



MEMORANDUM

Date: October 25, 2016
To: HPTN 078 Protocol Team, HPTN078 Sites
From: HPTN078 SCHARP Team
Re: **HPTN078 Enrollment and Retention Reports**

The **Enrollment and Retention Reports** for HPTN078 are updated nightly. Data included in the Enrollment Report are based on cumulative data received at SCHARP the day before the report is produced, and data included in the Retention Report are based on cumulative data received at SCHARP through the previous week. The reports are meant for use by the protocol team to monitor study progress. These reports contain information for sites that have been activated and include the following information:

1. Enrollment Report

- Summary table showing average and total weekly enrollment data, including enrollment targets, as well as total accrual duration by site and cumulatively
- Summary table showing the total and average number of participants enrolled by calendar month by site and cumulatively
- Graph showing actual and targeted monthly enrollment numbers for all sites combined
- Graphs showing actual and targeted monthly enrollment numbers for each active site

2. Retention Report

- Summary table showing the number of both participants evaluated and visits completed at each post-randomization visit (by site and cumulatively)

Please contact the HPTN078 Clinical Data Manager at SCHARP, Erin Hughes (eehughes@scharp.org), with any questions you may have regarding these reports.

Thank you.



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Definitions of Terms Used in the Enrollment Report

Accrual Summary by Site Table:

- **Activation Date** – Date of site activation for study.
- **First Enrollment Date** – Enrollment date of the first enrolled participant.
- **Last Enrollment Date** – Date of most recent enrolled participant.
- **Duration of Accrual** – Total number of weeks since the first participant enrolled.
- **Enrollment Target** – Number of targeted enrollments.
- **Total Enrolled** – Total number of participants actually enrolled in the study.
- **Average Enrolled Per Week** – Average number of participants enrolled each week
$$\text{Average Per Week} = \text{Total Enrollment} / \text{Total Weeks}$$

Accrual Summary and Accrual by Calendar Month and Site Table:

- **Activation Date** – Date of site activation for study.
- **First Enrollment Date** – Enrollment date of the first enrolled participant.
- **Total Enrolled** – Total number of participants enrolled in the study.
- **Enrollment Target** – Total number of targeted enrollments.
- **Percent Enrolled** – Percent of target enrollment attained thus far.
$$\text{Percent Enrolled} = \text{Total Enrolled} / \text{Enrollment Target}$$
- **Accrual (by Calendar Month)** – Total number of enrollments by calendar month.
- **Average Enrolled per Month** – Average number of participants enrolled by month (since month of first enrollment)
$$\text{Average Per Month} = \text{Total Enrollment} / \text{Total Months of Accrual}$$



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Definitions of Terms Used in the Retention Report

- **Evaluated** – Number of evaluated participants includes participants whose visit window for a given visit has closed, plus any participants that have completed the visit even though their visit window has not yet closed. Participants who have died show up once in the report, at the visit in which they are considered “terminated early”. After that time, they are removed from the report and from the evaluated category for the subsequent visits.
- **Visit Completed** – If a participant has completed the visit within the allowable window (i.e. before it closes), the participant visit is considered **completed**. If a visit is completed within the target window, it is considered to be completed “**on time**”. If a visit is completed after the allowable window opens but before the target window has opened, it is considered completed “**early**”. If a visit is completed after the target window closes but before the allowable window has closed, it is considered completed “**late**”.
- **Visit Not Completed** – Evaluated participants who did not complete the visit within the allowable window are categorized as **Visit Not Completed**. A participant did not complete the visit either because the visit was “**missed**” or because he/she **terminated early** from the study.