS

WHAT ARE THEY AND WHY ARE THEY DONE?

- Visits that take place between scheduled visits.
- There are a number of reasons why interim visits may take place, can you provide some examples?

INTERIM VISITS

- Are there any procedures that, per protocol, are required at interim visits?
 - Procedures required during an interim visit will depend on the reason for the visit.
- All interim contacts (e.g., phone calls and/or clinic visits) will be properly documented in study files and on applicable CRFs.

MISSED VISITS

For participants who do not complete any part of a scheduled visit within the allowable visit window, the visit is considered “missed” and a Missed Visit case report form must be completed to document the missed visit.

MISSED PERIOD END VISITS

- For participants that miss a Period End Visit (Visit 4, 7, and 10), the following missed procedures must be performed the next time participant presents to the site [e.g. Initiate Period Visits (Visits 5 and 8)]
 - Collection of unused study product
 - Collect Blood for HIV testing and counseling; Creatinine; and Plasma for storage
 - Conduct Data and PK Data Convergence Interviews
 - Administer Follow Up CASI Behavioral Questionnaire
 - Conduct In-Depth Phone Interview (only if Visit 4 is missed)
 - Rectal swab for CG/CT

MISSED PERIOD END VISITS

If a participant misses a Period End Visit (Visit 4, 7, and 10), would PK/PD procedures be done next time participant presents to the clinic?

QUESTIONS ABOUT FOLLOW STUDY PROCEDURES?

Which section of the SSP manual should you review if you have any questions about follow-up visits?

REMINDERS FOR FOLLOW-UP VISITS

- Locator information must be obtained/reviewed at all study visits.
- HIV testing and counseling will be done at all visits with the exception of the Initiate Period visits (unless clinically indicated).
- Urine will be collected only at the Period End 3 Visit/Final Clinic Visit, unless clinically indicated.
- Physical exams will be done if clinically indicated at all visits except the Period End 3 Visit/Final Clinic Visit, where it is required.
- Medical history, rectal exams, AE assessment and documentation, and assessment of concomitant medications will be done at all study visits.
- Male condoms will be provided at all study visits.

REMINDERS FOR FOLLOW-UP VISITS

- Follow-up CASI will be done only at End Period visits. If a participant misses a visit when CASI is required, administer the missed CASI questionnaire the next time the participant presents to the clinic.
- Data Convergence Interviews will be conducted at the Mid-Period and End Period Visits. This interview will be conducted when there are discrepancies between adherence data collected via SMS, adherence data via study product counts and, when available, the PK data.

REMINDERS FOR FOLLOW-UP VISITS

- All participants will provide specimens for PK analysis:
 - Blood will be collected at Mid-Period and Period End visits for all participants.
 - Rectal fluid will be collected via sponge for PK and PD at all follow-up clinic visits for all participants.

What are your
questions about
follow-up visits?

