

HPTN084-01 Data Communiqué #1 – April 6, 2021

This is official study documentation for HPTN084-01. Please circulate it among relevant staff for their review, print it, and place it in your HPTN084-01 SSP Manual in the Data Communiqués section. This document is considered part of the HPTN084-01 SSP manual.

UPDATES

Database Updates

1. CRF updates: *Additional instructions/clarification on form completion will be available in the CCGs on our Atlas site*
 - a. Inclusion Exclusion Criteria: 3 fields added, inclusion/exclusion criteria updated to reflect LoA #1.
 - i. “Has the participant screened for this study before”: Please select “Yes” or “No.”
 - ii. “If yes, record the first Rave PTID assigned”: If yes, enter in the previous PTID assigned in Rave.
 - iii. “Date participant was found ‘Eligible/Not Enrolled,’ ‘Ineligible,’ or ‘Incomplete screening’”: Only enter the date if the participant’s eligibility status is one of the three listed.
 - b. CASI: Correction to the visit selection (removed “Early Discontinuation Step 3” and added “V501.0 – Pregnancy Week 4)
 - c. Injection Administration: Updated to field format for “If no, what volume was given?”
2. Fasting Lipid Test Results CRF: Visit folder population updated to reflect LoA #1.
3. As part of the clinical database migration, additional system queries have been added, updated, and/or corrected. The goal of system queries is to provide real-time feedback in order to ensure clean data at the point of data entry.

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