

MTN-033 Data Communiqué #2 - June 27, 2018

This is official study documentation for MTN-033. Please circulate it among relevant staff for their review, print it, and place it in your MTN-033 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-033 SSP manual.

UPDATES

Inclusion Exclusion Criteria CRF:

The field “Select inclusion and/or exclusion criteria that contributed to participant’s study ineligibility” was updated to provide a 1:1 correlation with the inclusion/exclusion criteria specified per the MTN-033 protocol, Version 2.0, dated 08 DEC 2017. Specifically, the following criteria were added/removed:

- Removed: At Enrollment, if currently using mild/moderate CYP3A inducer(s)/inhibitors, willing to consistently use the inducer(s)/inhibitors for the duration of study participation
- Added: Hormone-replacement therapy in tablet, injectable or gel form (under “Anticipated use of and/or unwillingness to abstain from the following medications during study participation:”)
- Added: Use of systemic immunomodulatory medications within the 6 months prior to Enrollment, and/or anticipated use during trial participation

In addition, the inclusion/exclusion criterion numbers were added next to each inclusion/exclusion criterion per protocol, some spelling errors were corrected, and a few minor wording updates were made to accommodate for character length restrictions.

If participants screened out for any of the above criteria, sites should review and update the Inclusion Exclusion CRF as appropriate.

The updated Inclusion Exclusion Criteria CRF, Version 2.0, dated 27 June 2018 is located on the MTN-033 Atlas webpage:

<https://atlas.scharp.org/cpas/project/MTN/033/begin.view>

CLARIFICATIONS - None

REMINDERS - None