

To: MTN 001 Protocol Team
From: MTN 001 SCHARP Team
RE: MTN 001 Enrollment and Retention Report

The Enrollment and Retention Reports for MTN 001 are updated nightly and are based on cumulative data received at SCHARP through the previous week. They are meant for use by the MTN 001 Protocol Team to monitor study progress.

These reports include the following information:

1. Enrollment Report

- Summary table showing the number of participants enrolled each week
- Graph showing enrollment for both sites combined
- Graphs showing enrollment for each active site

2. Retention Report

- Summary tables showing number of participants retained across both sites
- Summary tables showing number of participants retained for each active site

Please contact the MTN 001 Project Manager at SCHARP, Karen Patterson (karen@scharp.org), with any questions you may have regarding this report.

Thank you.

MEMORANDUM

Definitions and examples of terms used in this report:

- **Retention Evaluation Date (RED)** - For each report, this is the cutoff date for study data to be included in the retention evaluation.
- **Total Enrolled** - Total number of participants under informed consent, overall or at each site, on or before the end of the target visit window for that visit. Total Enrolled = Inappropriately Enrolled + Active or Reached Endpoint (RE) + Known Lost to Follow-up (LFU).
 - **Inappropriately Enrolled** - Number of participants who were enrolled inappropriately **AND** inactivated from the study. These participants will not be having follow-up visits.
 - **Active or RE (Reached Endpoint)** - Number of participants who are still active for follow-up visits or who have reached a study endpoint.
 - **Death** - Number of participants from the Active or RE group who have died. Depending on whether the target visit window is closed or open, these participants are counted in either the ‘Completed or RE’ or ‘Completed before RED or RE’ groups.
 - **Known LFU (Lost to Follow-up)** - Number of participants who are not active for follow-up visits. Because these participants are known lost to follow-up (i.e., participant refused further participation, investigator decision, etc.), they are terminated early from the study.
- **Expected** - Number of participants whose target visit windows closed on or before the RED.
 - **Completed or RE (Reached Endpoint)** - Number of participants who completed the expected visit (early, on time, or late) or reached a study endpoint (includes deaths).
 - **Early** - Number of participants who completed the expected visit before the target visit window opens, but within the allowable visit window.
 - **On-Time or RE (Reached Endpoint)** - Number of participants who completed the expected visit within the target visit window, or who have previously reached a study endpoint.
 - **Late** - Number of participants who completed the expected visit after the target visit window closed, but within the allowable visit window.
 - **No Shows or Known LFU (Lost to Follow-up)** - Number of participants expected to have a visit, but have not appeared yet or are known lost to follow-up.
- **Not Expected** - Number of participants whose target visit windows are still open as of the Retention Evaluation Date (RED).
 - **Completed before RED or RE (RED - Retention Evaluation Date or RE - Reached Endpoint)** - Number of participants who completed the visit or reached a study endpoint (includes deaths), BUT are not considered “expected” because they have not reached the end of the target visit window.
 - **Not Completed or Known LFU (Lost to Follow-up)** - Number of participants who did not complete the visit and are not considered “expected” because they have not reached the end of the target visit window.
- **Percent Retained or RE (Reached Endpoint)** - Percentage of participants who completed their expected visits. Includes participants who have reached a study endpoint.

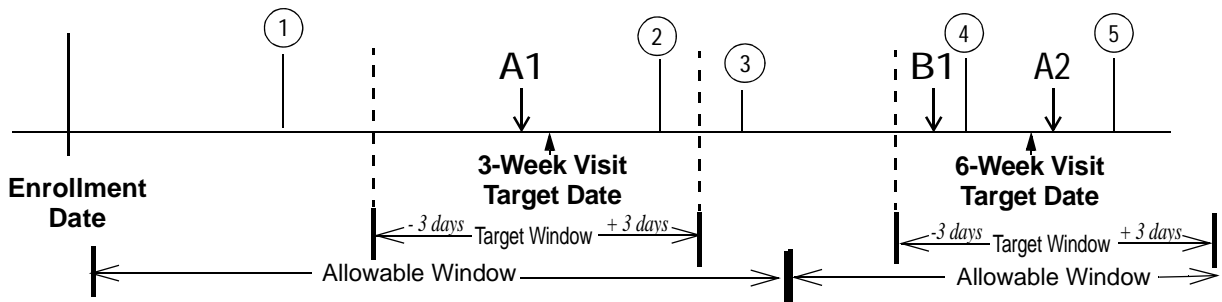
$$\% \text{ Retained or RE} = (\text{Completed or RE}) / (\text{Expected})$$

- **Percent LFU (Lost to Follow-up)** - Percentage of expected participants who are known lost to follow-up.

$$\% \text{ LFU} = (\text{Known LFU}) / (\text{Expected})$$

Detailed Example:

The following example shows how visits are counted in the report in relation to the target dates and target visit windows. In this example, participants A and B enrolled on the same day and therefore, will have the same 3-Week and 6-Week Visit target dates (with the same 3-day target visit window on both sides). Imagine participants A and B complete their visits on days other than the target date.



A = Participant A completes visit (A1 = 1st time seen in follow-up; A2 = 2nd time seen in follow-up)
B = Participant B completes visit (B1 = 1st time seen in follow-up)

Table 1: Retention status at different Retention Evaluation Dates (REDs)

RED	Participant	3-Week Visit	6-Week Visit
①	A	Not Expected, Not Completed	Not Expected, Not Completed
①	B	Not Expected, Not Completed	Not Expected, Not Completed
②	A	Not Expected, Completed before RED	Not Expected, Not Completed
②	B	Not Expected, Not Completed	Not Expected, Not Completed
③	A	Expected, Completed	Not Expected, Not Completed
③	B	Expected, No Show	Not Expected, Not Completed
④	A	Expected, Completed	Not Expected, Not Completed
④	B	Expected, No Show	Not Expected, Completed before RED
⑤	A	Expected, Completed	Not Expected, Completed before RED
⑤	B	Expected, No Show	Not Expected, Completed before RED