

MEMORANDUM

To: HPTN 061 Protocol Team
From: HPTN 061 SCHARP Team
RE: HPTN 061 Retention Report

The Retention Report for HPTN 061 is updated nightly and is based on cumulative data received at SCHARP through the previous week. It includes the summary table showing the number of participants retained for the site, and is meant to be used by the HPTN 061 Protocol Team to monitor study progress.

Please contact the HPTN 061 Project Manager at SCHARP, Corey Kelly (<mailto:ckelly@scharp.org>), with any questions you may have regarding this report.

Thank you.

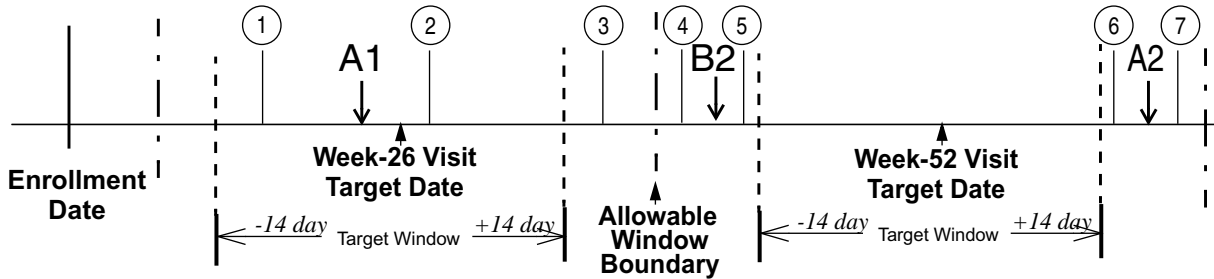
Definitions and examples of terms used in the retention report:

- Participants are not considered “**Expected**” for a visit until the target window for the visit has closed. The target window of the week 26 visit is from day 168 to day 196, and day 351 to day 379 for the week 52 visit.
- If an expected participant has completed the visit before the allowable window closes, the participant is considered as “**Retained**” at that visit. If an expected participant completed the visit before the target window opened, they are considered “**Early**”; if they completed the visit within the target window, they are considered “**On time**”; if the visit is completed after the target window closes but still within the allowable visit window, they are considered “**Late**”.
- Expected participants who did not complete the visit are categorized as “**Missed visits**”. These participants are further separated into “**Allowable window still open**” and “**Allowable window closed**” subcategories. A participant whose allowable window is still open could complete his visit before the allowable window closes and, on the subsequent report, would be counted in the “**Late**” category. The allowable window for the week 26 visit is from day 126 to day 308, and the week 52 visits' allowable visit window is from day 309 until site closure.
- Participants who completed the visit before they are expected for a visit (i.e. before their target window has closed) are reported in the “**Not expected but completed**” category. In the subsequent report they will move to either “**Early**” or “**On time**” category.
- “**Lost to follow-up**” is defined as those participants who are terminated early from the study.

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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 windows 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 (B2 = visit 52 occurred timepoint)

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

RED	Participant	Week-26 Visit	Week 52 Visit
①	A	Not Expected, Not Completed	Not Expected, Not Completed
	B	Not Expected, Not Completed	Not Expected, Not Completed
②	A	Not Expected but Completed	Not Expected, Not Completed
	B	Not Expected, Not Completed	Not Expected, Not Completed
③	A	Expected, Retained, On Time	Not Expected, Not Completed
	B	Expected, Missed Visit, Window Open	Not Expected, Not Completed
④	A	Expected, Retained, On Time	Not Expected, Not Completed
	B	Expected, Missed Visit, Window Closed	Not Expected, Not Completed
⑤	A	Expected, Retained, On Time	Not Expected, Not Completed
	B	Expected, Missed Visit, Window Closed	Not Expected but Completed
⑥	A	Expected, Retained, On Time	Expected, Missed Visit, Window Open
	B	Expected, Missed Visit, Window Closed	Expected, Retain, Early
⑦	A	Expected, Retained, On Time	Expected, Retain, Late
	B	Expected, Missed Visit, Window Closed	Expected, Retain, Early