



Follow-up Visit CRFs and Other Tools

MTN-036 Study Specific Training

Visit Windows

MTN-036 Visit Windows				
All windows are in days, unless stated otherwise				
Visit	Visit Code	Target Day	Window Opens	Window Closes
Visit 1 - Screening	1.0	N/A	N/A	
Visit 2 - Day 0 Enrollment	2.0	0	Up to 45 days after screening informed consent date	
Visit 3 - Day 1	3.0	1	no window	
Visit 4 - Day 2	4.0	2	no window	
Visit 5 - Day 3	5.0	3	3	4
Visit 6 - Day 7 / Week 1	6.0	7	6	8
Visit 7 - Day 14 / Week 2	7.0	14	13	15
Visit 8 - Day 28 / Week 4	8.0	28	26	30
Visit 9 - Day 56 / Week 8	9.0	56	54	58
Visit 10 - Day 91 / Week 13 Product End Use Visit (PUEV)	10.0	91	89	93
Visit 11 - Day 92/93/94* Final Contact	11.0	24 - 72 hours after PUEV (Visit 10)		

*NOTE: Visit 11 must occur between 24-72 hours after the PUEV (Visit 10); schedule within visit window accordingly.



Visit Calendar Tool

- An Excel file that can be used to create the follow-up visit schedule/calendar for a ppt with actual dates
- Requires entry of PTID, complete Enrollment Date, Visit 10 actual visit dates
- For each required follow-up visit, the target date, and allowable windows (if applicable) are generated
- Blank column provided for site to write-in actual visit dates
- For easy reference, print and place in the ppt's study notebook once ppt has enrolled

Visit Calendar Tool

MTN-036/IPM 047 Participant Visit Calendar								
PTID:		999-9999-9-0			Staff Initials:			
Enrollment Date:		11-Sep-17						
		<i>dd/mm/yy</i>						
Visit/Day	Visit Code	Visit Window Open		Visit Window Close		Target Visit Date		Actual Visit Date
Day 1	3.0		Same as target day		Same as target day	Tue	12-Sep-17	
Day 2	4.0		Same as target day		Same as target day	Wed	13-Sep-17	
Day 3	5.0		Same as target day	Fri	15-Sep-17	Thu	14-Sep-17	
Day 7	6.0	Sun	17-Sep-17	Tue	19-Sep-17	Mon	18-Sep-17	
Day 14	7.0	Sun	24-Sep-17	Tue	26-Sep-17	Mon	25-Sep-17	
Day 28	8.0	Sat	7-Oct-17	Wed	11-Oct-17	Mon	9-Oct-17	
Day 56	9.0	Sat	4-Nov-17	Wed	8-Nov-17	Mon	6-Nov-17	
Day 91 (PUEV)*	10.0	Sat	9-Dec-17	Wed	13-Dec-17	Mon	11-Dec-17	12-Dec-17
24 - 72 hours after PUEV (Final Contact)**	11.0	Wed	13-Dec-17	Fri	15-Dec-17	Anywhere in window		

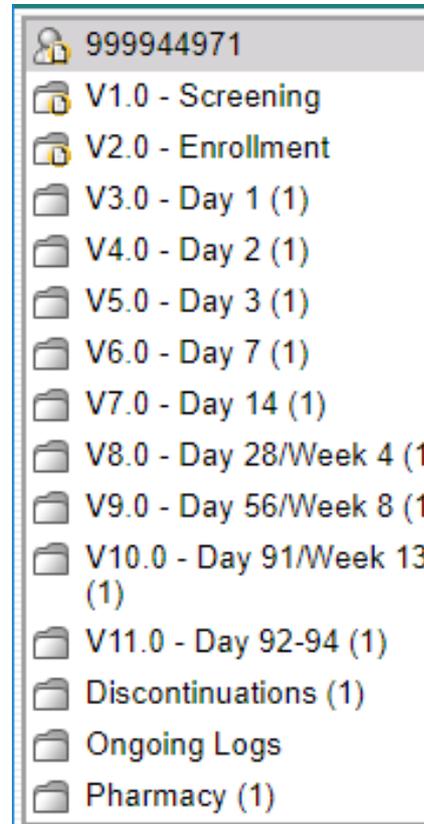
Instructions:

- Once a participant enrolls, enter the participant's ID (PTID), Staff Initials, and Enrollment Date (cells in green). This will generate the target dates and visit windows for follow-up visits through PUEV (Day 1 - Day 91).
- An actual visit date for Visit 10 must be entered to generate the visit window for Visit 11.
- Follow-up visits should be conducted on the Target Visit Date whenever possible. However, study visits can occur within the defined visit windows when absolutely necessary.
- As the participant completes her Follow-up Visits, record the date the visit was completed in the "Actual Visit Date" column (cells in blue).
- Print the calendar and place in the participant's study notebook. Sites may provide participants with a list of scheduled visit dates to assist with scheduling.

* Per protocol section 7.5.3, in the event of early permanent discontinuation of study product use, participants will be asked to complete an interim visit where all of the Visit 10-Day 91/Product Use End Visit (PUEV)/Early Termination procedures will be conducted.

Visit Codes

Visit	Visit Code
Screening	1.0
Enrollment	2.0
Day 1	3.0
Day 2	4.0
Day 3	5.0
Day 7	6.0
Day 14	7.0
Day 28/Week 4	8.0
Day 56/Week 8	9.0
Day 91/Week 13	10.0
Day 92-94	11.0



Visit name and visit code automatically appear in Medidata Rave in pre-defined study visit folders

Folder Dynamics During Follow-up

MTN026 Test site 2 999478554 V7.0 - Dosing (1) Follow-up Y/N

Subject: 999478554
Page: Follow-up Y/N - V7.0 - Dosing (1)

Did the participant complete this visit? Yes No

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CRF Version 501 - Page Generated: 23 Aug 2017 12:32:36 Pacific Daylight Time

Save Cancel

Display of forms for scheduled study visits dependent upon 1 form – Follow-up Y/N

V7.0 - Dosing (1)

Follow-up Y/N

Follow-up Visit Summary

Sexual Lubricant

Pregnancy Test

HIV Test Results

Anorectal Exam

Specimen Storage

Subject: 999478554
Page: Follow-up Y/N - V7.0 - Dosing (1)

Did the participant complete this visit? Yes No

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Save Cancel

Population of Forms within Folders – Missed Visit

- If the participant did not complete the visit, selecting “No” for “Was this visit completed?” on Follow-up Y/N will populate the Missed Visit form within the participant’s folder.

V8.0 - Dosing (1)
Follow-up Y/N
CRF History

Subject: 999478554
Page: Follow-up Y/N - V8.0 - Dosing (1)

Did the participant complete this visit? Yes No

V8.0 - Dosing (1)
Follow-up Y/N
Missed Visit
CRF History

Subject: 999478554
Page: Follow-up Y/N - V8.0 - Dosing (1)

Did the participant complete this visit? Yes No

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Save Cancel

Missed Visits



- A follow-up visit is missed once allowable window closes if she has not completed any part of visit
 - If a visit does not have a window and the participant cannot come in on target day, the visit is considered missed.
 - E.g., participant completes Enrollment and Visit 3, but is not able to come back into the clinic until Visit 5. Visit 4 is considered missed.
- Missed visits are not made up. Rather, sites should make every attempt to retain ppts at future visits.

Missed Visits



- Missed visits are documented in the study database using the Missed Visit CRF.
- The Missed Visit form will let SCHARP know not to expect any other forms for that participant at that study visit (with the exception of the Follow-up Yes/No CRF).
- A Protocol Deviations form is not required for missed visits. The Missed Visit eCRF satisfies the necessary documentation for the PD.

Interim Visits

- Visits that take place between scheduled visits
 - Additional study procedures and/or data collection conducted outside of what is specified in protocol for required study visit (Example: Report of new AE, issue with study product, etc.)
 - Required study visit procedures conducted outside visit window, either to make up certain procedures from missed visit or conduct Visit 10 Early Termination Visit procedures due to early product discontinuation
- All interim contacts (e.g., phone calls and/or clinic visits) will be properly documented in study files and on applicable CRFs

Interim Visit Documentation

- Add an interim visit via the “Add Event” → will create an “Interim Visit” folder

The screenshot displays the SCHARP (Standardized Clinical Research and Reporting Platform) interface. At the top, the 'REVIEW' tab is active. The user is logged in as 'Melissa Peda (Clinical Research Coordinator)'. The main area shows a 'Participant Identifier' section with a table for 'Visit' and 'Date'. To the left, a sidebar lists various visit events: V1.0 - Screening, V2.0 - Enrollment, V3.0 - Day 1, V4.0 - Day 2, V5.0 - Day 3, V6.0 - Day 7, V7.0 - Day 14, V8.0 - Day 15, V9.0 - Day 16, Discontinuations, Ongoing Logs, and Pharmacy. Below this list is a 'CRF History' section. An 'Add Event' button is visible, with a dropdown menu open showing 'Interim Visit' as the selected option. A large black arrow points from the 'Interim Visit' option in the dropdown to a separate window showing the updated list of visit events, where 'Interim Visit (1)' has been added to the bottom of the list.

999180741

Participant Identifier

Visit	Date
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Task Summary: Subject

- Requiring Signature 9
- NonConformant Data 0
- Open Queries 2
- Ongoing Logs-Pregnancy Report and History
- Discontinuations-Treatment Discontinuation 1
- Overdue Data 0

Add Event

Interim Visit

CRF History

999180741 - Adv

V1.0 - Screening

V2.0 - Enrollment

V3.0 - Day 1

V4.0 - Day 2

V5.0 - Day 3

V6.0 - Day 7

V7.0 - Day 14

V8.0 - Day 15

V9.0 - Day 16

Discontinuations

Ongoing Logs

Pharmacy

Interim Visit (1)

Interim Visit Documentation

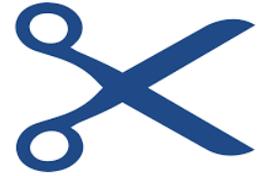
- One required form - Interim Visit Summary eCRF
- Interim Visit Summary CRF documents reason for interim visit and CRFs completed for it
- Select applicable procedures/forms and this will dynamically add the required forms.

Visit date	<input type="text"/> ... <input type="text"/>
Interim visit code	<input type="text"/>
Was study product use permanently discontinued (scheduled or early) at this visit?	<input type="radio"/> Yes <input type="radio"/> No
Did the participant exit/terminate the study at this visit?	<input type="radio"/> Yes <input type="radio"/> No
Were any new adverse events (AEs) reported at this visit?	<input type="radio"/> Yes <input type="radio"/> No
Is the participant taking any concomitant medications that have not been previously reported?	<input type="radio"/> Yes <input type="radio"/> No
Have any protocol deviations been reported at this visit?	<input type="radio"/> Yes <input type="radio"/> No
Reason for interim visit (Select all that apply.)	
AE report or follow-up	<input type="checkbox"/>
Return of product or need new product	<input type="checkbox"/>
Completion of missed visit procedures	<input type="checkbox"/>
If completion of missed visit procedures, for which visit are procedures being made up?	<input type="text"/>
Other	<input type="checkbox"/>
If other, specify	<input type="text"/>
What study procedures were completed at this visit? Select all that apply.	
Vital signs	<input type="checkbox"/>
Physical exam	<input type="checkbox"/>
Pelvic exam	<input type="checkbox"/>

Interim Visit Codes

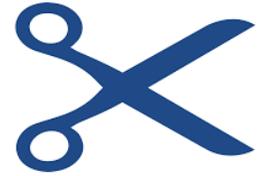
- If the interim contact results in at least one newly-completed eCRF, the interim visit is assigned an interim visit code.
- Interim visit codes use the box to the right of the decimal point – assign starting with .1
- For the numbers to the left of the decimal point, use the visit code of the most recently required visit, even if the interim visit date is in the next visit's window or if the visit was missed
 - The interim visit code will be a number in-between the two visit codes when the interim visit occurred
- E.g., a ppt has an interim visit 2 days after his/her Visit 6 to follow-up on an AE; assign interim visit code = 6.1 (in between Visits 6.0 and 7.0)

Split Visits



- A visit is a split visit when the required visit procedures are split (done) over 2 or more days
- The days must *all* fall within allowable visit window; any required procedures not done within allowable window are missed
- Enrollment Visit, Visits 3 & 4 cannot be split!
- For split visits, only 1 Follow-up Visit Summary eCRF is completed, and the Visit Date on this CRF is the date of the first part of the split visit
 - All CRFs completed for the split visit within the applicable study visit folder (e.g., CRFs completed for a split Visit 7 visit completed across Days 24 and 25 would all have visit code 7.0)

Split Visits



- Some procedures/collections should occur on the same day:
 - HIV pre- and post-test counseling and HIV testing
 - Any CASI questionnaire and behavioral-related CRFs completion
 - PK/PD and DVP specimens (blood, CVF, CVL, rectal, as applicable) to avoid complicating interpretability of the data
 - Ring Insertion and Removal CRF, Ring Adherence Y/N and Ring Adherence CRFs are completed on the same day the above specimens are collected to correlate VR use data with PK results

Follow-up Visits – Key CRFs

- ✓ Follow-up Yes/No & Follow-up Visit Summary
- ✓ Additional Study Procedures
- ✓ Pharmacy Dispensation
- ✓ Protocol Deviations Log
- ✓ Product Hold Summary & Log
- ✓ Product Discontinuation
- ✓ Ring Adherence (& Summary)
- ✓ Ring Insertion and Removal
- ✓ Study Discontinuation
- ✓ Interim Visit Summary
- ✓ Missed Visit



RAVE Visit Calendar

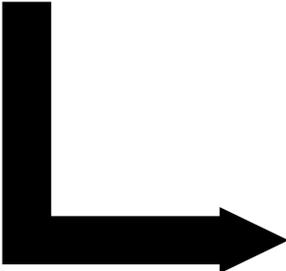
- Once the “Follow-up Yes/No” form has been entered, followed by the “Follow-up Visit Summary”, this will populate the actual Date on the participant’s Visit Calendar on the participant’s homepage.
- The next scheduled visit will appear with her *Target Visit Date* (gray). Once the “Follow-up Visit Summary” form has been entered, then this will populate with the *actual* visit date.

iMedidata Messages My Profile Help Home Logout
 You have 3 "Rave Modules" invitations in iMedidata. User: Melissa Peda (Clinical Research Coordinator)

TRAIN

Participant Identifier Grid View

Visit	Date	Task Summary: Subject	Pages
V1 - Screening (1)	01 Sep 2014	Requiring Signature	12
V2 - Enrollment (1)	20 Sep 2014	NonConformant Data	0
V3 - Month 1 (1)	18 Oct 2014	Open Queries	0
		Overdue Data	1



Visit	Date
V1 - Screening (1)	01 Sep 2014
V2 - Enrollment (1)	20 Sep 2014
V3 - Month 1 (1)	20 Oct 2014
V4 - Month 2 (1)	15 Nov 2014

Case Report Forms

- eCRF Rave output will be available as single PDF on MTN-036 ATLAS webpage
 - <https://atlas.scharp.org/cpas/project/MTN/036/begin.view?>
 - To be used as back-up (contingency) in event database cannot be accessed (e.g. temporary internet or power outage)
- Vision = EDC (NO paper CRFs)



Questions?

