



MTN-003D Operational Guidance: Recruitment

DATE: 3 December 2013
TO: MTN-003D Technical Team
FROM: Lisa Levy on behalf of the MTN-003D Operations Team
CC: MTN-003D Protocol Team

Dear MTN-003D Technical Team,

The purpose of this memo is to provide guidance related to meeting MTN-003D Stage 2 recruitment targets when there are not enough participants available in certain pre-specified categories (e.g. gel, HIV-positive, high adherer). In these instances, the sites should attempt to maintain the same overall number of IDIs/FGDs as specified in the protocol for Stage 2 by following these recommendations:

1. Recruit additional participants from the opposite HIV sero-status category while maintaining the other categorizations. For example, if there are not enough participants on the gel, HIV-positive, high adherer list to meet a recruitment target, the site should recruit additional participants from the gel, HIV-negative, high adherer list to make up the balance. This may include recruiting individuals listed as the “middle” adherence category on a given list, if needed.
2. If the above strategy does not work due to limited numbers of participants, the site may then recruit from the alternate product formulation category. For example, if there are not enough participants on the gel, HIV-positive, high adherer list to meet a recruitment target, and there are still not enough participants to recruit when drawing from the gel, HIV-negative, high adherer list, the site may recruit additional participants from the tablet, HIV-negative, high adherer list. Again, this may include recruiting individuals listed as the “middle” adherence category on a given list, if needed.

If the sites are still unable to fulfill the recruitment numbers using the outlined strategies, the operations team should be notified via email, mtn003d-ops@mtnstophiv.org, and it should be documented using a note-to-file, which will be included in the site’s essential files.

In addition to the above guidance, when recruiting for FGDs, sites should try to maintain a homogeneous group of participants (i.e. all participants listed as “low” or all participants listed as “middle” from the low recruitment lists), if possible.

Please note this is official study documentation and it should be filed as part of the study Essential Documents.