

MTN-042 Data Communiqué #1 – February 5, 2020

This is official study documentation for MTN-042. Please circulate it among relevant staff for their review, print it, and place it in your MTN-042 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-042 SSP manual.

UPDATES

The MTN042_C1 (cohort 1) Medidata Rave database was migrated to version 2.0 (1796) on 5 February 2020.

This migration included the addition of a new folder:

Congenital Anomaly Report

This folder was added to document the report and geneticist review of a congenital anomaly. This folder contains the Congenital Anomaly Review CRF, Photographic Survey CRF, and EAE Upload CRF. It can be added to a participant's casebook by selecting the "Congenital Anomaly Report" folder from the Add Event dropdown on the participant home page. When a congenital anomaly is being reported for an enrolled infant, the Congenital Anomaly Report folder should be added to the infant's casebook; if a congenital anomaly is being reported for a non-enrolled infant, the Congenital Anomaly Report folder should be added to the mother's casebook.

This migration included the addition of four new study case report forms:

Congenital Anomaly Review CRF

This form was added to report a congenital anomaly and document geneticist review of the anomaly. The first section of this form will be completed by the site to summarize what information about the congenital anomaly is reported within Rave. The second section of the form will be completed by the geneticist to document their review and determination of the congenital anomaly. If a congenital anomaly has been reported, this form must be retroactively completed.

Photographic Survey CRF

This form will be used to upload photographs to Rave for geneticist review when a congenital anomaly is reported and a photographic survey is taken. If a congenital anomaly has been reported, and photographs are available, this form must be retroactively completed. Note that this form should only be completed for infants who are enrolled and have photo consent provided. When the Congenital Anomaly Report folder is added to a mother casebook (i.e., the congenital anomaly is being reported for a non-enrolled infant), this form should not be completed.

EAE Upload CRF

This form will be used to upload EAE reports to Rave for geneticist review when a congenital anomaly is reported. Once initial comments have been addressed on EAE report, export a PDF of the EAE report from DAERS and upload to the EAE Upload CRF. If subsequent updates are made to the submitted EAE report, export a copy of the updated report from DAERS and upload to a new log line on the EAE Upload CRF. Inactivate the log line with the previous version of the EAE report. If a congenital anomaly has been reported, and an EAE report has been submitted to DAERS, this form must be retroactively completed.

Infant Inclusion/Exclusion CRF

This form was added to document whether or not an infant enrolls in MTN-042. The form will be added to the Participant folder when “Is this participant a mother or an infant” on the Participant Type CRF equals “Infant”. The form should be completed when it is determined that an infant will not enroll in the study (e.g., the mother screen fails or a pregnancy loss is reported), or when the infant enrolls. This form must be retroactively completed for any infant PTIDs in the database.

The migration also included changes to the following study case report forms:

Adverse Event Log CRF

Two new fields were added to the AE log CRF. One field was added to document if an AE is considered related to pregnancy. Clinicians must consider each AE reported on the AE Log in a mother casebook and select the “AE is associated with pregnancy” checkbox if deemed related to pregnancy. For any AEs that have already been reported, clinicians should re-assess and retroactively select the checkbox, if applicable.

A second field was added to document if Dapivirine (DPV) vaginal ring relatedness is attributed to the device or drug. If a mother participant is randomized to the DPV vaginal ring, and an AE reported on the AE log in a mother casebook is related to study product, the “If “related” to the DPV vaginal ring, is the AE related to the drug (dapivirine) or device (ring itself or ring insertion)?” field must be completed to document if the clinician thinks the AE is related to the drug, device, or if they cannot distinguish between the drug and device components. For any AEs that have already been reported, sites should review and, if related to DPV vaginal ring, complete the new field retroactively.

Chemistry Panel CRF

The field format for Creatinine Clearance result was updated to allow up to 2 decimals. If this form has been completed, this field should be retroactively updated to report Creatinine Clearance with two decimals.

Inclusion/Exclusion Criteria CRF

The response options for “Select reason(s) why participant is ineligible” have been corrected to separate Exclusion criteria 6a. through 6h. into separate response options. If “E6. At Screening, has any of the following laboratory abnormalities: Positive for hepatitis B surface antigen (HBsAg), Aspartate aminotransferase (AST) or alanine transaminase (ALT) \geq Grade 1, Hemoglobin \geq Grade 2, Platelet count \geq Grade 1, Creatinine \geq Grade 1, Estimated creatinine

clearance \geq Grade 1 (Cockcroft Gault formula), Glycosuria \geq Grade 2, or Proteinuria \geq Grade 2” was previously selected, the form should be retroactively to select the specific E6 criterion.

Infant HIV Confirmatory Results CRF

Two fields were added: “Were any additional tests besides RNA or DNA performed?” and “If “Yes”, specify”. If this form has already been completed, these fields should be retroactively updated.

Participant Type CRF

The field “If this participant is a mother, what is the infant's PTID?” was added to the Participant Type CRF. This field should be completed in a mother’s casebook to document the mother’s infant’s PTID. If this form has already been completed for a mother participant, the form must be updated retroactively to add the infant’s PTID.

Pregnancy Outcome CRF

An “Other” response option was added for the “If “Study designated delivery facility”, specify:” field. If “Other” is selected, the new “If “Other”, specify:” field should be completed. If this form has already been completed, and the mother delivered at a study-designated delivery facility that is not explicitly listed, the field must be updated retroactively.

The following fields were removed from the Pregnancy Outcome CRF (as these data will now be captured on other forms): “Were photos related to this outcome uploaded?”, “Was the infant enrolled in MTN-042”, “If “yes”, enter infant PTID”, and “If “No”, explain”.

Urine Test Results CRF

The response options for “Leukocyte esterase (LE)” were changed to: Trace, Small +, Moderate ++, Large +++, and Not done. If this form has already been completed, the field must be updated retroactively to select the correct response option.

An updated complete set of blank eCRFs and v2.0 of the MTN-042 CRF Completion Guidelines (CCGs) have been posted to the MTN-042 ATLAS webpage.

<https://atlas.scharp.org/cpas/project/MTN/042/begin.view?>