MTN-034 Data Communiqué #3 – May 23, 2019

This is official study documentation for MTN- 034. Please circulate it among relevant staff for their review, print it, and place it in your MTN-034 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-034 SSP manual.

UPDATES

The MTN-034 Medidata Rave database was migrated to version 7.0 (1340) on 23 May 2019. This migration included the following changes to the study case report forms:

Adverse Event Log CRF

A new field was added to the AE log CRF form to capture the SAE Onset Date if the adverse event meets SAE criteria. In addition to marking the SAE criteria that apply, the date that the adverse event first meets ICH criteria for seriousness is now required to be entered on the AE log CRF. A complete date is required for this field.

Eligibility Criteria CRF

The Eligibility Criteria CRF has been updated to include the text field, "If "Investigator decision", specify". This text field is required if 'E7. Has a condition that, per IoR/designee, preclude informed assent/consent, make study participation unsafe, complicate interpretation of outcome data or interfere with achieving study objectives' is selected as the reason for participant ineligibility. A maximum 200 characters is allowed for this text field.

Eligibility Criteria CRFs that have been completed to date with the reason for ineligibility specified as "E7. Has a condition that, per IoR/designee, preclude informed assent/consent, make study participation unsafe, complicate interpretation of outcome data or interfere with achieving study objectives" must be updated retroactively to provide the specification in the new text field.

Demographics CRF

The date of birth field on the Demographics CRF has been updated to allow for a partial date. At a minimum, a year is required.

Product Hold Log CRF

The field responses for the Item "Why is study product being held?" has been updated to allow for pregnancy and breastfeeding to be selected.

An updated complete set of blank eCRFs and v3.0 of the MTN-034 CRF Completion Guidelines (CCGs) have been posted to the MTN-034 ATLAS webpage.

https://atlas.scharp.org/cpas/project/MTN/034/begin.view?

CLARIFICATIONS

Specimen Storage CRF

In the event that a sample is not collected at a visit, indicate this by selecting "No" for the item "Was sample collected". All other fields for the specimen can be left blank (i.e., 'Specimen Collection Date', 'Was sample stored?' and 'If no, record reason why sample was not stored' can be left blank).

| | MTN034 | Test site 2 | 999137197 | V3.0 - Week 1 (1) | Specimen Storage |
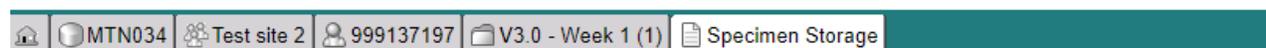
Subject: 999137197
Page: **Specimen Storage - V3.0 - Week 1 (1)**

#	Specimen Type	Was sample collected?	Specimen Collection Date	Was sample stored?	If no, record reason why sample was not stored.
1	Plasma	Yes	23 May 2019	Stored	
2	Dried Blood Spot for PK	No			
3	HSV-2 Antibody	No			

Enrollment CRF

If the participant receives an HPV or HBV vaccination at her Enrollment visit, select "No" to the item "Has the participant received an HPV vaccination prior to enrollment" or "Has the participant received an HBV vaccination prior to enrollment" and document this vaccination on the Concomitant Medications Log CRF. The intent of these items is to capture any vaccinations that the participant has received prior to study participation.

REMINDERS

Adherence Counseling

In the event that more than one drug result is available for counseling at a study visit, multiple drugs results can be entered onto the Adherence Counseling CRF. To enter a second drug result onto the same Adherence Counseling CRF, enter the first drug result on the eCRF and save the page. Navigate back to the item "Which drug levels are available?" on the eCRF and click the "Add a new Log line" option below the first drug result.

A new log line will appear as a second row for this item on the eCRF for completion. Continue to add new log lines to enter any additional drug results that are available at this study visit.

Per protocol, drug results are scheduled to be available to the participant during counseling sessions at Visits 5, 8, 12, 15, 19 and 22. At these specified study visits, when completing the item 'Is the participant scheduled to receive drug level feedback? at this visit', select "Yes" even if the results are not yet available for the participant.

eCRF Translations

Site-specific translations in Luganda, Zulu, Xhosa, and Shona of the following interviewer-administered eCRFs are available within Medidata to be used. To administer the translated eCRF to the participant, the Medidata user locale must be updated within the user Profile to the applicable language. To change a user's local, please refer to the REACH Medidata eCRF Translations training slide deck available on the MTN-034 ATLAS webpage under 'Medidata Rave Materials".