



MTN-023/IPM 030 Data Communiqué #3

6 April 2015

This is official study documentation for MTN-023/IPM 030. Please circulate it among relevant staff for their review, print it, and place it in your MTN-023/IPM 030 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-023/IPM 030 SSP manual.

UPDATES

1. Fenway, UAB, Denver, and Bronx Sites to Update In-depth Interview Item on MTN-023/IPM 030 Prescription
 - a. Under protocol version 1.0, the in-depth interview was conducted at week 12. Under protocol version 2.0, the in-depth interview is conducted at week 24. As a result of this change, study prescriptions for participants at the UAB, Fenway, Denver and Bronx sites who re-consent to protocol version 2.0 will need to be updated. In addition, study prescriptions for participants at these sites who enroll under protocol version 2.0 will need to be updated (once a participant randomizes and the randomization envelope is opened). For these participants, please make the following update:
 - In the “Participant selected to complete the in-depth interview at Week 12?” box, line through the “12” and write in “24”. Initial and date the change. Please see below for an example.

Note: this update does not apply to the following: participants who terminate the study under protocol version 1.0, participants who do not re-consent to protocol version 2.0, and participants at the Memphis and Pittsburgh sites.

MTN-023/IPM 030 PRESCRIPTION

Instructions: All entries must be made in dark ink. Press firmly when completing this form. Corrections may be made by drawing a single line through incorrect entries, recording correct information, and initialing and dating the correction.

CRS Name:	University of Colorado Denver	CRS ID:	ATN Site 22
CRS Location:	Aurora, CO	Randomization #:	999
Participant selected to complete the in-depth interview at Week 12? <i>24</i>	No		

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- b. Under protocol version 1.0, ten participants at each site were randomized to the in-depth interviews. Under protocol version 2.0, only six participants need to be randomized to the in-depth interviews. To account for this change, we ask that the Fenway, UAB, Denver, and Bronx sites complete six in-depth interviews each, according to the randomization assignments on the study prescriptions, then line through the “yes” randomization and write “no”, initial and date, for all subsequent randomizations to the in-depth interview. Please see the example below.

Note: this update does not apply to participants at the Memphis and Pittsburgh sites.

MTN-023/IPM 030 PRESCRIPTION

Instructions: All entries must be made in dark ink. Press firmly when completing this form. Corrections may be made by drawing a single line through incorrect entries, recording correct information, and initialing and dating the correction.

CRS Name:	University of Colorado Denver	CRS ID:	ATN Site 22
CRS Location:	Aurora, CO	Randomization #:	123
Participant selected to complete the in-depth interview at Week 42? 24	Yes No		
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2. SCHARP Staffing Update

Melissa Peda has assumed responsibility as sole SCHARP Project Manager on MTN-023/IPM 030. Please contact Melissa (mapeda@scharp.org) regarding any questions related to data collection or data management in MTN-023/IPM 030.

REMINDERS

None

CLARIFICATIONS

None