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## HPTN058 Data Communiqué #4

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October 23, 2009

**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.**

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### HPTN 058 Unresolved “AE” Listing Report

Please note that for this study “AE” refers to SAE and EAE that are reported on the AE Log CRF

Based on feedback received from Networks’ site staff, SCHARP has created a new report that includes a listing of all AEs that have been marked on the AE log as “continuing” for more than 90 days. This listing is protocol and site specific and is only meant to be used as a tool to help sites monitor AE resolution throughout the study. The report will be e-mailed to each site monthly.

For each unresolved AE, the report lists the PTID, page number, AE text, date reported to site, onset date, severity grade, and visit at which the AE was first reported. We understand that throughout the study, three possible scenarios may occur with AEs.

#### **Scenario 1**

The AE may be continuing and has not increased in severity or frequency since it was first reported/observed. In this case, you can leave the CRF as is, but continue to follow the AE each time the participant returns to the clinic.

#### **Scenario 2**

An AE may have resolved. In this case, please update the CRF by:

- drawing a line through the “continuing” response
- marking the “resolved” box
- recording the date that the AE resolved (i.e. the Status/Outcome Date)
- initialing and dating all changes
- refaxing the AE Log CRF to SCHARP

#### **Scenario 3**

The AE may have increased in severity or frequency. In this case, please update the CRF by:

- drawing a line through the “continuing” response
- marking the “severity/frequency increased” box
- recording the date that the AE increased in severity/frequency (i.e. the Status/Outcome Date)

- initialing and dating all changes
- refaxing the AE Log CRF to SCHARP
- completing and faxing a new AE Log CRF, if applicable per the protocol.

If an AE is continuing at the participants last study visit, mark the “continuing at end of study participation” box on the AE Log CRF. There will not be a Status/Outcome date. This list is only based on data that have been received and processed at SCHARP.

If an update was sent recently, and does not yet appear on the report, or if you have any other questions regarding the listing, please feel free to contact your Clinical Affairs Safety Associate, Yevgeny Gregoriev ([ygrigori@scharp.org](mailto:ygrigori@scharp.org)) and/or Project Manager, Huguette Redinger ([redinger@scharp.org](mailto:redinger@scharp.org)).