

**To:** MTN 008 Protocol Team  
**From:** MTN 008 SCHARP Team  
**RE:** MTN 008 Enrollment and Retention Report

The Enrollment and Retention Reports for MTN 008 are updated nightly and are based on cumulative data received at SCHARP through the previous week. They are meant for use by the MTN 008 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 all sites combined

Graphs showing enrollment for each active site

## 2. Retention Report

Summary table showing the number of participants retained across sites

Summary tables showing the number of participants retained for each active site

Please contact the MTN 008 Project Manager at SCHARP, Corey Miller ([corey@scharp.org](mailto:corey@scharp.org)), with any questions you may have regarding this report.

Thank you.

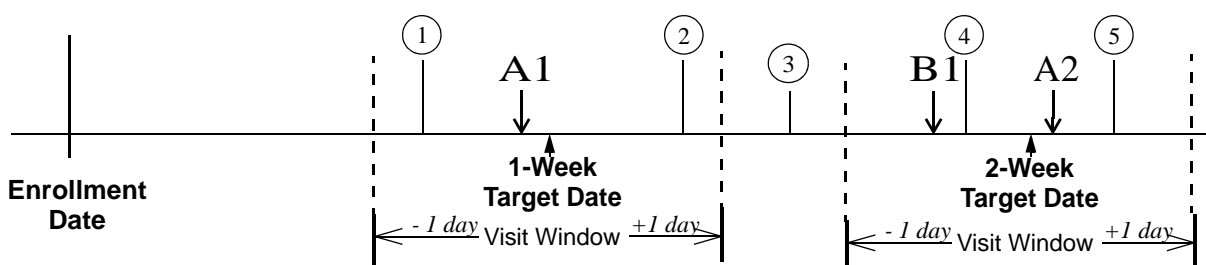
---

## Definitions and examples of terms used in the retention 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 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 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 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 visit window opens.
    - **On-Time or RE (Reached Endpoint)** - Number of participants who completed the expected visit within the visit window or previously reached a study endpoint.
    - **Late** - Number of participants who completed the expected visit after the visit window closed, but prior to the opening of the next 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 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 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 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 visit windows. In this example, participants A and B enrolled on the same day and will, therefore, have the same 1-Week and 2-Week Clinic Visit target dates (with the same 1-day 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	1-Week Clinic Visit	2-Week Clinic 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

## Definitions and examples of terms used in the enrollment report:

- **First Enrollment Date** - Enrollment date of the first enrolled participant.
- **Total Weeks** - Total number of weeks since the first participant enrolled.
- **Total Enrollment** - Total number of participants enrolled in the study.
- **Average Per Week** - Average number of participants enrolled each week.  $\text{Average Per Week} = \text{Total Enrollment} / \text{Total Weeks}$ .
- **Site Target** - Target number of evaluable participants for this site, as specified in the protocol.
- **Enrollment Needed** - Total number of evaluable participants still needed to be enrolled for this site.  $\text{Enrollment Needed} = \text{Site Target} - \text{Total Enrollment} + \text{Total number of enrolled participant that need to be replaced}$ .

