MTN-042 Operational Guidance #01:
Assessment and Documentation of Congenital Anomalies for Geneticist Review

Procedures for assessment of congenital anomalies, infant photography and upload of photos is provided in SSP sections 7.19.8-7.19.10. This operational guidance document supplements currently outlined SSP guidance in conjunction with Data Communique #01, which describes new CRFs available for documentation of congenital anomaly review by an external geneticist.

All congenital anomaly reports will be reviewed by an external consultant geneticist who confirm a final congenital anomaly determination. As part of this review process, sites will be responsible for completing the following:

- Review infant/delivery medical records for reported congenital anomalies.
    - Certified copies of any relevant medical records from evaluations conducted outside the clinic should be obtained, where possible, and filed in the participant binder.
- For enrolled infants, perform clinical assessments including a physical exam to assess for congenital anomalies and complete a full photo survey (if determined to be contributory and consented to by mother)
- Document assessment of the congenital anomaly in as much detail as possible on the source documents including:
    - For **enrolled infants** (born alive, infant IC obtained) complete the following in the infant casebook:
        - **Physical Examination CRF**
        - **Pregnancy Outcome CRF** (in maternal casebook)
        - **AE Log CRF** (if DAIDS criteria for EAE/SAE reporting met)
        - **EAE Report using Infant PTID** (if DAIDS criteria for EAE/SAE reporting met)
        - **Congenital Anomaly Review CRF**, items "Date of report" through "Are photographs available?" (note: the geneticist will complete items "Date of review" through "Comments")
        - **Photographic Survey CRF** (if photos warranted/consented to)
        - **EAE Upload CRF** (if reported to DAIDS as an EAE)
    - For **non-enrolled infants** (not born alive and/or infant IC not provided) complete the following in the maternal casebook:
        - **Pregnancy Outcome CRF**
        - **Non-Enrolled Infant AE Log CRF** (if DAIDS criteria for EAE/SAE reporting met)
        - **EAE Report using Maternal PTID** (if DAIDS criteria for EAE/SAE reporting met)
        - **Congenital Anomaly Review CRF**, items "Date of report" through "Are photographs available?" (note: the geneticist will complete items "Date of review" through "Comments")
        - **EAE Upload CRF** (if reported to DAIDS as an EAE)
- Respond to any clinical queries related to submitted congenital anomalies, as needed (see below)

Upload of DAERS EAE Reports to Medidata RAVE

If the congenital anomaly meets DAIDS defined criteria for reporting as an EAE, then a report should be submitted to DAERS (see SSP section 8.17). Report EAE using the infant PTID for enrolled infants. Report EAE using the maternal PTID for non-enrolled infants. All reporting timelines as outlined in the EAE manual should be followed. Once initial comments have been addressed on EAE report, export a PDF of the EAE report for uploading using the **EAE Upload CRF**. If subsequent updates are made to the submitted EAE report, export a copy of the updated report from DAERS. Add a new log line to the **EAE**

Upload CRF and upload the updated report. Inactivate the log line with the previous version of the EAE report.

Photographic Survey and Upload to Medidata RAVE

See SSP section 7.19.9 for details regarding the photographic survey. Additional details including views required and file naming conventions can be found in the MTN-042 Infant Photography Guide (available on the MTN website under Study Implementation Tools). If photos are taken, use the **Photographic Survey CRF** to upload to Medidata RAVE. Select the best photo from each view and upload only one per required view, with the exception of the close-up anomaly images, which should include as many perspectives as possible is requested (front, rear, left and right lateral, as appropriate).

Addressing Queries from the Geneticist

It is possible that after completing their review, the geneticist may request more information from the site in order to make their final determination. Should this be necessary, sites will receive a clinical query from the SCHARP Clinical Safety Associate within Medidata.

All Operational Guidance documents must be printed and filed with regulatory documentation. This guidance will be incorporated into the SSP on next revision.

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