Lessons Learned

Recent Site Visits:
Chitungwiza, Durban, Harare, Kampala
Pat yourself on the back!

- 11 sites activated
- 313 participants enrolled
  - as of 12 March 2010
Overview

- Central files
- Participant binders
- Study procedures
- Communication
- Suggestions
Central Files
Central Files

- Filing key correspondence
  - Announcements
  - Requests for guidance
  - Instructions

- Conference call summaries
  - Study coordinators call
  - Investigators call
  - Lab call
Central Files

- Be sure to file Clarification Memos and Letters of Amendment with the current protocol

- Maintain a current version of the SSP Manual along with all Data Communiqués

- Also maintain and file all old versions of the protocol and SSP sections
Central Files

For new staff:
- Update delegation of authority log
- Document study specific training, GCP, HSP, etc.
- Ensure CV is current (update annually)

A monthly review is suggested for these documents
Participant Binders
Visit checklists should reflect the correct order of procedures.
Participant Binders

- Consistently use and file tracking and calculation tools
  - AEs
  - Hepatitis B vaccinations
  - Safety monitoring flow sheets *
  - Creatinine clearance †
  - Study product ordering †

* Can be essential for helping to identify the need for product hold
† Be sure to use the most current tools
Use the comments section of the Unused Product Returns Slip

- E.g. Provide explanation of discrepancies between the expected vs. actual returns or the actual vs. available returns.
When participants sign the ICFs with their first initial and surname, document in the chart notes if this is their official signature.

- Note: Full name should still be printed!
- All consent forms should be signed the same way.
Be sure that the site-specific lab records indicate which HIV rapid test is used.
Participant Binders

- Consistently use the counseling worksheets
  - Check all boxes to indicate what has been completed
  - Write “n/a” instead of leaving an item blank
Participant Binders

- Chart notes are often repetitive and do not need to include lab values or other details found in other source documents.

- Chart notes should describe participants’ condition, questions, concerns, anything unusual, etc.
Participant contact log should contain all contact made with the participant:
- Scheduled visits
- Phone calls
- Home visits
If a participant has a pre-existing condition or an AE, it does not need to be recorded on the Medical and Menstrual History form at a later visit if you have indicated that it has been resolved.
If a protocol specified procedure is not done, it should be clearly documented why:
- Document in the chart notes and in the memo section of the form
- Draft a memo to file if appropriate
Study Procedures


Study Procedures

- Consistently collect unused study product early in the study visits.
  
  - Be sure that the visit checklists reflects this
  
  - Assess if the participant has taken her product that day
  
  - Communicate to the pharmacy if no product has been returned (if applicable at your site)
Study Procedures

- Only the last study product dose prior to quarterly visits needs to be recorded for VOICE
The first Hepatitis B vaccine should be administered at enrollment and not during the screening visits.
If pharmacy staff are providing product adherence counseling, this should be reflected in chart notes or other study documents.
Communication
Alert the management team when the following things happen:
- Leave dates of key staff
- Pregnancy
- Pregnancy loss
- SAEs
- Protocol deviations
- Anything else that you are unsure about
Suggestions
Suggestions

- Create a specific section in your central files to file IRB correspondence for Protocol Deviations and SAEs

- Maintain an IRB submission tracking log in the front of the binder
Suggestions

- Continually evaluate the clinic flow and participant wait times as the number of daily study visits increase.
Suggestions

- For participants on injectable contraception, obtain medical records of their injection schedule or postpone enrollment for 2 weeks to ensure they are not pregnant.
Suggestions

- Consistently file product ordering tools, prescriptions, product memos, etc.
  - Either file all of them at the at a specific tab created for these documents in the participant binder or all within the monthly visit section

- Put the following in the front of the participant binder:
  - Flow sheets
  - HepB reminder
  - Injectable contraception reminders
Suggestions

- Use both sides of the page for chart notes to save space in the binders
Questions?