

# Ultrasound in MTN-016

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# Why Ultrasound in MTN-016?

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- Performed properly, an accurate method of determining gestational age (GA)
- Fetal anatomy assessed adequately after ~18-20 weeks GA, with some individual variation
  - MTN-016 prefers 20-28 weeks for anatomy scan
- Both dating and anatomy important for understanding potential impact of drugs in pregnancy
  - Understand timing of exposure and potential impact on intrauterine growth/development

# Ultrasounds at Your Site

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- Who here has performed obstetric ultrasound?
  - Which trimesters?
  - Will you perform any obstetric ultrasound in MTN-016?
- How is ultrasound ordered at your site?
  - Where is it performed?
  - Standard form or handwritten order?
  - How are results communicated?

# If Study Site Orders the U/S

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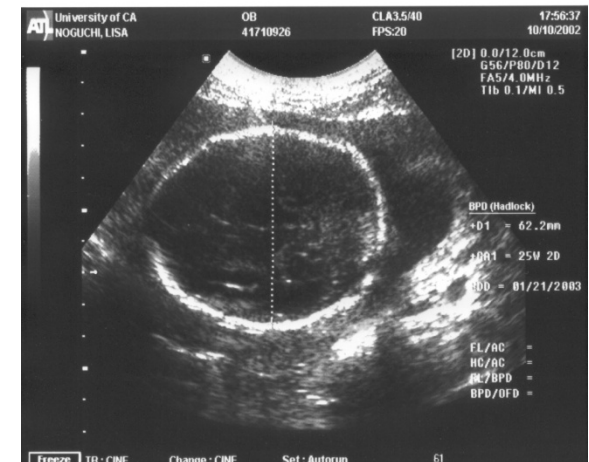
- Have the UR-1 CRF on hand when you fill out or write your order!
  - If feasible, consider a new preprinted order format for MTN-016 participants
- Clearly request of the ultrasound provider
  - Gestational age determination
  - If estimated GA by LMP is >18 weeks, **request evaluation of all components of anatomy that are listed on the CRF**

# Gestational Age Determination

- GA determination most accurate in first half of preg.
  - First trimester crown-rump measurement is most accurate for U/S dating
  - Order first trimester U/S when LMP unknown or when size/dates do not match
- Pregnancy should not be “re-dated” after dates are calculated from an accurate earlier scan



CROWN RUMP LENGTH (CRL)



BIPARIETAL DIAMETER (BPD)

# Biparietal Diameter



In this image, BPD = 70.4 mm

- ❑ Technically more challenging than CRL
- ❑ Measure at level of thalami and cavum septi pellucidum
- ❑ Cerebral hemispheres should not be visible in this scanning plane
- ❑ Measure from outer edge of proximal skull to inner edge of distal skull

# When to Change Dates?

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- In general, U/S-established dates take preference over menstrual dates when discrepancy is greater than:
  - 7 days in the first trimester
  - 10 days in the second trimester (up to 20 weeks gestation)
- Reassigning GA in the third trimester should be done with **great** caution – accuracy is only within 3-4 weeks

**SAMPLE**. DO NOT FAX  
TO DATAFAX

MTN 016 (164)



UR-1 (120)

**Ultrasound Results (UR-1)**

Pregnancy # [ ][ ] Visit Code [ ][ ] [1]  
Page 1 of 1

**Participant ID**

[ ][ ][ ] - [ ][ ][ ] - [ ][ ] - [0]  
Site Number Participant Number Chk Cohort

**Ultrasound Results**

**Exam Date**

[ ][ ] [ ][ ][ ] [ ][ ][ ]  
dd MMM yy

- Are ultrasound exam results available at this visit?  yes  no  
 1a. Reason ultrasound exam results not available:  
 participant not pregnant at this time  
 other, specify: \_\_\_\_\_  
**End of form.**
- Estimated gestational age (at time of ultrasound): \_\_\_\_\_ weeks days  
 2a. Crown-rump length: \_\_\_\_\_ cm  
 2b. Biparietal diameter: \_\_\_\_\_ cm  
 2c. Femur length: \_\_\_\_\_ cm OR  Not done/Not collected  
**If estimated gestational age is ≥ 14 0/7 weeks, go to item 2b.**  
**Go to item 3.**

**ANATOMICAL SURVEY DATA**

	not visualized	normal	abnormal	If abnormal, record description:
3. Intracranial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
4. Face/lip	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
5. Spine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
6. Thorax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
7. Four-chamber heart	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
8. Stomach	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
9. Kidneys	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
10. Bladder (urinary)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
11. Cord insertion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
12. Upper limbs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
13. Lower limbs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
14. Gender	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

# Ultrasound Results (UR-1)

- Complete/fax to SCHARP at Enrollment and each completed Quarterly visit
- “Pregnancy #” refers to number of pregnancy corresponding to MTN-016 participation, NOT her Gs and Ps
- Exam Date = date U/S is completed, NOT date reviewed
- Item 2a: Complete if GA at time of U/S is < 14w 0d
- Items 2b and 2c: Complete if GA at time of U/S is ≥ 14 w 0d
- Items 3–14: For each item marked “abnormal,” record description



# What if Ultrasound Report is Incomplete?

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- ❑ Contact the ultrasound provider
  - Are images or video still available?
  - Can a revised report be sent to the site?
- ❑ If a revised report is not available, order another ultrasound, when possible, and specifically request evaluation of the missing items
- ❑ Set up routine expectations and establish a line of communication with your ultrasound provider, when possible

# What if Results are Abnormal?

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- **Communication!**
  - **With participant's obstetric care provider**
  - With the participant – discuss communication strategy with obstetric care provider
  - With the MTN-016 Management Alias and DAIDS Medical Officer
- Clinically appropriate follow-up plan – **consult if results are abnormal/unclear**
- Source documentation

# A Few Last Words...

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- ❑ Order/perform to the CRF, at a minimum
- ❑ Get comfortable with ultrasound abbreviations and terminology used at your site
- ❑ If you can only get one...the ideal single ultrasound in MTN-016 is a dating confirmation and thorough anatomical survey at about 20 weeks gestation
- ❑ Protocol allows for multiple ultrasounds, if necessary
- ❑ Send your ultrasound questions to the MTN-016 Management Alias and DAIDS Medical Officer



# A Few Different Scenarios

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1. Report is reviewed and states only “normal IUP at 18 2/7 wks”
2. Report states “normal IUP at 22 wks except marginal placenta previa”
3. Images reviewed and BPD looks like it was measured in the wrong plane
4. Participant calls, “I think something was wrong on the ultrasound today, but no one would explain it to me.”