MTN-003D Data Communiqué #1 - October 29, 2013
This is official study documentation for MTN- 003D. Please circulate it among relevant staff for their review, print it, and file in the study's essential document files.

UPDATES

1. Participant Status Form (PSF) CRF, version 1.0 (version date: 16 August 2013)

For question 8 of the Stage 2 PSF CRF, sites should consider the following operational definition of low, inconsistent, and high drug detection levels:

*   Low drug: Those participants listed as "low" on the recruitment list adherence group, or "E" from the adherence category (tea pot);
*   Inconsistent drug: Those participants listed as "middle" on the recruitment list adherence group, or "C-D" from the adherence category (tea pot);
*   High drug: Those participants listed as "high" on the recruitment list adherence group, or "A-B" from the adherence category (tea pot).

These definitions are based upon the information found on Stage 2 recruitment lists, in the columns labeled "adherence group (low/middle/high)" and/or "adherence category (tea pot)." This information should be referenced for completion of the Stage 2 PSF question 8.

Sites should begin implementing these instructions immediately.