



MTN-036 Screening and Enrollment Visit CRFs, Tools, and Processes

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PTID Assignment

- PTID generated in Medidata Rave
- Unique 9 digit number
- MTN-036 PTID assignment is defined as completion of entry on MTN-036 PTID-Name Linkage Log

PTID Assignment

- PTID structure within RAVE

CRS Name	DAIDS ID	Rave ID
Birmingham	31788	821
Bridge	30305	764

9 digits

XXX-YYYYYZ

RAVE ID Participant Number
+ Check digit

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-036/IPM 047 Calculation of Last Possible Day to Enroll

Screening Visit Date: <i>Date Screening/Enrollment Informed Consent form was marked or signed</i>	Monday, September 11, 2017	<i>site to enter date</i>
Estimated Date of LAST day of menstrual bleeding:	Sunday, August 28, 2016	<i>site to enter date</i>
Last day to enroll based on 45-day screening window:	Thursday, October 26, 2017	

Instructions:

1. Complete the participant's Screening Date by entering mm/dd/yy. This will generate the last day that the participant can enroll.
2. Enter the participant's estimated last day of menstrual bleeding during the Screening Window. Consider the timing of participant menses when scheduling the Enrollment Visit, to allow for 7 days of product use off menses.

CRF Completion and approach to training for MTN-036

- CRF Completion Guidelines (CCGs) to aid in form completion will be available on the MTN-036 ATLAS webpage
- Help text available on select items within Rave to provide key guidance on form completion
- Focus on CRF content/purpose of forms

MTN-036 EDC Approach

- Direct data entry of eCRFs into Medidata RAVE starting at Screening Visit
- RAVE system queries will be issued for all participants upon data entry of the Eligibility Criteria eCRF

MTN-036 EDC Approach

Once a participant's eligibility has been determined:

- If eligible and enrolled –
 - Complete Eligibility Criteria eCRF at Enrollment Visit
 - Respond to any queries on all Screening forms

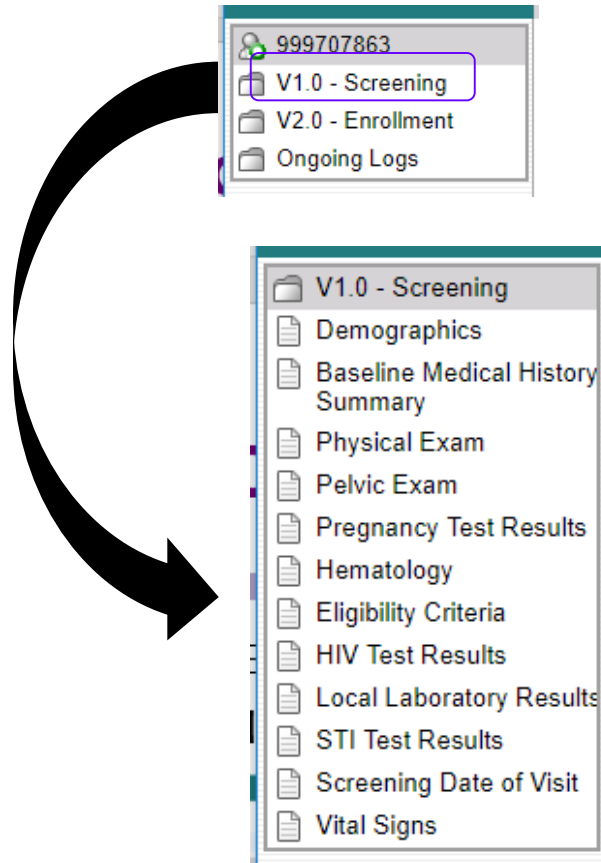
- If not eligible –
 - Complete Eligibility Criteria eCRF
 - Respond to any queries on the Eligibility form only
 - The SDMC will close any queries on all other forms
 - Other eCRFs completed during failed screening attempt may remain in study database and will not undergo QC review

Screening CRFs

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

Initial Population of Forms/Folders

- All forms for Screening and Enrollment are automatically generated within a participant's visit folder, including Ongoing Logs



Things to know about Screening Forms

- The Screening Date of Visit should be completed first
- The Demographics form should be filled out *prior to the Local Laboratory Results, Hematology and Vital Signs eCRFs*
 - *The age field is derived from date of birth and is used to generate laboratory reference ranges*
 - *Date of birth is trigger for height*
 - *These fields will display only at Screening*

Things to know about Screening Forms – Pelvic Exam

- No AEs expected at Screening or Enrollment

Subject: 999425057

Page: Pelvic Exam - V1 - Screening (1)



Exam date

1 SEP 2014



Pelvic exam assessment

No abnormal findings



Abnormal findings. Mark all that apply.

VULVAR

Vulvar lesions

VAGINAL

Abnormal vaginal discharge

Vaginal lesions

CERVICAL

Cervical lesions

GENERAL/OTHER

Were any new pelvic finding AEs reported at this visit?

No



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 (Pelvic Exam, Physical Exam, Vital Signs) and make sure all needed items entered on Baseline Medical History Log
- Review completed CRFs based on participant responses to ensure completeness and consistency (Demographics, Baseline Medical History, Concomitant Medications)
- Ensure particular attention paid to QC1 and QC2 process as RAVE system queries will only be issued upon completion of the Enrollment CRF at the Enrollment Visit.

Screening Visit QA/QC

- Complete Eligibility Criteria as applicable 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)
- Behavioral Summary and CASI Tracking
- Pharmacy Dispensation
- Vital Signs
- Physical Exam
- Specimen Storage
- HIV Test Results
- Cervical Specimen Storage
- Pelvic Exam
- Pregnancy Test Results
- Ring Insertion and Removal

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IDI Randomization

- Participants will be randomized to In Depth Interviews outside of Medidata Balance
 - MTN SDMC will provide separate IDI randomization lists to each site
 - After ring strength randomization in Balance, use Randomization ID to look up IDI group on IDI randomization list

Is the participant ready to be randomized?	Yes	📄
Randomization Date and Time [?]	11 SEP 2017 08:40:03	✅
Randomization date	11 SEP 2017	✅
Randomization ID	123456	✅

- Document IDI Randomization on Enrollment CRF

Page: Enrollment - V2.0 - Enrollment

Date the participant marked or signed the study screening and enrollment consent form

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Did the participant consent to long-term specimen storage and future testing?

Yes No

Was the participant randomized to participate in IDI (In Depth Interview)?

Yes No

Was the participant invited to participate in IDI?

Invited Not invited

Will this participant participate in IDI?

Yes No

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, 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 (Baseline Medical History, Concomitant Medications)
- Complete the Eligibility Criteria CRF (within the Screening Visit folder)

Enrollment Visit QA/QC

- For participants who screen-out:
- If participant enrolled:
 - Ensure all Screening and Enrollment eCRFs completed in Medidata Rave
 - System queries for Screening and Enrollment eCRFs will be issued upon completion of the Enrollment CRF

Questions?

