

HPTN052 Data Communiqué #10

09 November, 2010

This is official study documentation for the HPTN052 trial. Please print and circulate it among relevant staff for their review, and file it in your HPTN052 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

CLARIFICATION

The **Index Non-study ART CRF (INA-1)** collects information on non-study ART use prior to study ART initiation. This CRF is expected each time a result of RNA < 1000 is reported for a participant who has not initiated study ART. The CRF will likely be completed at a later visit, after RNA results become available and the participant comes for another follow-up visit.

The visit code and visit date on the INA-1 must match the visit code and specimen collection date for the RNA result < 1000.

Example: a participant’s 10.0 visit was on 15 January 2009. His RNA is reported as 800 copies. When the participant returns for his 13.0 visit, the INA CRF is completed *with the 10.0 visit code and RNA collection date of 15 January 2009.*