

HPTN 052 Protocol-Specific Training

SSP Overview

Significant Differences Between V1.3 and V1.4



Overview

- ◆ These slides focus only on significant changes between V1.3 and V1.4 of the SSP– they do not cover all the changes.
- ◆ It is important to review all changes between V1.3 and V1.4 of the SSP with site staff.

Section 1: Introduction

Table 1-2

- ◆ Two additional SOPs are now required for implementation of V3.0 of the protocol:
 - LDMS reconciliation
 - Critical value reporting

Section 3: Documentation Requirements

Section 3.4: Reportable Protocol Deviations

- ◆ This section was re-written to reflect the new HPTN policy on reporting protocol deviations.
- ◆ These procedures replace Protocol Event Reporting.

Section 4: Participant Accrual

Section 4.2: Target Enrollment

- ◆ This section was revised to reflect the enrollment targets for the full study.
- ◆ Sites are expected to enroll 2 couples in month 1, and 14 couples per month for the next 17 months.

Section 5: Participant Follow-up

Section 5.4.2: Allowable Visit Windows

- ◆ Information was added about what to do if all the enrollment procedures cannot be completed during the initial visit.
 - The participant may return to the clinic to complete these procedures within 7 days of enrollment.
 - Lab procedures and adherence counseling should take place before administering ART for the first time.

Section 5: Participant Follow-up

Section 5.8.1: Pregnancy Testing and Sterility Documentation

- ◆ This section was added to explain when pregnancy testing is required and defines acceptable documentation for proof of sterility.
 - Due to the risk of fetal exposure to ART, all women must undergo pregnancy testing according to the SOE except those who are sterile or post-menopausal.

Section 5: Participant Follow-up

Section 5.8.1: Pregnancy Testing and Sterility Documentation (continued)

- For women not on ART or on ART regimens that do not include efavirenz, acceptable documentation includes self-reported history of:
 - Surgical sterilization
 - Menopause,
 - Male partner's azoospermia
- Any statement of self-reported sterility or that of her partner's must be entered in the source documents.

Section 5: Participant Follow-up

Section 5.8.1: Pregnancy Testing and Sterility Documentation (continued)

- For women on ART regimens that include efavirenz, acceptable documentation includes:
 - Oral communication from a clinician or clinician's staff
 - A physician report/letter
 - A discharge summary
 - An FSH measurement elevated into the menopausal range

Section 7: Participant Retention and Termination

Section 7.5: Retention Strategies

- Bullet 18 was revised to allow home visits.

Section 8: Study Product Considerations

Section 8.3.2: Procedures for Ordering and Receiving Kaletra/Aluvia

- This section was revised to replace the information for ordering efavirenz with the information needed to order Aluvia.

Section 8: Study Product Considerations

Section 8.7: Study Product Return and Destruction

- Information was added instructing sites that they may discard empty bottles returned from participants once the pharmacy logs are updated appropriately.

Section 9: Clinical Counseling Procedures

Section 9.2.2.1: Screening

- The information about the use of short-course ART during pregnancy as an exception to the exclusion criteria was revised to match the latest decision by the CMC.
- Single-dose nevirapine (NVP) or single-dose NVP followed by up to 7 days of 2 nucleoside reverse transcriptase inhibitors (NRTIs). If a woman has had multiple pregnancies with this type of exposure to NVP, she is still eligible. Any woman who has received NVP as part of a regimen for pMTCT must have atazanavir as part of her starting regimen.

Section 9: Clinical Counseling Procedures

Section 9.2.2.1: Screening

- Short-course zidovudine (ZDV) therapy (≤ 12 weeks) per pregnancy.
- Combination antiretroviral therapy of 3 or more agents for ≤ 16 weeks as long as there is an undetectable viral load measurement up to 4 weeks prior to delivery (per pregnancy).
- Women who receive both NVP and ZDV simultaneously (meeting both the criteria in categories 1 and 2), are also eligible for HPTN 052.

Section 9: Clinical Counseling Procedures

Section 9.3.2: Couples Counseling

- A note was added indicating that a condom demonstration is only required annually.

Section 10: Laboratory Procedures

- This Section of the SSP has changed substantially, the appropriate study staff should carefully read this section and revise site SOPs accordingly.

Section 11: Data Management

- This Section of the SSP has been changed, the appropriate study staff should carefully read this section and revise site SOPs accordingly.
- Leslie Cottle will conduct a training to cover changes in data management, including CRF completion, prior to initiation of V3.0.

HPTN 052 SSP V1.4

Questions?