

## MTN-029 Data Communiqué #2 - April 28, 2016

This is official study documentation for MTN-029. Please circulate it among relevant staff for their review, print it, and place it in your MTN-029 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-029 SSP manual and is posted on the MTN web site at <http://www.mtnstopshiv.org/node/7100>.

### UPDATES

#### 1. Updated Pelvic Exam Diagrams CRF (non-DataFax)

The non-DataFax Pelvic Diagrams form has been updated to version 2.0 (dated 22-APR-16). Specifically, the check box label at the top of the form has been corrected from “abnormal findings observed” to “no normal variants or abnormal findings observed”. The updated version 2.0 label is consistent with the form instructions on the back of the form, which state, “If there are no variants of normal or abnormal findings observed mark the “no normal variants or abnormal findings observed” box.

Version 2.0 of the Pelvic Exam Diagrams form can be implemented immediately, and should be used going forward when completion of this form is required. Please discontinue further use of version 1.0 of the form.

All of the CRF files listed below have been updated to include version 2.0 of the Pelvic Exam Diagrams form, and are available for site download, printing, and data collection at <https://atlas.scharp.org/cpas/project/MTN/029/begin.view>.

#### ☐ Case Report Forms

<i>Document:</i>	<i>Language:</i>	<i>Page size:</i>
Complete Set (Alphabetical)	English	U.S. Letter

#### ☐ Visit Packets

<i>Document:</i>	<i>Language:</i>	<i>Page size:</i>
Screening Visit 01.0	English	U.S. Letter
Enrollment Visit 02.0	English	U.S. Letter
Day 1 Visit 03.0	English	U.S. Letter
Day 7 and 14 Visits 04.0 and 05.0	English	U.S. Letter
Day 16/Early Termination Visit 06.0/varies	English	U.S. Letter

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For version 1.0 Pelvic Exam Diagram forms that already have been completed, please consider the front of the form as correct and ensure that the check box is marked based on the existing label, “abnormal findings observed”. Please disregard the inconsistent instruction on the back of the form referring to a “no normal variants or abnormal findings observed” box.

## **CLARIFICATIONS**

None

## **REMINDERS**

None