

HPTN074 Data Communiqué #1

7 August 2015

This is official study documentation for the HPTN074 trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN074 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

UPDATES

None.

CLARIFICATIONS

Timing the submission of screening visit CRFs: As a result of the large window around screening (currently 45 days) the appropriate timing of when to submit screening CRFs is clarified in the following scenarios. This approach attempts to balance the need to collect screening data in the database in a reasonably timely fashion while minimizing re-work for the sites during this period.

- 1) If an Index partner screens but for some reason is likely not able to meet the enrollment criteria (for example they can't recruit a partner and it seems unlikely that they will recruit a partner) or if they screen fail (for example, they lose interest in the study) we recommend that you submit the screening outcome CRF marked “did not enroll” as soon as you are relatively certain that the Index will not enroll.
- 2) If an Index partner screens, but has remaining time in their window to meet the enrollment requirements, we recommend that you do not submit the screening outcome CRF until s/he enrolls or meets the criteria above in item 1.
- 3) If the screening window closes and the Index is not yet enrolled but s/he is willing to re-screen, please file the original screening CRFs in the participant file but do not submit to DataFax.
 - a) If the Index re-screens, please complete a new set of screening CRFs that reflect the information collected during the second screening. If the Index becomes a successful enrollment, please submit these updated CRFs when the Index finally enrolls or when it is determined that the second re-screening will not result in an enrollment (screen fail).

In the case of re-screening when you have already submitted screening CRFs from a previous screening visit: the database can only accept one copy of the screening CRFs. You will receive a data QC if there is more than one screening record(s) for the same PTID at visit 1.0. In this situation, please mark the originally submitted screening CRFs for deletion following the procedures outlined in

the Data Management SSP and then submit the updated CRFs from the second screening to DataFax.

The Lab Program may also be in contact to discuss QCs for specimen monitoring QCs that can be ignored based on the screening scenarios outlined above.

We appreciate your continued help navigating the crossroads between site processes and the data management requirements for this protocol. Note that the primary purpose of QCs is to be a useful tool to identify these kinds of issues so that we may problem solve around them, QCs are not demerits. Please do not hesitate to contact SCHARP with any questions.

REMINDERS

None.