

Section 16. Data Communiqués

For HPTN084, SCHARP will use “Data Communiqués” to document and communicate data decisions and procedures that are made or revised during the study.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is distributed, please circulate it among relevant staff for their review, print the Data Communiqué, and place it in this section of each HPTN084 SSP binder in your possession. Consider each Data Communiqué an official part of the SSP.

Each Data Communiqué sent will consist of three sections: a Reminders section, used to remind sites of specific data collection or forms completion procedures; a Clarification section, used to clarify data collection or form completion procedures; and an Updates section, used to communicate when an updated version of a form is being issued or to notify the sites that an updated version of the forms instructions is about to be distributed (for example).

Note that a “Data Communiqué” does not request specific actions or corrections to a particular participant’s data - it is just a listing of general items to keep in mind when performing data collection for the study.