MTN-030/IPM 041 Data Communiqué #1 - July 14, 2017

This is official study documentation for MTN-030/IPM 041. Please circulate it among relevant staff for their review, print it, and place it in your MTN-030/IPM 041 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-030/IPM 041 SSP manual.

UPDATES

1. CRF UPDATE

The following CRF has been updated within the clinical database:

Hormone Tests

The Hormone Tests eCRF has been updated to include the "<" and "=" symbol for progesterone levels, in order to indicate values that are at the lower limit of detection.

This item is a required item and should be completed retroactively for all participants who have already completed the Hormone Tests CRF. For example, if a participant's progesterone value is reported as <0.25 ng/mL, then select the "<" symbol and enter the value and select the appropriate units for Progesterone. If a participant's progesterone value is reported as 0.75 ng/mL (i.e. no lower limit of detection), then select the "=" symbol and enter the value and select the applicable units for Progesterone.

2. DATABASE UPDATES

As part of the MTN-030 clinical database migration, system queries have been updated and corrected. The goal of system queries is to provide real-time feedback in order to ensure clean data at the point of data entry. Specifically, the following updates have occurred within the clinical database:

Bleeding SMS

The skip pattern on the Bleeding SMS CRF has been corrected so that if the participant did not report any vaginal spotting or bleeding via SMS, then then is the end of form and remaining items should be blank. Sites should update the data for all participants so that it is consistent with the correct skip pattern per the CRF Completion Guidelines.

Ring Insertion and Removal

The skip pattern on the Ring Insertion and Removal has been updated so that if a ring was not removed at this visit, skip to item "Was a ring inserted at this visit?". This is a required item and should be completed, regardless whether the ring was not removed at this visit.

3. CRF COMPLETION GUIDELINES (CCGs)

The CRF Completion Guidelines have been updated to v1.2 (dated 14 July 2017) and are posted on the MTN-030 Atlas webpage ((https://atlas.scharp.org/cpas/project/MTN/030/begin.view?).

4. REPORTS

Medidata Reports

Medidata Rave reports are available for internal site data cleaning and review and are available on the site-specific Medidata homepage. The following reports are available:

- Productivity Report
- Query Details Report
- Query Summary Report
- Comprehensive Page Status Report

Procedures Completion Report

The MTN-030 Procedures Completion Report is posted and available for viewing on the MTN-030 Atlas webpage. The Procedures Completion Report lists overall and by site, the number and percentage of required ('expected') follow-up visit procedures that were complete. Procedures are considered 'expected' if the visit was completed (i.e. if the study visit was not missed) and when the visit window for that visit has closed.

Navigate to the MTN-030 Atlas webpage (https://atlas.scharp.org/cpas/project/MTN/030/begin.view?), agree to the Terms of Use, and click on "Current" to the right of the report title. No sign-in or password is required. This report is updated each da based on data received and entered at SCHARP.

CLARIFICATIONS

None

REMINDERS

None