

# Study Closeout Procedures

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MTN 001





# Introduction

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- 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

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## Completion of participant visits and contacts:

- ❑ Complete and document all remaining study visits.
- ❑ Review/update participant contact information. Document participant consent to be contacted for study results.
- ❑ Follow-up on any unresolved AE(s)/EAE(s) per MTN-001 SSP manual, Section 6.12.7.

# Study Closeout Checklist

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## Completion of participant visits and contacts (cont):

- Notify local IRBs/ECs of study closure of accrual and 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 DAERS when applicable.
  - Protocol de-registration may take place after all responsible IRBs are informed that all participant study visits and data collection have been completed.
  - Regardless of when protocol de-registration is completed, all sites must maintain continuing review until study is considered completed/closed per IRB policies.



# Study Closeout Checklist

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## Data submission and verification:

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

# Study Closeout Checklist

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## Data submission and verification (cont)

- Perform final participant file reviews, complete Participant Data Verification forms and fax these forms to SCHARP DataFax.
- Return all unused study randomization envelopes to SCHARP.
- Destroy (shred) all unused replacement randomization prescriptions and notify (e-mail) the SCHARP Project Manager once this is done.



# Study Closeout Checklist

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## Specimen shipment and destruction:

- Resolve all outstanding discrepancies and errors on the LDMS Specimen Monitoring Reports
- Resolve all outstanding discrepancies and errors on the LDMS Specimen Monitoring Reports.

# Study Closeout Checklist

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## Specimen shipment and destruction (cont)

- **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 (a list of PTIDs will be provided by SCHARP), destroy all remaining specimens. Document destruction using destruction logs approved by the MTN NL; also document destruction in LDMS.



# Study Closeout Checklist

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## Study Product Shipment:

- ❑ Conduct final study product accountability procedures.
- ❑ In accordance with instructions provided by the DAIDS Pharmaceutical Affairs Branch, return or dispose of all investigational drug/product supplies.



# Study Closeout Checklist

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## Review of essential documents:

- Complete internal review of essential document files, focusing on completeness and organization of records.
  - Ensure that all protocol documents are on file.
  - Ensure that all versions of all SSP Manual sections are on file.
  - Ensure that all IRB correspondence is on file.
  - Review and update (if needed) all financial disclosure documentation.

# Study Closeout Checklist

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## Review of essential documents (cont):

- Review and assemble for long term storage all required study documents, including:
  - Administrative, regulatory, and other essential documents
  - Screening and enrollment log
  - Log linking participant names and PTIDs
  - All randomization documentation
  - All study documents bearing participant names

# Study Closeout Checklist

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## Review of essential documents (cont):

- Review and assemble for long term storage all required study documents, including:
  - All study documents bearing PTIDs
  - All study-specific laboratory documentation
  - All study product receipt, dispensing, accountability, and final disposition documentation
  - 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

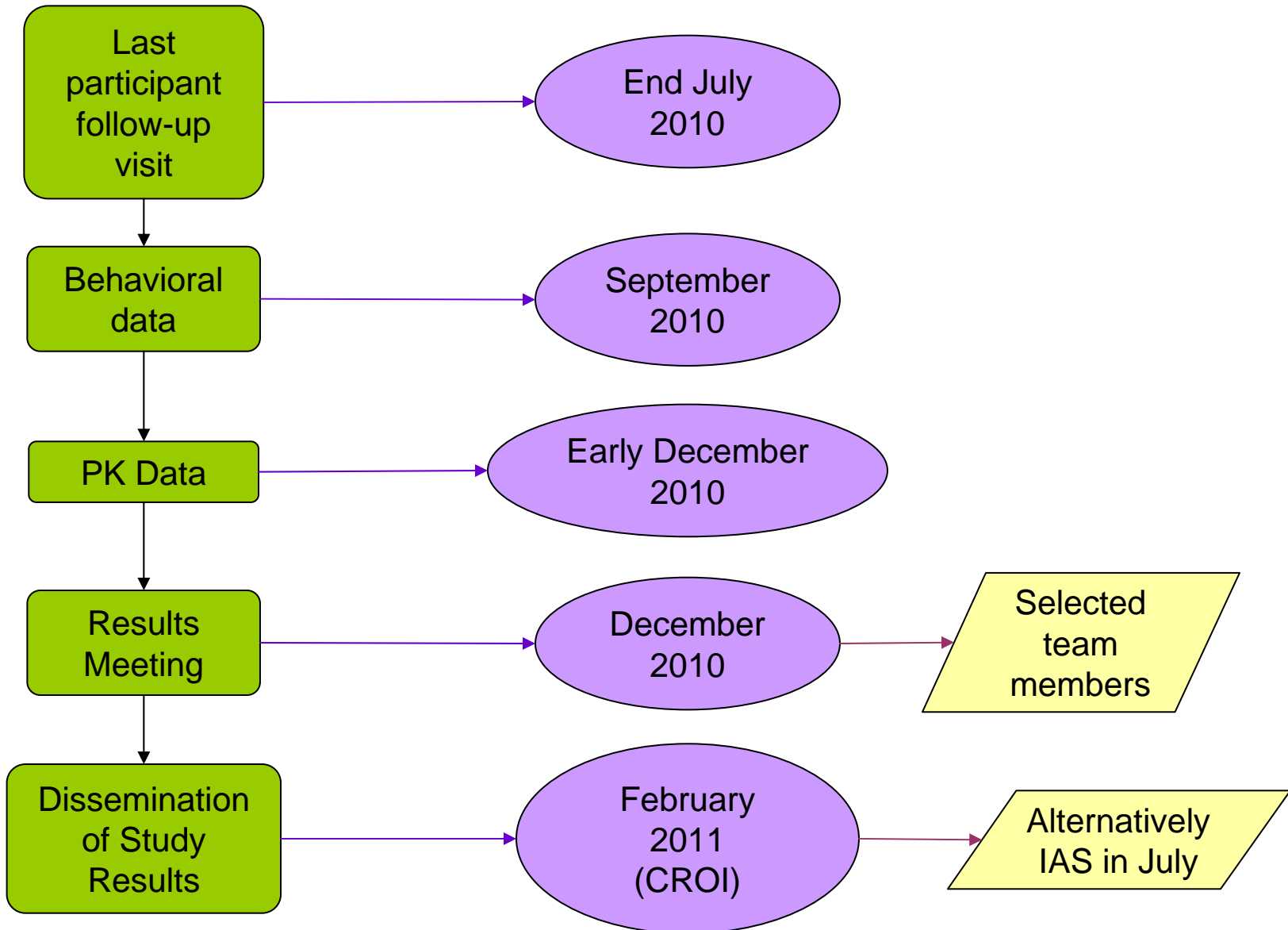


# Study Closeout Checklist

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

# Dissemination Timeline





# Action Items

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- For sites that have completed follow-up:
  - Ensure QCs are resolved
  - All AEs are properly followed at study exit
  - All participant documentation is up to date and well organized
  - Shipment of samples in a timely manner
  - IRB submissions for continuing review until all study data has been locked



# Action Items

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- For sites that have not completed follow-up:
  - **Participant Retention**
  - QCs should be resolved promptly
  - Communication with management team

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# Questions

