

MTN-033 Data Communiqué #1 - June 21, 2018

This is official study documentation for MTN-033. Please circulate it among relevant staff for their review, print it, and place it in your MTN-033 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-033 SSP manual.

UPDATES

Visit Calendar Tool

The MTN-033 Visit Calendar Tool, (Version 2.0 21JUN2018), was updated to correct a date calculation error for Visit 5. Please use V2.0 Visit Calendar Tool moving forward. The previous version calculated the V5 visit window as 2-4 weeks from the actual visit date for Visit 3. This has been corrected to provide the visit window for Visit 5 as 2-4 weeks from Visit 4. Please note the site will need to enter actual visit dates for Visits 3.0, 4.0, 5.0, and 6.0 in order to generate the correct visit windows and target visit dates for subsequent visits. The updated tool is located on the MTN-033 study webpage located here:

<http://www.mtnstopshiv.org/research/studies/mtn-033/mtn-033-study-implementation-materials>

MTN-033 Participant Visit Calendar						
PTID: 999-9999-9		Staff Initials: <input type="text"/>				
Enrollment Date: 08-09-17						
		<i>mm/dd/yyyy</i>				
Visit	Visit Code	Visit Window Open	Visit Window Close	Target Visit Date	Actual Visit Date	
Visit 3: Study Product Administration Visit	3.0	09-Sep-17	18-Sep-17	15-Sep-17	15-Sep-17	<-- Site to enter date
Visit 4: 24 Hour Post-dose Visit	4.0	16-Sep-17	16-Sep-17	16-Sep-17	16-Sep-17	<-- Site to enter date
Visit 5: Study Product Administration Visit	5.0	30-Sep-17	14-Oct-17	7-Oct-17	7-Oct-17	<-- Site to enter date
Visit 6: 24 Hour Post-dose Visit	6.0	08-Oct-17	08-Oct-17	8-Oct-17	8-Oct-17	<-- Site to enter date
Visit 7: Termination Visit	7.0	12-Oct-17	22-Oct-17	15-Oct-17		

CLARIFICATIONS

In the event that a Medidata system query (data QC) is placed on data point in error or if the data entered falls outside of the normal parameters for a programmed edit check, note within the query response text box that the data is correct as entered and provide any other applicable information that helps to contextualize the scenario. SCHARP will review the site response text box and close these erroneous system queries, as needed.

REMINDERS - None