

MTN-036/IPM 047 Data Communiqué #2- February 21, 2018

This is official study documentation for MTN-036/IPM 047. Please circulate it among relevant staff for their review, print it, and place it in your MTN-036/IPM 047 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-036/IPM 047 SSP manual.

1. CLARIFICATIONS

Documenting brief ring outages during Pelvic Exam

During a pelvic exam, the site clinician may remove the vaginal ring (VR) temporarily for the speculum exam and then replace the VR once done. For additional information, please refer to SSP Section 8.5.2. If a clinician briefly removes a ring during the pelvic exam, the VR outage should be documented in a chart note and in the “If not stored, specify reason” field that corresponds with the CVF for PK sample on the Cervical Specimen Storage eCRF within the Medidata Rave database. The comment should include the reason for the outage and the time of the outage.

Was CVF for PK collected?						Yes
Collection date						18 JAN 2018
#	Time point of CVF collection	Collection time	Was blood visible on the swab?	Cervicovaginal fluid (CVF) for PK	If not stored, specify reason	
1	Not applicable	08:24	No	Stored	THE VR WAS REMOVED BY THE CLINICIAN DURING THE PELVIC EXAM TO BETTER VISUALIZE THE CERVIX. THE VR WAS OUT FROM 08:28 - 08:31.	
Add a new Log line Inactivate Cervical tissue for PK						

A system query will fire if “Stored” is selected and “If not stored, specify reason” is not empty. The site does not need to respond to this query. The SCHARP Clinical Data Manager will cancel the query.

If this type of outage has already occurred, update the Cervical Specimen Storage eCRF per this guidance and resave the eCRF with these changes.