



MATRIX-001 Study-Specific Procedures (SSP) Manual Section 13 – Data Communiqués and Operational Guidance

For MATRIX-001, “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 13-1. Data Communiqué and Operational Guidance memos are considered official study documentation. Data Communiqué and Operational Guidance memos will be emailed to sites and will also be posted to the MATRIX-001 webpage under SSP Section 13. The memos will be considered an official part of the MATRIX-001 SSP Manual. Sites are responsible for ensuring appropriate staff review and understand the content of each memo.

Table 13-1: MATRIX-001 Data Communiqué and Operational Guidance Memo Descriptions

Name of Memo	Type of change/update	More information
Data Communiqué	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, pharmacy, laboratory, sociobehavioral data, etc.

Additional information about Data Communiqués

By using Data Communiqués, the Data Management & Statistical Support (DMSS) team 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 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 a list of general items to keep in mind when performing data collection for the study.