

HPTN058 Data Communiqué # 10

August 12, 2011

This is official study documentation for the HPTN058 clinical trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN058 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

Completing AE Log following EAE reporting Manual, Version 2

HPTN 058 LoA #2 introduced the new EAE reporting manual version 2, where relationship to product has been reduced to two main categories: ‘related’ and ‘not related’, when reporting EAEs to DAIDS through DAERS.

For HPTN 058, the AE Log CRF will remain the same. Sites can continue to check any of the 5 relationship categories in item #4 (Relationship to Study Product) on the CRF. However, sites will need to use the following OCSO proposed mapping for study product relationship when completing their EAE report to DAERS under EAE Manual Version 2 as follows:

Categories In AE Log	Corresponding Categories in DAERS Report
Definitely related	Related
Probably related	Related
Possibly related	Related
Probably not related	Not Related
Not related	Not Related

NOTE 1: Since HPTN 058 only reports EAEs and SAEs, under the new DAIDS EAE reporting, all expedited AEs will now be reported as SAEs. Items 8 and 9 on AE Log CRF should be always marked as “YES”.

NOTE 2: In HPTN 058, SAE reporting on CRFs and to DAIDS RSC will proceed up to 28 days following end of Dosing Week 52. SUSARs reporting category to DAIDS will be used after the protocol-defined AE reporting period until the end of the study.

Please refer to HPTN LoA #2 for complete details.

If you have any questions regarding this Communiqué, please contact SDMC Project Manager, Huguette Redinger (redinger@scharp.org).