

## MTN-026 Data Communiqué #3 - June 28, 2018

This is official study documentation for MTN-026. Please circulate it among relevant staff for their review, print it, and place it in your MTN-026 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-026 SSP Manual.

### UPDATES

#### 1. Updated Eligibility Criteria CRF

The field “Select inclusion and/or exclusion criteria that contributed to participant’s study ineligibility” has been updated to provide a 1:1 correlation with the inclusion/exclusion criteria specified per the MTN-026 protocol, Version 2.0, dated 21 July 2017. Specifically, the following criteria were added:

- Anticipated use of and/or unwillingness to abstain from the following medications during study participation:
  - Aspirin (greater than 81 mg)
  - Any other drugs that are associated with increased likelihood of bleeding

In addition, spelling errors were corrected, and a few minor wording updates were made for consistency.

**If participants have screened out for any of the above criteria, sites should review and update the Eligibility Criteria CRF as appropriate.**

An updated Medidata Rave eCRF output, Version 4.0, dated 28 June 2018, has been posted onto the MTN-026 Atlas webpage: <https://atlas.scharp.org/cpas/project/MTN/026/begin.view?>

#### 2. CRF Completion Guidelines (CCGs)

The CRF Completion Guidelines have been updated to Version 1.3 (dated 28 June 2018) and are posted on the MTN-026 Atlas webpage (<https://atlas.scharp.org/cpas/project/MTN/026/begin.view?>) for download. A Summary of Changes summarizing the specific updates is included at the end of the CCGs document.

### CLARIFICATIONS

No updates

### REMINDERS

No updates