

MTN-020 Data Communiqué #14 – February 4, 2015

This is official study documentation for MTN- 020. Please circulate it among relevant staff for their review, print it, and place it in your MTN-020 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-020 SSP manual.

UPDATES – none

CLARIFICATIONS - none

REMINDERS

1. Ring Adherence (RA-1) CRF, item 4

In item 4 of the Ring Adherence CRF (version 1.0), provide the longest number of days in a row the vaginal ring was out during the *past study month*. If a participant missed her previous visit and was not dispensed an additional ring, the target date of that missed visit should be used when calculating the number of days the ring was out.

Example: A participant misses her Month 7 and 8 visits. Her Month 8 visit target date was on 08Oct14. She returns for her Month 9 visit on 10Nov14 with a used vaginal ring and reports that she removed the ring on 07Sep14. To complete item 4 on the RA-1 CRF, calculate the number of days the ring was out using the last missed visit's target date, in this case 08Oct14. In other words, report in Item 4 that the ring was out for the past 34 days (the amount of days between 10Nov14 and 08Oct14).

The Ring Adherence CRF should be completed at scheduled monthly visits only. This form should not be completed at interim visits. If a participant has an interim visit between study visits, chart note any outages that the participant has had in order to provide a complete recording of ring outages for the entire previous study month.

iDATAFAX CORNER – No updates