Follow-up Visit CRFs and Other Tools

MTN-026 Study Specific Training

Visit Windows

Visit Code	Visit Type	Target Day	Visit Window
1.0	Visit 1: Screening	No more than 45 days prior to Enrollment	N/A
2.0	Visit 2: Enrollment	Day 0*	+45 days after Screening Visit
3.0	Visit 3: Single Dose Administration Visit	Day 7 ~ 7 days after Enrollment Visit	+7-21 days after Enrollment Visit
4.0	Visit 4: Sampling Visit - 24 Hours After Application of Study Product	Day 8 24 hours after Visit 3.0	No window (Same as target day)
5.0	Visit 5: Sampling Visit - 48 Hours After Application of Study Product	Day 9 48 hours after Visit 3.0	No window (Same as target day)
6.0	Visit 6: Sampling Visit - 72 Hours After Application of Study Product	Day 10 72 hours after Visit 3.0	+1-2 days after Visit 5.0
7.0	Visit 7: Study Product Administration Visit	Day 24 ~ 14 days after Visit 6.0	+14-28 days after Visit 6.0
8.0	Visit 8: Study Product Administration Visit	Day 25 1 day after Visit 7.0	No window (Same as target day)
9.0	Visit 9: Study Product Administration Visit	Day 26 2 days after Visit 7.0	No window (Same as target day)
10.0	Visit 10: Study Product Administration Visit	Day 27 3 days after Visit 7.0	No window (Same as target day)
11.0	Visit 11: Study Product Administration Visit	Day 28 4 days after Visit 7.0	No window (Same as target day)
12.0	Visit 12: Study Product Administration Visit	Day 29 5 days after Visit 7.0	No window (Same as target day)
13.0**	Visit 13: Last Study Product Administration Visit/Early Termination*	Day 30** 6 days after Visit 7.0	No window (Same as target day)
14.0	Visit 14: Sampling Visit - 24 Hours After Last Application of Study Product	Day 31 24 hours after Visit 13.0	No window (Same as target day)
15.0	Visit 15: Sampling Visit - 48 Hours After Last Application of Study Product	Day 32 48 hours after Visit 13.0	No window (Same as target day)
16.0	Visit 16: Sampling Visit - 72 Hours After Last Application of Study Product	Day 33 72 hours after Visit 13.0	+ 1-2 days after Visit 15.0
17.0	Visit 17: Follow-up Safety Contact and Termination Visit	Day 40 ~ 7 days after Visit 16.0	+4-14 days after Visit 16.0

*Consider the timing of participant menses when scheduling the Enrollment Visit as menses must not coincide with Study Visits 2-6.

**Early Termination Visit Code may vary depending on where participant is in his/her visit schedule.

**If the participant permanently discontinues study product use early (i.e. prior to Visit 13), participants will be asked to complete the Visit 13 – Last Study Product Administration Visit/Early Termination procedures.

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, full Enrollment Date, Visit 3, 6, 7, and 16 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 placed in the ppt's study notebook once ppt has enrolled

Visit Calendar Tool

MTN-026 Participant Visit Calendar

PTID: 999-9999-9   **Staff Initials:**

Enrollment Date: *9/8/2017*

mm/dd/yyyy

Visit	Visit Code	Visit Window Open	Visit Window Close	Target Visit Date	Actual Visit Date	
Visit 3: Single Dose Administration Visit	3.0	*15-Sep-17*	*29-Sep-17*	**15-Sep-17**	*15-Sep-17*	<-- Site to enter date
Visit 4: Sampling Visit - 24 Hours After Application of Study Product	4.0	No window		**16-Sep-17**		
Visit 5: Sampling Visit - 48 Hours After Application of Study Product	5.0	No window		**17-Sep-17**		
Visit 6: Sampling Visit - 72 Hours After Application of Study Product	6.0	*18-Sep-17*	*19-Sep-17*	**18-Sep-17**	*18-Sep-17*	<-- Site to enter date
Visit 7: Study Product Administration Visit	7.0	*2-Oct-17*	*16-Oct-17*	**2-Oct-17**	*2-Oct-17*	<-- Site to enter date
Visit 8: Study Product Administration Visit	8.0	No window		**3-Oct-17**		
Visit 9: Study Product Administration Visit	9.0	No window		**4-Oct-17**		
Visit 10: Study Product Administration Visit	10.0	No window		**5-Oct-17**		
Visit 11: Study Product Administration Visit	11.0	No window		**6-Oct-17**		
Visit 12: Study Product Administration Visit	12.0	No window		**7-Oct-17**		
Visit 13: Last Study Product Administration Visit	13.0	No window		**8-Oct-17**		
Visit 14: Sampling Visit - 24 Hours After Application of Study Product	14.0	No window		**9-Oct-17**		
Visit 15: Sampling Visit - 48 Hours After Application of Study Product	15.0	No window		**10-Oct-17**		
Visit 16: Sampling Visit - 72 Hours After Application of Study Product	16.0	*11-Oct-17*	*12-Oct-17*	**11-Oct-17**	*11-Oct-17*	<-- Site to enter date
Visit 17: Follow-up Safety Contact and Termination Visit	17.0	*15-Oct-17*	*25-Oct-17*	**18-Oct-17**		

Instructions:

1. Once a participant enrolls, enter the participant's PTID, Staff Initials, and Enrollment Date. This will generate the target date and visit windows for the Single Dose Administration Visit (Visit 3).

2. 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.

3. As the participant completes his/her Follow-up Visits, record the date the visit completed in the "Actual Visit Date" column.

4. An actual visit date for Visit 3.0, 6.0, 7 and 16.0 must be entered to generate the target dates and visit windows for the remaining follow-up visits.

5. Print the calendar and place in the participant's study notebook. Sites may provide participants with list of scheduled visit dates to assist with scheduling.

Visit Codes

Visit	Visit Code
Screening	1.0
Enrollment	2.0
Dosing	3.0
24 hr PK	4.0
48 hr PK	5.0
72 hr PK	6.0
Dosing	7.0
Dosing	8.0
Dosing	9.0
Dosing	10.0
Dosing	11.0
Dosing	12.0
Final Dosing	13.0
24 hr PK	14.0
48 hr PK	15.0
72 hr PK	16.0
Termination	17.0
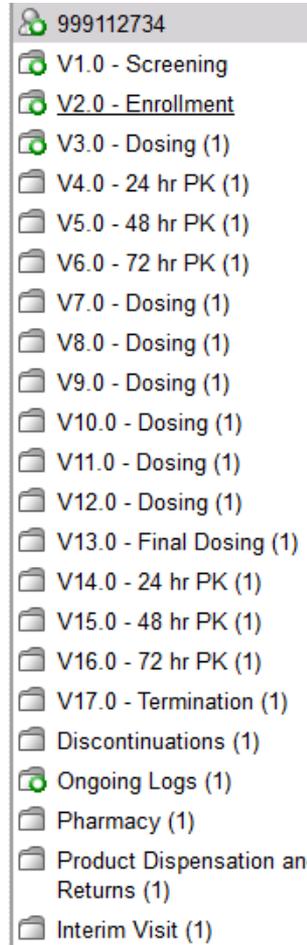
999112734
- V1.0 - Screening
- V2.0 - Enrollment
- V3.0 - Dosing (1)
- V4.0 - 24 hr PK (1)
- V5.0 - 48 hr PK (1)
- V6.0 - 72 hr PK (1)
- V7.0 - Dosing (1)
- V8.0 - Dosing (1)
- V9.0 - Dosing (1)
- V10.0 - Dosing (1)
- V11.0 - Dosing (1)
- V12.0 - Dosing (1)
- V13.0 - Final Dosing (1)
- V14.0 - 24 hr PK (1)
- V15.0 - 48 hr PK (1)
- V16.0 - 72 hr PK (1)
- V17.0 - Termination (1)
- Discontinuations (1)
- Ongoing Logs (1)
- Pharmacy (1)
- Product Dispensation and Returns (1)
- Interim Visit (1)

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

Missed Visits

- A follow-up visit is missed once allowable window closes if he/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 (Single Dose), but is not able to come back into the clinic until Visit 5. The Visit 4 Sampling Visit is considered missed.
    - E.g., The Visit 8 has no visit window, thus is missed

- If a participant misses Visit 3 (Single Observed Dose) or all Visits 7-13 (Daily Dose Study Product Administration), the management team should be notified as this participant will need to be replaced.

- 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).

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 13 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

- Interim visits documented using the Interim Visit Summary eCRF

- Need sites to document reason for interim visit and CRFs completed for it

Interim Visit Codes

- If the interim contact results in at least one <u>newly-completed eCRF</u>, 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

- 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)

- Note: All PK/PD/mucosal safety specimen collections must occur on the same day

Follow-up Visits – Key CRFs

- ✓ Follow-up Visit Summary, including Follow-up Yes/No
- ✓ Additional Study Procedures
- ✓ Directly Observed Dosing
- ✓ Product Dispensation and Returns
- ✓ Protocol Deviations Log
- ✓ Treatment Discontinuation
- ✓ Study Discontinuation
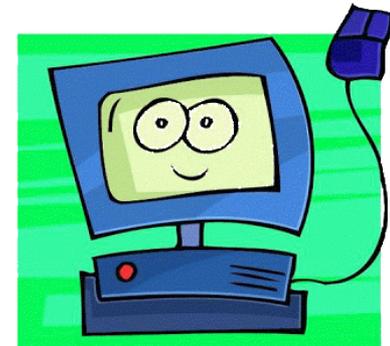- ✓ Participant Replacement

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.

Visit	Date
V1.0 - Screening	31 Oct 2017
V2.0 - Enrollment	03 Nov 2017
V3.0 - Dosing (1)	10 Nov 2017
V4.0 - 24 hr PK (1)	11 Nov 2017
V5.0 - 48 hr PK (1)	12 Nov 2017
V6.0 - 72 hr PK (1)	13 Nov 2017
V7.0 - Dosing (1)	27 Nov 2017
V8.0 - Dosing (1)	28 Nov 2017
V9.0 - Dosing (1)	29 Nov 2017
V10.0 - Dosing (1)	30 Nov 2017
V11.0 - Dosing (1)	01 Dec 2017
V12.0 - Dosing (1)	02 Dec 2017
V13.0 - Final Dosing (1)	03 Dec 2017
V14.0 - 24 hr PK (1)	04 Dec 2017
V15.0 - 48 hr PK (1)	05 Dec 2017
V16.0 - 72 hr PK (1)	06 Dec 2017
V17.0 - Termination (1)	13 Dec 2017

MTN026 | Test site 2 | 999611301

Participant Identifier

999611301
- V1.0 - Screening
- V2.0 - Enrollment
- V3.0 - Dosing (1)
- V4.0 - 24 hr PK (1)
- V5.0 - 48 hr PK (1)
- V6.0 - 72 hr PK (1)
- V7.0 - Dosing (1)
- V8.0 - Dosing (1)
- V9.0 - Dosing (1)
- V10.0 - Dosing (1)
- V11.0 - Dosing (1)
- V12.0 - Dosing (1)
- V13.0 - Final Dosing (1)
- V14.0 - 24 hr PK (1)
- V15.0 - 48 hr PK (1)
- V16.0 - 72 hr PK (1)
- V17.0 - Termination (1)
- Discontinuations (1)
- Ongoing Logs
- Pharmacy (1)
- Product Dispensation and Returns (1)

Case Report Forms

- eCRF Rave output available as single PDF on MTN-026 ATLAS webpage
  - https://atlas.scharp.org/cpas/project/MTN/026/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?