

Section 13. Data Communiqués

13. Introduction

For MTN-038, 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 re-distribute a revised version of the Data Collection section of this SSP every time a data collection clarification or revision is made.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is sent (via email), please circulate it among relevant staff for their review, print the Data Communiqué, and place it in this section of each MTN-038 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 procedures; a Clarification section, used to clarify data collection procedures; and an Updates section, used to communicate when an updated data collection tool or report is being issued or to notify the sites that an updated version of the CRF Completion Guidelines document has been posted (for example).

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