

MTN-042 Data Communiqué #13 – 30 June 2023

This is official study documentation for MTN-042. Please circulate it among relevant staff for their review, print it, and place it in your MTN-042 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-042 SSP manual.

UPDATE

Interim Visit Coding

The Data Collection SSP (#11) specifies:

To the left of the decimal point, record the visit code of the most recently required follow-up visit.

When a participant has missed consecutive post-pregnancy visits, given the SSP wording “the most recently required follow-up visit” - particularly in a series that starts with the first PPO visit (101.0 or 201.0) - it might be assumed that this would indicate V101.0 or 201.0. However, this scenario is further explained in Example #3 of the SSP Visit Codes for Interim Visits section, wherein a mother gives birth a couple days after her last regularly scheduled visit:

She gives birth two days later, on July 13. The participant calls and completes her Visit 102 – 1-week PPO Phone Contact on July 19. She and her baby return to the clinic on July 31; the mother’s PO data is collected and the infant attends his first visit.

mother’s visit code = 102.01
infant’s visit code = 202.01

Please see this visual representation:

	Pregnancy Outcome	Vs 101.0 & 201.0	Vs 102.0 & 202.0	Interim Visits
Date	13-Jul	-	19-Jul	31-Jul

While Visits 101.0 and 201.0 were the ones missed and, regardless of the fact that the required data have been collected for the second PPO visits, per the protocol-defined visit schedule, Visits 102.0 and 202.0 are the most recently required. As such, the interim visits must be coded 102.01 and 202.01. Any subsequent interim visits that occur prior to the next regularly scheduled visit (Vs 103.0 and 203.0 in this scenario), are then coded with “02” following the decimal point.

In the event that a participant misses several consecutive PPO visits (e.g. through V204.0), the same principle applies. The mother, having missed all three of her PPO visits, is terminated from the study; the infant completes V201.0 assessments in an interim visit coded 204.01 and continues from there.