Study Closeout Procedures

VOICE Protocol Team Meeting

19 February 2012

VOICE
VAGINAL + ORAL INTERVENTIONS TO CONTROL THE EPIDEMIC

MTN
microbicide trials network

Introduction

- Per the MTN MOP, each protocol team will plan for study close-out procedures and develop:
  - Study-specific close-out checklist
  - Plans, procedures, and materials for verification of primary study endpoints
  - Plans, procedures, and materials for release of study results to the protocol team, study staff, participants, and participant communities
  - Plans for data analysis, manuscript preparation, and publications

Study Closeout Checklist

Site Name: _____ **DAIDS Site Number:** _____

Completion of participant visits and contacts:

- ☐ Complete and document all remaining study visits.
- ☐ At termination visits, review/update participant contact information. Document participant consent to be contacted for study results and participation in future studies.
- ☐ Follow guidance in Section 6.14 of the SSP manual for Study Exit Considerations.
  - ☐ Follow-up on any unresolved AE(s)/EAE(s)
  - ☐ Assess pregnancy outcome, if indicated
  - ☐ Complete HIV testing algorithm
  - ☐ Contact participants to provide test results, counseling, and treatment
- ☐ Notify local IRBs/ECs of completion of participant follow up. Complete study close-out reporting requirements per local IRBs/ECs guidelines.
- ☐ Complete protocol de-registration with the DAIDS Protocol Registration Office via DPRS when applicable, meaning that all participants at all sites are off study and the primary analysis has been completed. Study closure/termination with a site's IRB/EC is not required for a CRS to deregister with DAIDS. If a site plans to complete the DAIDS deregistration process for a study but will not be closing/terminating the study at their IRB/EC, the site should consult their IRB/EC to confirm any requirements and/or standard operating procedures that must be met prior to deregistering with DAIDS. A site's IRB/EC may require the continued submission of safety information and/or other data (e.g., from data queries) for the study. In this case, deregistration with DAIDS cannot be done until the study has been completed and closed out with the IRB/EC. Regardless of when protocol de-registration is completed, all sites must maintain continuing review until the study is considered completed/closed per IRB policies.

Data submission and verification:

- ☐ Complete and submit all required DataFax forms to SCHARP.

Study Closeout Checklist:
Participant visits and contacts

- Complete and document remaining study visits
- Review/update participant contact information
  - Document consent to be contacted for study results and participation in future studies
- Follow guidance in Section 6.14 of the SSP manual for Study Exit Considerations

Study Closeout Checklist:
Participant visits and contacts

- Notify local IRBs/ECs of completion of follow up
  - Complete study close-out reporting requirements per IRBs/ECs guidelines.
- Complete protocol de-registration with the DAIDS Protocol Registration Office when applicable.
  - Protocol de-registration may take place before closing the study with all responsible IRBs. However, it is recommended to consult with your IRB since they may require the continued submission of safety information and/or other data for the study. In this case, deregistration with DAIDS cannot be done until the study has been completed and closed out with the IRB/EC

Study Closeout Checklist:
Data Submission and Verification

- Complete and submit all required DataFax forms to SCHARP
- Resolve all outstanding data QC notes and clinical queries
- Confirm with SCHARP that there are no outstanding QC notes or clinical queries

Study Closeout Checklist:
Data Submission and Verification

- Perform final participant file reviews of both clinic and pharmacy records. Ensure all documents are properly filed and up to date.
- Return all unused study randomization envelopes to SCHARP

Study Closeout Checklist:
Specimen Shipment and Destruction

- Resolve all outstanding discrepancies and errors on the LDMS Specimen Monitoring Reports
- Destroy all specimens collected during failed screening attempts.
  - This includes participants who did not enroll and participants that required a new screening attempt before being enrolled.
  - No prior notification from the NL or SCHARP is required.

Study Closeout Checklist:
Specimen Shipment and Destruction

- **After** receiving notification from the MTN NL (or other designated laboratory) ship all pending biological specimens
- **After** receiving notification from SCHARP for participants who did **not** provide informed consent for long term specimen storage and future research testing, destroy all remaining specimens.
  - Document destruction using destruction logs approved by the MTN NL; and in LDMS.

Study Closeout Checklist:
Study Product

- Conduct final study product accountability procedures
- Per instructions provided by the DAIDS Pharmaceutical Affairs Branch, return or dispose of all study product supplies

Study Closeout Checklist:
Essential documents

- Complete internal review of essential document files
- Review and assemble for long term storage all required study documents
  - Prepare a written inventory of all documentation and storage locations
  - Store all documents on-site with adequate protection of participant confidentiality and per all applicable IRB policies

Study Closeout Checklist:
Essential documents

- Pharmacy source documents must be kept in the pharmacy until the study has reached the DAIDS enterprise System status of *Concluded*. Once this occurs, these documents should be archived in a folder or envelope marked as "*pharmacy records*" and stored together with other clinic documents (see DAIDS PAB Pharmacy Guidelines).

Study Closeout Checklist

- Resolve any outstanding PPD monitoring findings and/or action items
- Complete, sign, and date the checklist. File original with other study documentation and provide a copy to FHI 360

Action Items

- Ensure QCs are resolved promptly
- Follow AEs at study exit per SSP guidelines
- Review participant documentation so that it is up to date and well organized
- Ship samples in a timely manner
- Prepare IRB submissions for continuing review per your IRB’s guidelines

Questions