

HPTN061 Data Communiqué #7

08 September 2010

This is official study documentation for the HPTN061 trial. Please print and circulate it among relevant staff for their review, and file it in your HPTN061 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

CLARIFICATIONS: **Follow-up Visit Allowable Windows Extended**

On 3 September 2010, the Protocol Chairs decided to extend the allowable visit windows for the Week 26 and Week 52 Follow-up Visits. This decision supersedes the decision in Data Communiqué #6. From now on, please disregard Data Communiqué #6, all visits conducted outside of allowable visit windows are Interim Visits.

The Week 26 allowable visit window now opens two weeks earlier on day 126 and closes on day 308. The Week 52 Visit also opens two weeks earlier on day 309, and remains open until the site closes. Target Visit dates and windows remain unchanged. This is also documented in the latest version of the SSP –Section 9.

This decision allows sites to conduct full follow-up study visits earlier than previously allowed, including administering the ACASI and SSN surveys. Visits conducted outside of the allowable visit windows still constitute interim visits and the SSN and ACASI surveys should not be administered.