

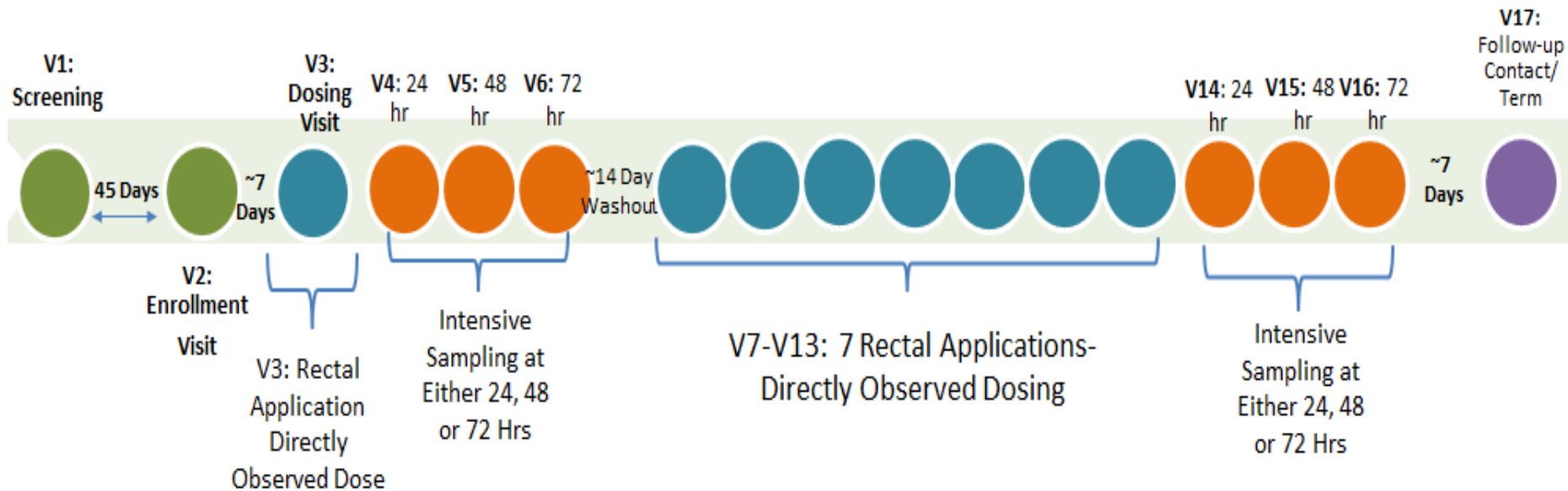
# MTN-026

## Follow-up Visit Requirements

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Study-Specific training

# Follow-up Visit Schedule



# Types of Follow-up Visits: Interim

- **Interim visits:** take place between scheduled visits.
  - All interim contacts (e.g., phone calls and/or clinic visits) will be documented in study files and on applicable CRFs
  - Procedures required will depend on the reason for the visit

# Visit 3-Dosing Visit (7 days after Enrollment)

- First product administration
- Samples required:
  - Blood for PK:
    - Hour 0 for all participants AND
    - Either 30-60 minutes or 120 minutes (2 hours) after product use based on participants' time assignment
  - Rectal Fluid and Tissue for PK/PD/Mucosal Safety
    - Either 30-60 minutes or 120 minutes (2 hours) after product use based on participants' time assignment

# Visits 4, 5 and 6 (Sampling Visits) 24, 48 or 72 hours *after* Visit 3

- Blood for PK
  - All participants will have blood collected at each of visits
- Samples required:
  - Pelvic Fluid/Tissue for PK/PD: Based on participants' day assignment
  - Rectal Fluid/Tissue for PK/PD: Based on participants' day assignment

# September 2017



Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5 Enrollment Visit (Day 0)	6	7	8	9
10	11	12 Single Dose Administration (Visit 3)	13 Visit 4 (~24 hours)	14 Visit 5 (~48 hours)	15 Visit 6 (~72 hours)	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30



# 14-day Washout Out Period

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- Occurs after Visit 6
- Minimum of 14 and a maximum of 28 days
- Should be timed to coincide with female participants' menses (i.e. avoiding female participants being on their menses during Study Visits 7-16)

# Visits 7-12

(7 daily directly-observed dose administration)

- Samples required:
  - Female participants: Urine for hCG: Visit 7
  - Blood for:
    - PK: Visit 7 (Hr. 0) and Visit 8 (24 hrs)
    - Plasma Storage: Visit 7
  - Rectal Fluid for PK:
    - Visits 7 (Hr. 0) and 8 (24 hrs)



# Visit 13

## (Last Dose/Early Termination)

- Samples required:
  - Blood for PK:
    - Hour 0 for all participants AND
    - Either 30-60 minutes or 120 minutes (2 hours) after product use based on participants' time assignment
  - Pelvic and Rectal Fluid/Tissue for PK/PD/Mucosal Safety:
    - Either 30-60 minutes or 120 minutes (2 hours) after product use based on participants' time assignment.

# Other Considerations for an Early Termination Visit

- If Visit 13 serves as an ET visit, sample collection will be based on timing of last dose
  - Plasma, vaginal and/or rectal fluid samples may be collected if rectal gel was applied within the previous 7 days, prior to the visit.
  - Tissue samples may be collected within three days of last product use. If product was not applied within the three days prior to the visit, tissue sample collection should not occur.

# Visits 14-16 (Sampling Visits) 24, 48 or 72 hours after Visit 13

- Samples required:
  - Urine for hCG: Visit 14
  - Blood for:
    - Safety Labs: Visit 16
  - Plasma for Storage: Visit 16
  - Plasma for PK: Visits 14, 15 and 16
  - Pelvic Fluid/Tissue: Based on participants' day assignment
  - Rectal Fluid/Tissue: Based on participants' day assignment

# October 2017

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4 Visit 7 (Dosing Visit) *Labs Required	5 Visit 8 (Dosing Visit) *Labs Required	6 Visit 9 (Dosing Visit)	7 Visit 10 (Dosing Visit)
8 Visit 11 (Dosing Visit)	9 Visit 12 (Dosing Visit)	10 Visit 13 (Final Dose) *Labs Required	11 Visit 14 (Sampling Visit) *Labs Required	12 Visit 15 (Sampling Visit) *Labs Required	13 Visit 16 (Sampling Visit) *Labs Required	14
15	16	17	18	19	20 Visit 17 (Follow-up Contact)	21
22	23	24	25	26	27	28
29	30	31				

# Pharmacokinetics, Pharmacodynamics, and Mucosal Safety Assignment

<b>Day Assignment</b>	<b>Sample collection window</b>
Visit 4: 24 Hours After Application of Study Product <b>Visit Code 4.0</b>	(+/- 1 hour)
Visit 5: 48 Hours After Application of Study Product <b>Visit Code 5.0</b>	(+/- 2 hours)
Visit 6: 72 Hours After Application of Study Product <b>Visit Code 6.0</b>	(+/- 4 hours)
Visit 14: 24 Hours After Last Application of Study Product <b>Visit code 14.0</b>	(+/- 1 hour)
Visit 15: 48 Hours After Last Application of Study Product <b>Visit code 15.0</b>	(+/- 2 hours)
Visit 16: 72 Hours After Last Application of Study Product <b>Visit code 16.0</b>	(+/- 4 hours)

# Visit 17 (Study Termination)

- Occurs 7 days after Visit 16 (last sampling visit)
- Allows for follow up of adverse events as well as healing of biopsy sites from last sampling visit
- May be scheduled as an in-clinic visit or as a phone call
- Dependent on results from labs collected during Visit 16 or if Visit 16 is missed and procedures need to be made up (e.g. HIV testing/counseling, plasma storage, and chemistries)

## TRIVIA??

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How many follow-up visits are participants expected to complete?

14 follow-up clinic visits plus a follow-up contact (in-person or by phone)

# Follow-up Visit Procedures

## Considerations

**At every follow up visit, the following will occur:**

- Review/update locator information
- Provide protocol counseling
- Review/update medical and/or menstrual history
- Provide available lab results
- Assess AEs
- Review/update concomitant medications
- Provide reimbursement
- Schedule next visit/contact
- Provide condoms (visit 6 only)



# Follow-up Visit Procedures

## Considerations

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- For female participants, pregnancy test is only required at visits 7 and 14
- HIV testing and counseling are only required at visits 7 and 16
- Chemistries are required only at visit 16

# TRIVIA??

List all study procedures that are only done if clinically indicated during follow up.

- Done only if clinically indicated:
  - Targeted physical exam
  - CBC with differential and platelets
  - Dipstick UA and Urine culture
  - NAAT for GC/CT
  - STI/RTI treatment

# Missed Visits

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- Visits not completed within the allowable visit window are considered “missed”
- Missed Visit case report form must be completed
- Follow your site-specific retention SOP for procedures to be done and proper documentation of efforts to contact participant

# Missed Visits (SSP Section 5)

- If a participant misses, when he/she returns to site for their next scheduled visit, in addition to protocol-specified procedures for the applicable visit, the following procedures need to be completed:
  - Visit 3: IDI and CASI
  - Visit 7: HIV testing/counseling and pregnancy testing
  - Visit 13: Collection of unused study product
  - Visit 14: Pregnancy test, IDI and CASI
  - Visit 16: HIV testing/counseling, plasma storage, and chemistries

# Missed Visits

If a participant misses Visit 13, but presents to the site for Visit 15, what procedures should be done?

- Protocol-required Visit 15 procedures
- Collection of unused study product
- Behavioral assessment (IDI and CASI)
- For female participants: Pregnancy test

# Participant Replacement

- Individuals lost to follow-up or to permanent product discontinuation may be replaced in consultation with the SDMC and study leadership.
- To ensure accurate study results are obtained, participants that meet the following criteria will be replaced:
  - Single Observed Dose (Visit 3) is missed
  - 7-Day Observed Product Administrations (Visits 7-13) are missed
- Note: to be replaced, the participant must miss all of the 7 observed daily doses. If the participant attends at least one of these visits, the participant does not need to be replaced.

# What are your questions?

