

**NVPO Definitions Project  
DATA COLLECTION FORM v1.0 June 28, 2108  
PRETERM LABOR (PTL)**

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**ADMINISTRATIVE INFORMATION**

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Initials of person performing the review: \_\_ \_\_

Outcome code: PTL

Country code: US, AU, UK: \_\_ \_\_

Site code: BC, CC, EM, UW, MO, SG, SU: \_\_\_\_

Origin code CT=clinical trial MR= medical record: \_\_ \_\_

Subject ID number PTL \_\_\_\_\_  
  Country Site Origin Number (starting with 01)

Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of PTL: (from case identification log): \_\_\_\_\_

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**COMMON VARIABLES**

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1. If case from clinical trial (tick and list study drug/vaccine):

- Vaccine \_\_\_\_\_
- Drug \_\_\_\_\_
- Epidemiologic \_\_\_\_\_
- Other \_\_\_\_\_

2. Year of event: \_\_\_\_\_ (full year)

### 3. General pregnancy variables

a. **Maternal Age (whole years) at time of delivery**

\_\_\_\_\_ (number if unknown fill UNK)

b. **Race** (tick one, please tick other and state UNK, if unknown/uncertain)

- Black
- White
- Asian
- Other \_\_\_\_\_

c. **Ethnicity** (tick one, please tick other and state UNK if unknown/uncertain)

- d.  Hispanic
- Not Hispanic
- Native Population
- Other \_\_\_\_\_

e. **Infant gender** (tick one, please tick other and state UNK if unknown/uncertain)

- Male
- Female
- Other \_\_\_\_\_

f. **Mode of delivery** (tick one, please tick other and state UNK if unknown/uncertain)

- Vaginal
- C-section:
- Other: \_\_\_\_\_

g. **Singleton pregnancy** (tick one, please tick other and state UNK, if unknown/uncertain)

- Yes
- No
- Other: \_\_\_\_\_

- h. **Parity (fill 1-4 each with full number based on the status at start of this pregnancy).** **Gravidity** is defined as the number of times that a woman has been pregnant and **parity** is defined as the number of times that she has given birth to a fetus, regardless of whether the child was born alive or was stillborn

(fill what you see in chart, if absent state UNK)

**Gravidity/Parity reported**

**G.... P.....**

1. **Prior Term Pregnancies**\_\_\_\_\_ (number or fill UNK if unknown)
2. **Prior Preterm Pregnancies (<37 wk)** \_\_\_\_\_ (number or fill UNK if unknown)
3. **Abortions/miscarriage (<20 wk)**\_\_\_\_\_ (number or fill UNK if unknown)
4. **Born Alive** \_\_\_\_\_ (number or fill UNK if unknown)

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**GESTATIONAL AGE ASSESSMENT**

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**4. Recorded gestational age (from chart)**

\_\_\_\_\_ (Number: weeks/days, if absent or unknow state UNK)

**5. How was reported gestational age above assessed (tick one, and if unknown tick other and state UNK)**

- Antenatal Maternal US
- LMP
- Infant Exam,
- Other (describe) \_\_\_\_\_

6. Elements of GA available in the record. (tick one option on each line for a-l)

	Recorded	NOT recorded	Incomplete/uncertain	Comments/Issues
a. Intrauterine insemination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
b. Embryo transfer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
c. Certain LMP (LMP known)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
d. Uncertain LMP (LMP not known)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
e. First trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
f. Second trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
g. Third trimester US	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
h. Fundal height (any)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
i. Fundal height in 2 <sup>nd</sup> trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j. Maternal physical exam in 1 <sup>st</sup> trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
k. Birth weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
l. Newborn GA by physical exam	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

7. Assessment of Gestational Age LOC based on GAIA Definition (Use Case Definition

Checklist:see appendix 2):

a. Level of certainty \_\_\_\_\_ (1,2,3,4,5 or UNK: unable to assess)

b. If unable to assign GA LOC, describe the reason(s):

Reason \_\_\_\_\_

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**PTL CASE DEFINITION SPECIFIC VARIABLES**

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**8. Elements of the PTL case definition in maternal clinical or study record (tick each line):**

Parameter	Evidence in Medical Record or Study Record			Comments
	Yes*	No*	Uncertain/ not recorded	
a. Patient is preterm >20, but <37 weeks, with labor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. On presentation, >4 documented uterine contractions per hour as determined by tocodynamometer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Documented change in length or dilation of cervix by physical examination over a two hour period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Documented change in length or dilation of cervix by transvaginal sonogram over a two hour period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Clinical criteria for documenting cervical change by exam include cervical dilation 2 cm or greater at the internal os or cervical length of 1 cm or less or 50% or greater effacement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Documented change in length or dilation of cervix transvaginal ultrasound over a two hour period	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

\*Yes means: evidence in record      \*No means evidence of absence of this condition

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**QUALITY ASSESSMENT CASE DEFINITION**

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**9. Case abstractor's best assessment of LOC for PTL is (Use Case Definition in appendix 1 ):**

a. Level of certainty \_\_\_\_\_ (1,2,3 or UNK: unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason \_\_\_\_\_

**10. PI's assessment of LOC for PTL (Use Case Definition Checklist in appendix 1):**

a. Level of certainty \_\_\_\_\_ (1,2,3 or UNK: unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason \_\_\_\_\_

**11. Other comments:**

\_\_\_\_\_

**PreTerm Labor (PTL)**  
**NVPO Data Abstraction and LOC Assignment Tool**  
**Guide for LOC assignment for PTL (check all that are present)**

Preterm Labor is characterized by cervical change in the preterm period with gestational age >20 wks but <37 wks.

**Case definition of Preterm Labor**

**For all LEVELS:**

- 1. Pregnancy  $\geq$  20 weeks gestation AND
- 2. Pregnancy < 37 weeks gestation

**Level 1 of diagnostic certainty**

- 1. on presentation, >4 documented uterine contractions per hour as determined by tocodynameter AND
- 2. documented change in length or dilation of cervix by physical examination over a two hour period OR
- 2. documented change in length or dilation of cervix by transvaginal sonogram over a two hour period AND
- 3. Clinical criteria for cervical change by examination of cervical dilation 2 cm or greater at the internal os by digital examination OR
- 3. Cervical length of 1 cm or less by digital examination OR
- 3. Cervical effacement 50% or greater by digital examination

**Level 2 of diagnostic certainty**

- 1. on presentation, >4 documented uterine contractions per hour as determined by tocodynameter AND
- 2. documented change in length or dilation of cervix by physical examination over a two hour period AND
- 3. Clinical criteria for cervical change by examination of cervical dilation 2 cm or greater at the internal os by digital examination OR
- 3. Cervical length of 1 cm or less by digital examination OR
- 3. Cervical effacement 50% or greater by digital examination

**Level 3 of diagnostic certainty**

- 1. on presentation, >4 documented uterine contractions per hour as determined by clinical assessment AND
- 2. documented change in cervical examination (change in dilation or effacement) over a two hour period

No Level 4,5 for GAIA definition for PTL



## Appendix 2:

### Gestational Age Assessment Guide

#### Definitions of terms used:

**Intrauterine insemination (IUI)** – A procedure in which a fine catheter is inserted through the cervix into the uterus to deposit a sperm sample directly into the uterus, to achieve fertilization and pregnancy.

**Embryo transfer** – The procedure in which one or more embryos are placed in the uterus or fallopian tube.

#### **Ultrasound (U/S):**

- 1st trimester ( $\leq 13 \frac{6}{7}$  weeks).
- 2nd trimester scan ( $14 \frac{0}{7}$ – $27 \frac{6}{7}$  weeks).
- 3rd trimester ( $28 \frac{0}{7}$  + weeks).

**LMP** (last menstrual period) – GA is calculated from the first day of the mother's LMP. If LMP and U/S do not correlate, default to U/S GA assessment.

**\*Certain LMP:** (LMP date + 280 days): Use LMP if within 7 days at  $\leq 14$  weeks; within 14 days at  $\leq 26$  weeks; within 21 days beyond 26 weeks.

**\*Uncertain LMP – first trimester ( $\leq 13 \frac{6}{7}$  weeks by LMP):** Use the approximate date of the last menstrual period (LMP) if corroborated by physical exam, or a first trimester ultrasound. If there is a discrepancy of  $>7$  days between the LMP and the first trimester ultrasound, the ultrasound-established dates will take preference over LMP for gestational age dating.

**\*Uncertain LMP – second trimester ( $14 \frac{0}{7}$ – $27 \frac{6}{7}$  weeks by LMP):** Use the approximate date of the LMP if corroborated by physical exam including fundal height, or a second trimester ultrasound. If there is a discrepancy of  $>10$  days between the LMP and the second trimester ultrasound, the ultrasound-established dates will take preference over LMP for GA dating.

**\*Uncertain LMP – third trimester  $>28$  weeks –** third trimester ultrasound.

**\*No LMP date:** If menstrual dates are unknown, the ultrasound established dates will be used for gestational age dating or 2nd trimester fundal height and/or newborn physical examination.

**Pregnancy symptoms**– nausea, fatigue, tender swollen breasts, frequent urination.

**Antenatal Physical Examination**– pelvic bimanual examination confirming enlarged uterus.

**Newborn Physical Examination**– New Ballard Score – physical and neurological assessment.

**Fundal Height (FH)** in cm

**Birth Weight (BW)** in grams

**GA Levels of Certainty (check all that are present)**

**Level 1**

1. Certain LMP\* or intrauterine insemination (IUI) date or embryo transfer (ET) date with confirmatory 1st trimester scan ( $\leq 13 \frac{6}{7}$  weeks).

OR

2. 1st trimester scan ( $\leq 13 \frac{6}{7}$  weeks).

**Level 2A**

1. Certain LMP\* with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks). If LMP and U/S do not correlate, default to U/S GA assessment.

OR

2. Certain LMP\* with 1st trimester physical examination.

**Level 2B**

Uncertain LMP with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks).

**Level 3A**

1. Certain LMP with 3rd trimester scan – 28 0/7 weeks +.

OR

2. Certain LMP with confirmatory 2nd trimester FH.

OR

3. Certain LMP with birth weight.

OR

4. Uncertain LMP with 1st trimester physical examination.

**Level 3B**

1. Uncertain LMP with FH.

OR

2. Uncertain LMP with newborn physical assessment.

OR

3. Uncertain LMP with Birth weight.

