

**To:** HPTN 058 Protocol Team  
**From:** HPTN 058 SCHARP Team  
**RE:** HPTN 058 Enrollment and Retention Report

The Enrollment and Retention Reports for HPTN 058 are updated nightly and are based on cumulative data received at SCHARP through the previous week. They are meant for use by the HPTN 058 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

**2. Retention Report**

- Summary table showing the number of participants retained for the site

Please contact the HPTN 058 Project Manager at SCHARP, Huguette L Redinger ([redinger@scharp.org](mailto:redinger@scharp.org)), with any questions you may have regarding this report.

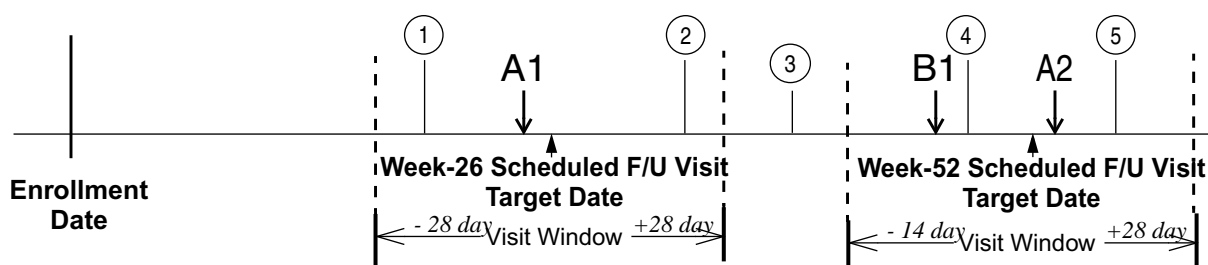
Thank you.

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

- The denominator for the retention calculation includes the participants whose target window is closed (target date plus 28 days) on the retention evaluation date, and those whose target window is not closed but completed the visits.
- The numerator for the retention calculation includes all participants who have completed the visits.
- Deaths are included in the numerator and the denominator for the retention calculation if the target window is closed on the evaluation date.
- Late refers to participants who completed the visit after the target window closed, but within the extended window. Extended window closes 30 days prior to the next semi-annual visit.
- Loss to follow-up is defined as those participants who are terminated early from the study for reasons other than death.

### 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 Week-26 and Week-52 Scheduled Follow-up Visit target dates (with the corresponding 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 = visit 26 occurred timepoint; A2 = visit 52 occurred timepoint)

B = Participant B completes visit (B1 = visit 52 occurred timepoint)

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

RED	Participant	Week-26 Scheduled F/U Visit	Week 52 Scheduled F/U 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.  $\text{Enrollment Needed} = \text{Site Target} - \text{Total Enrollment} + \text{Total number of enrolled participant that need to be replaced}$ .