CARE PrEP PREGNANCY DATING GUIDE

PREGNANCY DATING DEFINITIONS

- Last menstrual period (LMP): The first day of blood flow of the last menstrual period. Can be 'certain' or 'uncertain.'
- **Date of conception (DoC):** In a typical menstrual cycle, the egg is released during ovulation and conception occurs within the next couple of days. The date of conception is considered to be about 2 weeks after the LMP.
- **Estimated Date of Delivery (EDD):** Best estimate for when the pregnant person will reach 40 weeks (280 days) gestation. Also, referred to as Estimated Date of Confinement (EDC) or due date.
- **Gestational Age (GA):** Age of the pregnancy in weeks and days based on the EDD. Term pregnancy is 37 weeks and 0/7 days.

WORKING EDD AND FINAL EDD

- Working EDD: Working EDD is the estimated date of delivery based on the pregnant person's best estimate of their last menstrual period (LMP) or date of conception
- **Final EDD:** Confirmed after the first ultrasound when the gestational age based on the LMP can be compared to the gestational age based on fetal growth measurements from the ultrasound. The Final EDD is the best estimate possible for 40 weeks gestation, either based on the LMP (or by extension the DoC) or the ultrasound.

A Working EDD will be accepted or re-dated based on ultrasound as the Final EDD. Once a Final EDD is set, it is never changed.

- If a Final EDD is set and several months later the baby is measuring very, very small (i.e., for the currently understood gestational age), the EDD is **not** changed; the baby is considered small for gestational age (SGA)
- If a Final EDD is set and two days before the Final EDD the participant delivers, the EDD does not change. Rather, the participant delivered at 39 weeks and 5 days (2 days before 40 weeks).

PREGNANCY DATING AT ENROLLMENT VISIT

Dating for Eligibility determination

Study eligibility depends in part on gestational age at enrollment and PrEP use since beginning of the pregnancy (date of conception). The **Eligibility CRF** includes a section on pregnancy dating to determine LMP, Date of conception, Working EDD, and GA.

Use the Perinatology.com website (https://perinatology.com/calculators/Due-Date.htm) to calculate the dating outputs.

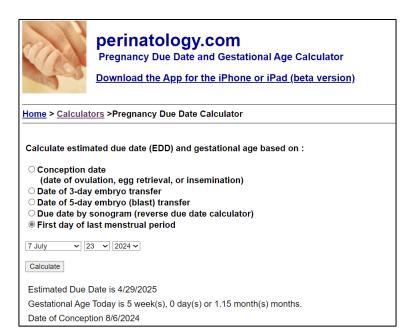
Note: The website is US-developed; all dates provided are in the format of MM-DD-YYYY. <u>Convert the dates to DD-MM-YYYY</u> when entering them into study CRFs.

Choose the <u>best</u> input to "Calculate estimated due date (EDD) and gestational age based on:" The outputs will include all the other needed dating information. If multiple inputs available, order of preference is: 1) ultrasound, 2) <u>certain</u> conception date, and then 3) LMP.

1. Using "first day of last menstrual period" (LMP)

Usually the easiest and most accessible starting point for determining the working EDD. Use the following questions to help the participant estimate LMP if it is uncertain.

- Do you remember what you were doing when you had your last period?
- Where were you? Were you with anyone?
- Was it before or after XXX holiday/birthday?
- Do you record this information somewhere? Your phone, in a journal?



An LMP date can be entered into the perinatology website even if the participant is very uncertain. Within the Eligibility CRF, the LMP entered must be indicated as 'certain' or uncertain.'

In some instances, people become pregnant during a time of amenorrhea (no menstruation cycle). The most common example of this is falling pregnant while using DMPA. If a participant reports that the last menstrual period was years ago, asking about the last negative pregnancy test may provide clues about when the pregnancy was conceived. For example, if a participant reports that she has been amenorrheic for years but had a negative pregnancy test 2 months ago, you can deduce that she achieved pregnancy within the last 2 months. In this instance, use the estimated date of the negative pregnancy test as the LMP and indicate in the CRF that it is uncertain.

2. Using "Conception Date"

"Conception date" may be the best entry point, especially if LMP is uncertain, there were limited sexual encounters, and/or the participant's menstruation cycle is not consistent.

Example: A participant has only one sexual partner who is a truck driver and he was home for only one night six weeks ago. Prior to that it had been three months since the participant had intercourse (and an intervening menses). You can assume that conception happened during this sexual encounter 6 weeks ago.

3. <u>Using "Due date by sonogram" (ultrasound)</u>

Expected to be rare that a prior ultrasound is available for review at enrollment. However, if the results of a prior ultrasound are available which clearly state the EDD, entering the "Due date by sonogram" will provide the best input.

Once you choose the most reliable data to enter into the Perinatology website (ultrasound, DoC, or LMP), select 'Calculate." A number of dates will be generated based on your input. Complete the Eligibility CRF Pregnancy Dating section with relevant inputs/outputs.

Completing Estimated Due Date (EDD) CRF at Enrollment Visit

Complete **EDD CRF** for all enrolled participants during obstetric history and care assessment. *The Working EDD is expected at this visit unless the participant has an adequate dating ultrasound available.* Enter the <u>same EDD and certainly of LMP indicated on the Eligibility CRF.</u>

PREGNANCY DATING AT FOLLOW-UP - Establishing Final EDD after Study-Directed Ultrasound

All participants should receive a study-directed ultrasound, ideally before the 1^{st} Antenatal Visit (V102) for the purpose of determining a Final EDD (the best estimate).

Antenatal Care CRF includes question of "Do you have a new and final EDD to report?"

A Final EDD can only be ascertained after the first study-directed ultrasound results are available, meaning study staff have
a completed paper Ultrasound Results CRF. If an ultrasound is not available for review, this answer will be marked "no" on
the CRF.

Comparing the working EDD to the EDD based on ultrasound

- Working EDD (based on LMP or DoC) and ultrasound derived EDD are the same → Working EDD becomes the Final EDD (based on LMP consistent with ultrasound)
- Working EDD and ultrasound derived EDD differ → re-dating depends on 1) timing of the ultrasound and 2) how much the two EDDs differ.
 - Earlier ultrasounds are more accurate for dating and have less variance range around the EDD. See SSP Section 6 for variance table.
 - o If working EDD differs from the ultrasound EDD more than the accepted variation → Re-date the Final EDD (based on <u>ultrasound not consistent with LMP)</u>
- Use **Gestational Age (GA) Dating Tool,** which will apply the variance ranges to the participant's particular information and determine whether re-dating is in order.

GA Dating Tool Instructions

- 1. Open the GA Dating Tool file in Excel (on laptop).
- 2. Enter the PID and data from the Ultrasound Results CRF into the blue fields in the Excel tool: Ultrasound Date, GA per Ultrasound report (GA on date of the ultrasound), EDD per ultrasounds scan, and LMP.

- 3. The yellow portion of the Excel will populate, including the number of days discrepant between the GA based on LMP versus the ultrasound. Based on the number of days discrepant, the tool will indicate if the pregnancy should be redated based on the ultrasound. If redating response is:
 - a. 'YES' use 'EDD per ultrasound scan' as the Final EDD
 - b. 'No' use the 'EDD per LMP' as the Final EDD (this should be the same as the Working EDD)
- 4. Print the Excel spreadsheet, add study staff initials and date, and file in the participant chart
- 5. Clear the information in Excel before using for another participant.
- Open the already completed EDD CRF in the participant's REDCap record and update the CRF with the Final EDD and indicate if the date is 'consistent with the LMP' (same as working EDD) or 'ultrasound, not consistent with LMP' (redated).

DISCREPANCIES BETWEEN CLINICAL CARE AND RESEARCH EDD

A copy of the study-directed ultrasound report (paper CRF) with the Final EDD noted by study staff on the bottom of the report should be provided to the participant's clinical care team.

Ideally the clinical care team will adjust their pregnancy dating and update ANC records accordingly

- Because the EDD can impact clinical decision making, make an effort to discuss this discrepancy with the clinical care team if feasible.
- Ultimately, if the clinical care team elects to use their own EDD, this should not impact the study pregnancy dating for determining pregnancy outcome (term or preterm delivery, for example).