



MTN-020 Data Communiqué #4 - November 20, 2012

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

1. New Protocol Deviation Log CRF (plate 495, form date of 14-NOV-12)

A new Protocol Deviation Log (PDL) case report form has been created for use in ASPIRE. The new form (PDL- same acronym as before) has several changes: for items 3 and 4, the response boxes have been changed to yes/no; item 5 is now a 2-digit code rather than a “mark only one” field. The codes for item 5 are present in the form instructions. There are 3 new protocol deviation categories present. Guidance for when to use these categories in ASPIRE is provided below.

- **05 (study product use/non-use deviation):** use for cases in which the study ring has been out for more than 7 consecutive days, excluding cases in which a participant is on a clinical study product hold or has been permanently discontinued from study ring use. In addition, product non-use includes all cases in which a participant has declined study product (as documented on RCI form item 4a). Finally, for those sites not yet operating under LoA #2, cases in which a participant has had a ring in place for more than 35 days is also a reportable deviation.
- **06 (study product sharing):** use when staff become aware that a participant has shared study product (used or unused) with another individual, even if the individual is an ASPIRE participant.
- **07 (study product not returned):** use when a participant does not return study product as scheduled. For example, if a participant presents for her Month 5 visit and does not bring her ring with her, report this as a deviation (even if she returns the ring at a later date). Refer to protocol Table 3 (p.29) for product retrieval requirements.

As always, contact MTN Regulatory (mtnregulatory@mtnstopshiv.org) with questions related to protocol deviation reporting.

IMPLEMENTATION INSTRUCTIONS

The original) version of the PDL CRF (plate 499, dated 26-APR-12), should not be used as of November 27, 2012. SCHARP will not accept newly-completed plate 499 CRFs from November 27th onwards. If a plate 499 with a Form Completion Date on or after 27-NOV-12 is received, the site will be QC'd and requested to transcribe the information onto the new PDL form (plate 495). If a newly-completed plate 499 is accessed for data entry on or after 27-Nov, an alert will appear directing you to the new CRF (plate 495).

The new version (plate 495) for site use was sent with this email. The CRF can also be accessed in the “As needed” pdf file for printing located on the Atlas MTN-020 web page.

CLARIFICATIONS - None

REMINDERS - None