

Section 10 – Data Communiqués

For MTN-009, SCHARP will use “Data Communiqués” to document and communicate data decisions and procedures that are made or revised during the study. By using Data Communiqués, SCHARP avoids having to redistribute a revised version of the Data Collection section of this Study-specific Procedures Manual (SSP) every time a form completion clarification or revision is made.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is sent (via e-mail), please circulate it among relevant staff for their review, print the Data Communiqué, and place it in this section of each MTN-009 SSP binder in your possession. Consider each Data Communiqué an official part of the SSP.

Each Data Communiqué will consist of three sections: a Reminders section, used to remind sites of specific data collection or forms completion procedures; a Clarifications section, used to clarify data collection or form completion procedures; and an Updates section, used to communicate new information, such as when an updated version of a form and/or form instructions is being issued.

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