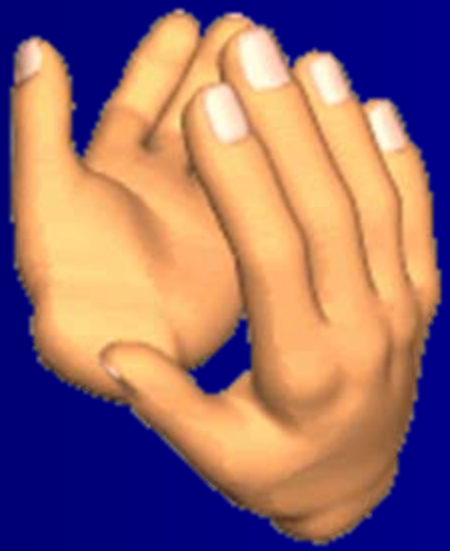
Lessons Learned

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

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

Participant Binders

- 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.

Participant Binders

- 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

Participant Binders

- 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 Binders

- Participant contact log should contain all contact made with the participant
  - Scheduled visits
  - Phone calls
  - Home visits

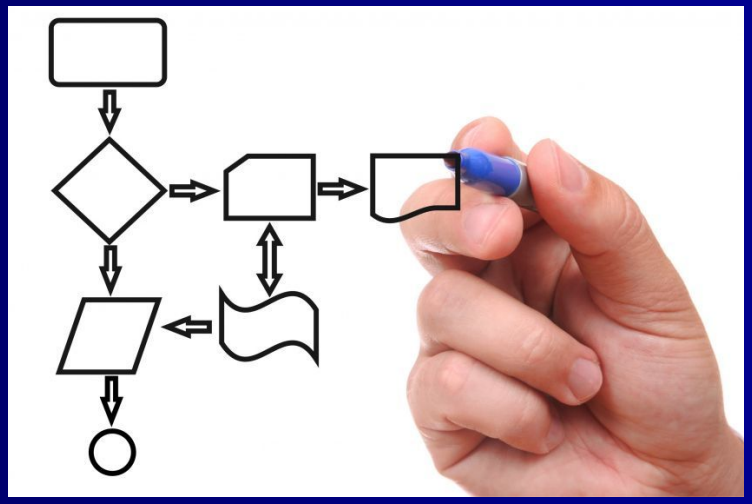
Participant Binders

- 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

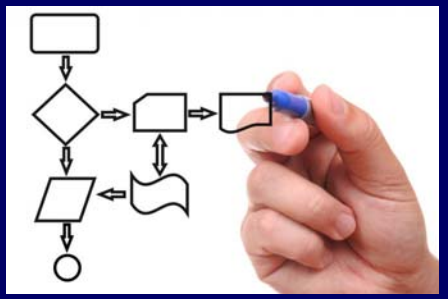
Participant Binders

- 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

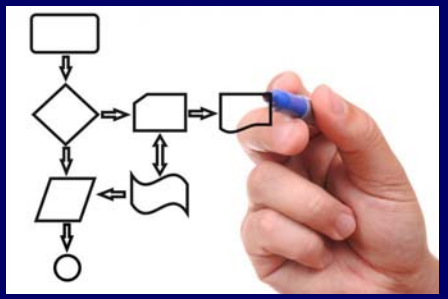


Study Procedures



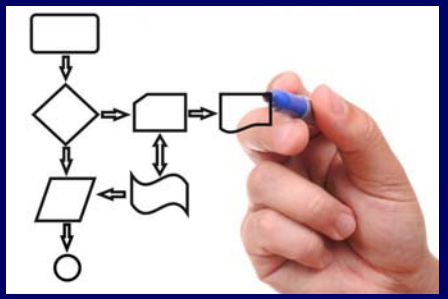
- Consistently collect unused study product early in the study visits.
  - Be sure that the visit checklists reflects this
  - Assess if the participant has taken her product that day
  - Communicate to the pharmacy if no product has been returned (if applicable at your site)

Study Procedures



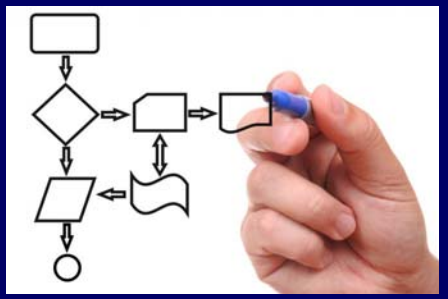
- Only the last study product dose prior to quarterly visits needs to be recorded for VOICE

Study Procedures



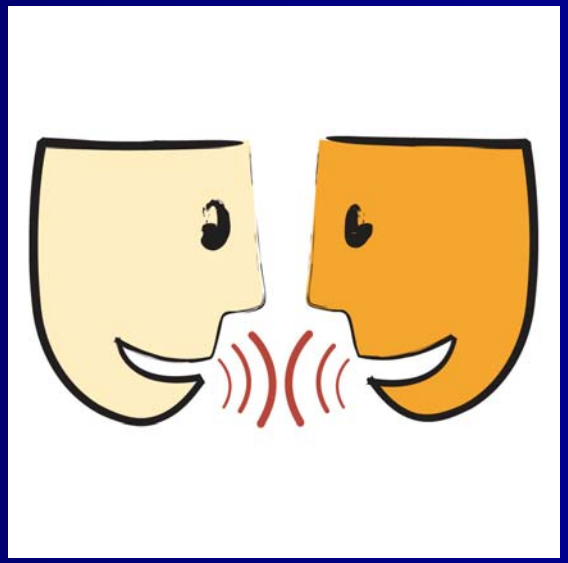
- The first Hepatitis B vaccine should be administered at enrollment and not during the screening visits

Study Procedures

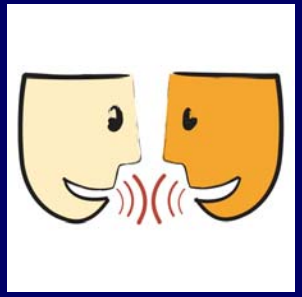


- If pharmacy staff are providing product adherence counseling, this should be reflected in chart notes or other study documents

Communication



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?