MATRIX-007 Study-Specific Procedures (SSP) Manual Section 8 – Data Communiqués and Operational Guidance

8   Introduction

For MATRIX-003, "Data Communiqué" and "Operational Guidance" memos will be used to document any data-related and study procedure/implementation updates during the study as detailed in Table 8-1. Data Communiqué and Operational Guidance memos are considered official study documentation and part of the MATRIX-003 SSP Manual. Data Communiqué and Operational Guidance memos will be posted to the CARE PrEP Data SharePoint Study Resources page, MATRIX-003 webpage under SSP Section 8 and will be emailed to sites. Sites are responsible for ensuring appropriate staff review and understand the content of each memo.

Table 8-1: MATRIX-007 Data Communiqué and Operational Guidance Memo Descriptions

Name of memo	Type of change/update	More Information
Data communique	Information or changes related to data collection forms or systems	Data Communiqués will be issued by the Data Management Center to clarify and communicate data-related updates during the study (usually to announce a new or updated CRF, or to clarify expectations on data entry, etc.)
Operational guidance	Information or changes related to anything other than data collection forms/systems as described in the SSP	Operational Guidance memos can be issued by different members of the management team, and may be related to any aspect of study conduct such as clinical procedures, etc.

Additional information about Data Communiqués

By using Data Communiqués, the Leadership and Operations Group (LOG) avoids having to re-distribute a revised version of the relevant section of this SSP every time a form completion clarification or revision is made.

Each Data Communiqué sent may consist of up to three sections:

- A Reminders section, used to remind sites of specific data collection or form completion procedures
- A Clarification section, used to clarify data collection or form completion procedures
- 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 form's 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 a list of general items to keep in mind when performing data collection for the study