



# MTN-026 Screening and Enrollment Visit CRFs, Tools, and Processes

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Melissa Peda  
SCHARP  
Seattle, WA

# PTID Assignment

- PTID generated in Medidata Rave
- Unique 9 digit number
- MTN-026 PTID assignment is defined as completion of entry on MTN-026 PTID-Name Linkage Log

# PTID/Name Linkage Log

- Sample site-specific PTID/Name Linkage Log

	Participant ID	Name	Date ddMMMyy	Initials
1				
2				
3				
4				
5				
6				
7				

# Last Day to Enroll Calculator

## MTN-026 Calculation of Last Possible Day to Enroll

<b>Screening Visit Date:</b> <i>Date Screening/Enrollment Informed Consent form was marked or signed</i>	<div style="border: 1px dashed black; padding: 5px; background-color: #e0f2f7;">             Friday, September 01, 2017           </div>	<i>site to enter date</i>	<b>Instructions:</b> <ol style="list-style-type: none"> <li>1. Complete the participant's Screening Date by entering dd/mmm/yy. This will generate the last day that the participant can enroll.</li> <li>2. For female participants, enter the participant's estimated last day of menstrual bleeding during the Screening Window. Use this date when scheduling a participant's Enrollment Visit as menses must not coincide with Study Visits 2-6.</li> </ol>
<b>Last day to enroll based on 45-day screening window:</b>	Monday, October 16, 2017		
<b>Estimated Date of LAST day of menstrual bleeding:</b> <i>for female participants only</i>	Friday, September 08, 2017	<i>site to enter date</i>	

# CRF Completion and approach to training for MTN-026

- CRF Completion Guidelines (CCGs) to aid in form completion will be available on the MTN-026 ATLAS webpage
- Help text available on select items within Rave to provide key guidance on form completion
- Focus on CRF content/purpose of forms

# Screening CRFs

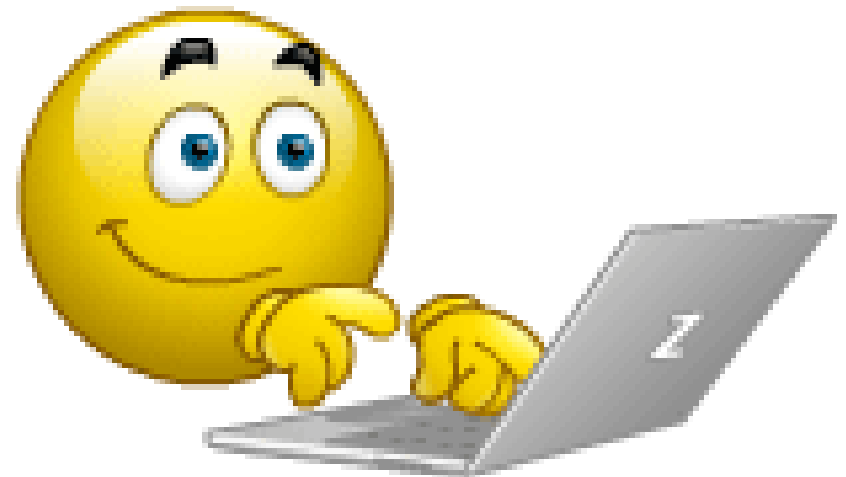
- Participant Date of Visit
- Demographics
- Baseline Medical History Summary and Log
- Concomitant Medications Summary and Log
- Eligibility Criteria
- Screening Menstrual History ♀
- Vital Signs
- Physical Exam
- Anorectal Exam
- Local Laboratory Results
- Hematology
- STI Tests
- HIV Test Results
- Pelvic Exam ♀
- Pregnancy Test ♀

# Screening CRFs

- Let's practice!

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# Screening Visit QA/QC

- Before participant leaves:
  - Review Screening Visit and Pelvic Exam checklist for completeness
  - Review Screening Behavioral Eligibility Worksheet for completeness
- Ensure lab requisition docs are in order
- Review exam forms (Anorectal Exam, Pelvic Exam ♀, Physical Exam, Vital Signs) and make sure all needed items entered on Baseline Medical Conditions Log
- Review completed CRFs based on participant responses to ensure completeness and consistency (Demographics, Baseline Medical History, Concomitant Medications, Screening Menstrual History)
- Complete Eligibility Criteria if participant will not proceed to Enrollment
- Make sure systems are in place for enrollment, including scheduling, participant files, Pharmacy is aware of potential enrollment, etc.



# Enrollment CRFs

- Randomization
- Enrollment
- Baseline Medical History Log (Updated)
- CASI Summary and Tracking
- Sexual Lubricant
- Vital Signs
- Physical Exam
- Anorectal Exam
- Specimen Storage
- Cervical Specimen Storage ♀
- Pelvic Exam ♀
- HIV Test Results
- Pregnancy Test ♀

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# Enrollment Visit QA/QC

- Before participant leaves:
  - Make sure eligibility is confirmed per SOP prior to Enrollment
  - Review visit checklist and Pelvic Exam checklist to make sure all required procedures completed
  - Review Enrollment Behavioral Eligibility Worksheet for completeness
- Ensure lab requisition docs are in order
- Review exam forms (Pelvic Exam ♀, Anorectal Exam, Physical Exam, Vital Signs) and make sure all needed items updated on Baseline Medical Conditions Log
- Review completed CRFs based on participant responses to ensure completeness and accuracy (Sexual Lubricant, Baseline Medical History, Concomitant Medications)
- If participant enrolled:
  - Ensure all Screening and Enrollment eCRFs completed in Medidata Rave.