

# MTN-016

## Evaluation of Potential Major Malformations



# Major Malformations

- Defined as structural abnormalities that meet the following criteria:
  - Have surgical, medical, or cosmetic importance
  - Ascertained up to one year of age
- NOT considered as major malformations:
  - All birth marks
  - All minor physical features
  - Deformities that represent normal response of fetal tissue to mechanical forces

# Minor Malformations



# Deformities

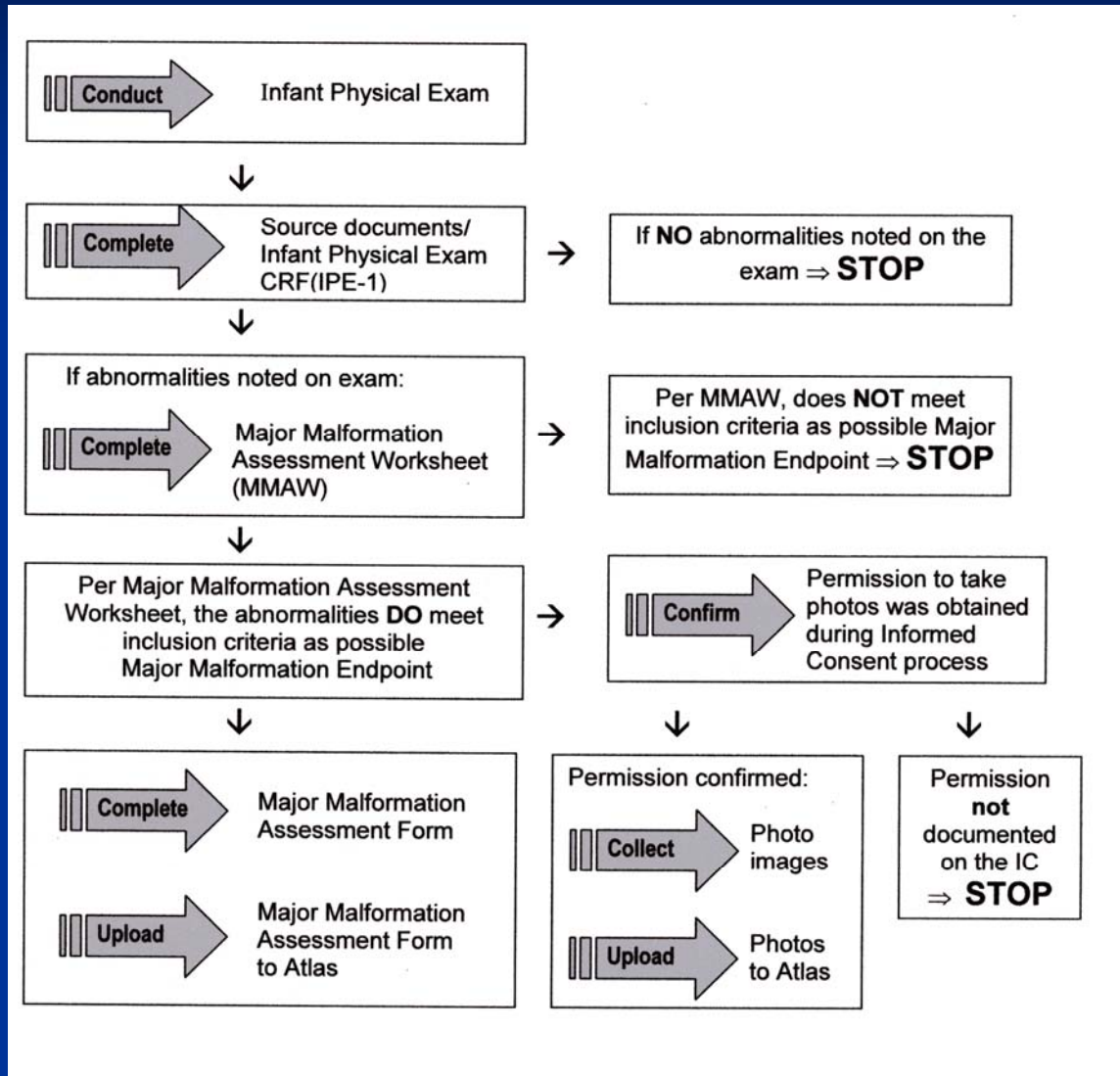




# Major Malformations



# Documentation of Anomalies



# MMA

## Worksheet

- Used to determine if abnormality noted during the PE meet inclusion criteria for possible Major Malformation Endpoint.

1. Is/are the abnormality/abnormalities identified during the physical exam a structural abnormality with surgical, medical or cosmetic importance?
  - Yes
  - Unsure
  - No → If no, abnormality identified during the physical exam does NOT meet the inclusion criteria as a major malformation endpoint for MTN-016. The Major Malformation Assessment of these findings is complete. **STOP, end of worksheet.**
2. Was/were the abnormality/abnormalities ascertained prior to one year of age?
  - Yes
  - Unsure
  - No → If no, the abnormality identified during the physical exam does NOT meet the inclusion criteria as a major malformation endpoint for MTN-016. The Major Malformation Assessment of these findings is complete. **STOP, end of worksheet.**
3. Is/are the abnormality/abnormalities identified during the physical exam any of the following:
  - a. Birth mark?
    - Yes
    - Unsure
    - No
  - b. A deformity or deformities that represent the normal response of fetal tissue to mechanical forces? That is, an atypical body part growth and/or appearance attributable to fetal position and/or pressure of surrounding maternal tissue(s). For example, molding of the skull, also known as positional plagiocephaly, would not be considered a major malformation.
    - Yes
    - Unsure
    - No
  - c. Minor physical feature(s)?
    - Yes. Were 2 or more minor physical features identified on this exam?
      - Yes
      - No
    - Unsure
    - No

Presuming that questions 1 and 2 are answered either "yes" or "unsure":

If the responses to items 3a, 3b, or 3c are "no" or "unsure"	→	<b>proceed with evaluation</b> as a potential major malformation endpoint as described in section 10.7. Complete the MTN-016 Major Malformation Assessment form and, if consent has been obtained and documented, obtain photographic documentation as outlined in section 10.7.3.
If there are 2 or more minor physical features identified for item 3c		
For all other responses to items 3a, 3b, and 3c	→	the malformation(s) identified does NOT meet the inclusion criteria as a major malformation endpoint MTN-016. The Major Malformation Assessment is complete. <b>STOP and do not complete the Major Malformation Assessment form.</b>

Note: Do not submit this worksheet to Atlas. Store it with participant MTN-016 study records.

**Instructions:** This form is completed if indicated per the instructions on the Major Malformation Assessment worksheet. Submit this completed form to Atlas within 2 business days of completion  
*Note: Do not submit the worksheet to Atlas, but store it with participant MTN-016 study records.*

**IMPORTANT:** Complete all required fields so the clinical reviewers have all information required to follow-up as needed.

**Site Name:** \_\_\_\_\_ **Physical Exam Date (dd-MMM-yy):** \_\_\_\_\_  
**Completed by:** \_\_\_\_\_ **Email Address:** \_\_\_\_\_

**Infant PTID:** \_\_\_\_\_ **Infant Birth Date (dd-MMM-yy):** \_\_\_\_\_

**History:**  
All relevant data submitted via DataFax will be made available to the MTN-016 clinical reviewers and do not need to be resubmitted. However, information collected on non-DataFax forms (such as the Woman Medical History Log form and the Infant Medical History Log form) will not be in the MTN-016 database. Therefore, pertinent information from those forms or other source documents must be provided here. It is important that all records are consistent.

**Description of malformation(s)**  
The Infant Physical Exam form, Woman Concomitant Medications Log form, Genetic Screening History form and Pregnancy Report and History form will be available to the MTN-016 Clinical Team, so there is no need to repeat findings already submitted. However, additional details can be provided here. Particularly if you were unable to collect and send photographs, a detailed description and/or sketch of the physical findings should be included.

**Assessment** (What is your assessment of malformation(s) described?)

**Plan** (What is your plan for referral or follow up of these malformations?)

*Note: Store this completed MTN Major Malformation Assessment form with participant MTN-016 study records.*

# MMA Form

- Completed when abnormality noted on PE may be eligible as a major malformation endpoint.
- Use MMA worksheet to determine if MMA form should be submitted.
- Done with or without photographic documentation





# Photographing Infant

- Head/Neck/Torso – 4 Views



# Photographing Infant

- Palm view of hands



- Top view of hands



- Top view of feet



# Tips for taking the photos

- Mother should be present
- Keep the baby warm
- Easiest when baby is fed and calm
- Don't force any positions
- Extra lighting may be needed; do use a flash if available
- Solid background is preferred
- Write the infant PTID on a piece of paper and position near the infant in the photo
- Take extra views and select the best for uploading!

# Uploading to ATLAS



Spilhaus\_301123491\_22OCT2009\_facenecktorso\_1



# Uploading to ATLAS

- Sites should schedule a practice submission to confirm that:
  - On-site camera is adequate
  - Bandwidth is sufficient
  - Uploading is possible from your clinic computer

# Major Malformation Scenario

Alfonso is a 3 day old with a very large discoloration on his forehead.

# Major Malformation Scenario

- Is this a simple birthmark?
  - If yes, not a major malformation.
  - If this is more than a birthmark, refer to Pediatrician
  - Complete the MMA Worksheet to confirm, and then...
  - Complete the MM Assessment Form
  - Review IC to confirm permission granted to photograph infant.
  - Take photographs per site SOPs and upload to ATLAS.

# Major Malformation Scenario

Thomas is born with albinism.

- Is this a major malformation?



# Scenario Answer

- Albinoism is to be documented as a major malformation for this protocol.