



Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

The first day of the last menstrual period (LMP) is determined, and a judgment made as to whether or not the patient has a certain or "sure" LMP date.

- Most charts will not identify a menstrual period as normal or entirely normal. Rather, what should be expected is a comment when things were not entirely normal (e.g., less flow than usual, irregular flow, history of irregular cycles, flow that did not occur when expected, etc.). The absence of such comments is sufficient to accept the LMP as entirely normal.
- If studies are designed prospectively and LMP is determined, the protocol should stipulate obtaining the following data: date of LMP, length of cycle, regularity of cycle, first cycle following discontinuation of contraception. For cycle lengths other than 28 days the EDD should be adjusted accordingly (i.e., if cycle length is 32 days, 4 days should be added to the calculated EDD prior to comparison with ultrasound. Similarly, if cycle length is 26 days, 2 days should be subtracted from the calculated EDD prior to comparison with ultrasound).

If the LMP date is uncertain, ultrasound measurement(s) obtained at the patient's earliest ultrasound examination should be used to determine the project gestational age.

- If more than one first trimester ultrasounds are available, the earliest ultrasound with a crown rump length (CRL) equivalent to at least 7 weeks (or 10 mm) should be used (given the imprecision of measurement in very early scans).
- If the first dating ultrasound was conducted before 14 weeks 0 days, the measurement should be based on crown rump length (CRL) up to and including 84 mm and on BPD above 84 mm.
- For pregnancies of multiples the measurement of the largest fetus should be used.

If the LMP date is certain, and menstrual cycles have been regular, project gestational age is determined by a comparison between the gestational age by LMP

and by ultrasound measurement.

- If more than one first trimester ultrasound is available, the earliest ultrasound with a crown rump length (CRL) equivalent to at least 7 weeks (or 10 mm) should be used (given the imprecision of measurement in very early scans).
- If the first dating ultrasound was conducted before 14 weeks 0 days, the measurement should be based on crown rump length (CRL) up to and including 84 mm and on BPD above 84 mm.
- For pregnancies of multiples the measurement of the largest fetus should be used for pregnancy dating.
- If the ultrasound confirms the gestational age by LMP (as in the table below) the LMP-derived gestational age is adopted as the project gestational age. Otherwise, the ultrasound derived gestational age is adopted as the project gestational age

Gestational age at first ultrasound by LMP	Ultrasound method of measurement	Ultrasound agreement with LMP
Up to and including 8 weeks 6 days	CRL	± 5 days
9 weeks 0 days to 13 weeks 6 days	CRL	± 7 days
14 weeks 0 days to 15 weeks 6 days	Per institution	± 7 days
16 weeks 0 days to 21 weeks 6 days	Per institution	± 10 days
22 weeks 0 days to 27 weeks 6 days	Per institution	± 14 days
28 weeks 0 days and beyond	Per institution	± 21 days

If the patient has undergone an assisted reproductive technique by in vitro

fertilization to achieve pregnancy (standard IVF, IVF with donor egg, or IVF with ICSI) the IVF calculator should be used to estimate project EDC.

- the embryo is transferred at two days of age, the project EDC is 264 days after the date of transfer;
- the embryo is transferred at three days of age, the project EDC is 263 days after the date of transfer;
- the embryo is transferred at five days of age, the project EDC is 261 days after the date of transfer;
- the embryo is transferred at six days of age, the project EDC is 260 days after the date of transfer.

The following calculators may be used to determine project gestational age and project EDD once the principles detailed above have been followed:

EDD calculator

<http://perinatology.com/calculators/Due-Date.htm>

EDD from Ultrasound Report

<http://www.perinatology.com/calculators/EDDSono.htm>

Protocol source: <https://www.phenxtoolkit.org/protocols/view/240902>