



## MTN-020 Data Communiqué #18 – February 1, 2016

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

#### 1. Post Database Lock Data Correction

Post DataFax database lock, SCHARP instructed sites to flag any MTN-020/ASPIRE CRFs that required a post-lock update or correction so that they may be identified and refaxed to SCHARP at a later date. These CRF updates could have resulted from data corrections identified during site FDA mock audit visits, from the Contraceptive Action Team data collection endeavor, or from any other review process at the sites after the time of DataFax database lock.

SCHARP is now ready to accept these post-lock data corrections. Sites are asked to locate these CRFs, to ensure that all corrections have been dated and initialed, and to fax these additional CRFs to SCHARP by no later than **Friday, February 12<sup>th</sup>**. All faxes must be sent as internet faxes (using an internet-enabled fax machine) to [datafax@scharp.org](mailto:datafax@scharp.org) in order to be received at SCHARP.

If any updates are required to a Protocol Deviations Log (PDL-1) or a Missed Visit (MV-1) CRF that was previously submitted to SCHARP via EDC, please ensure that these updates are made using EDC, in addition to making the correction to the paper copy of the CRF.

### CLARIFICATIONS – none

### REMINDERS – none

### iDATAFAX CORNER – No updates