Title: National Cancer Institute/Division of Cancer Prevention

Cancer Prevention Clinical Trials Network

Master Data Management Plan for Lead Academic Organizations and Affiliated Organizations

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
1.0	AUG-17-2020	Original version of document

1. INTRODUCTION AND PURPOSE

- Data Management is the administration and supervision of "tasks associated with the entry, transfer and/or preparation of source data and derived items for entry into a clinical trial database." (CDISC Glossary, December 2019) It is an essential activity for those data collected during the conduct of clinical trials funded by the National Cancer Institute (NCI)/Division of Cancer Prevention (DCP) to ensure data quality and accuracy; and compliance with Good Clinical Practice (GCP) guidelines, federal regulations (such as the Health Insurance Portability and Accountability Act (HIPAA)), and NCI/DCP policies and guidelines.
- The purpose of the Cancer Prevention Clinical Trials Network (CP-CTNet) Master Data Management Plan (DMP) is to describe data management practices and processes to be followed by Lead Academic Organizations (LAOs) and Affiliated Organizations (AOs) to ensure the authenticity, integrity, and confidentiality of study data, and the protection of human subjects participating in CP-CTNet studies. Medidata Rave will be used as the clinical data management system for all CP-CTNet studies and will be managed by the Data Management Auditing and Coordinating Center (DMACC).
- The CP-CT-Net DMP applies to all studies conducted within the CP-CTNet. Study-specific data management plans will be developed by the DMACC and the LAO as required.

2. PRINCIPAL INVESTIGATOR RESPONSIBILITY

- LAO and AO Principal Investigators (PIs) have the ultimate responsibility for ensuring that CP-CTNet protocols are conducted in compliance with the data management requirements as documented in this DMP. Additionally, the LAOs have oversight responsibility for the AOs as specified in SOP 03-03 Lead Academic Organization Oversight of Affiliated Organizations and SOP 01-02 Study Initiation Meeting.
- NCI/DCP requires that all data management practices adhere to NCI/DCP policies and guidelines as well as Federal regulations, including but not limited to 21 CFR Part 11, GCP and HIPAA requirements, and that organizations conducting clinical trials under NCI/DCP funding demonstrate their compliance with these regulations. LAO and AO compliance will be monitored through routine audit visits performed by the DMACC, with additional LAO oversight of the AOs.

3. ELECTRONIC CASE REPORT FORM (ECRF) DEVELOPMENT

- The LAO will submit the study-specific System Variable Attribute Report (SVAR worksheet, as per SOP 02-03 Electronic Case Report Forms Development). Data fields must be represented as Common Data Elements (CDEs), and all Minimum Data Set (MDS) elements as specified in the MDS Guidelines must be included in the SVAR worksheet.
- NCI/DCP CDEs, where available, will be used for all new and modified eCRFs. All terms and questions included in the SVAR worksheet must use CDEs that are currently available in the Cancer Data Standards Repository (caDSR). Where new data elements are required, the LAO will work with the CDE Curator to develop these data questions, and the eCRF Review Team will review the new and standard CDEs.
- In general, new data elements will be developed if they are important for collecting data points relative to the science of the protocol and reporting requirements, and/or if they will potentially be analyzed to support the scientific intent of the study.

- The LAO will assess any special data collection requirements for pharmaceutical collaborators or the local institution, and address these issues with NCI/DCP and the DMACC during protocol development.

4. DATA ENTRY AND PROCESSING

- LAOs and AOs will use the DMACC Stars System, which is the registration/randomization system, to record participant recruitment and screening data, and to enroll participants to a study.
- The LAOs and AOs will enter both Recruitment Journaling information and study data into the Medidata Rave clinical data management system, which is the CP-CTNet database of record, and subject to NCI and Food and Drug Administration (FDA) audits.
- The LAOs and AOs are responsible for entering complete, reliable and accurate study data into Rave.
- The LAO or AO PI or designee is responsible for review and approval of these data.
- Procedures should be established by the LAO to maintain the integrity of blinded data as required. Circumstances and procedures for breaking the blind will be developed per study and will be documented in the protocol.
- Data entry should be completed in Rave by the LAO and AO within 14 calendar days of the scheduled visit.
- Data will be queried for quality control:
    - For certain data fields, edit checks are pre-programmed into Rave. Data entry that is nonconformant with data requirements (e.g., out of range, missing, etc.) will automatically trigger these edit checks, and queries will then be displayed. These queries can be immediately resolved by the site directly in Rave.
    - Data fields without automatic edit checks will be quality controlled by the Data Managers (DMs) at the DMACC. For data that are incorrect or discrepant in these fields, the DM will manually enter a query in Rave.
- LAOs have “view-only” access to data from their AOs to facilitate their review of these data. If a LAO finds any data that requires further clarification, the LAO should email their questions to the DMACC DMs, who will review the questions and enter the appropriate queries into Rave.
- Overdue data and outstanding queries will be visible in Rave by LAO/AO staff; sites should regularly log into Rave to complete data and resolve queries. All queries must be resolved within 14 calendar days.
- To respond to a query, sites may either correct the data or provide the reason directly within Rave why the data are accurate and do not need correction.
- Reports regarding overdue data and queries will be sent to the LAOs and AOs on a monthly basis. Additionally, LAOs and AOs can access data submission/query response status at any time within Rave.

5. TRAINING AND DOCUMENTATION

- NCI/DCP requires site staff performing any aspect of data management have the education, training, and experience required to perform their assigned tasks.
- As stipulated in 21 CFR Part 11, LAO and AO staff who will be entering data or officially reviewing data for a protocol must complete training. Access will not be granted to systems holding participant data until training is complete.
  - Training for Rave is provided via eLearnings within Rave; records of training completion are retained within Rave.
  - All staff who will be performing screening and enrollment must read and sign-off on the Stars user manual; this acknowledgement will be maintained in Stars.
  - Any other systems implemented in the conduct of CP-CTNet trials will also require training for appropriate personnel.
- The LAOs and AOs will comply with all CP-CTNet SOPs, guidelines and other documents distributed by the DMACC and/or DCP.
- The site should maintain training documentation.
- Training requirements will be monitored by the DMACC through routine LAO and AO audit visits, with additional LAO oversight of the AOs

6. STUDY CLOSE-OUT AND DATABASE LOCK

- At the completion of a study, data in Rave must be accurate (reflecting a true representation of the information in the source document), complete (all required data are keyed into the system), cleaned (all data discrepancies must be corrected and completely resolved), audited (all required quality assurance and quality control activities must be performed as well as the final site visit by DMACC and NCI/DCP completed), and locked for analysis within three months of the last participant's exit from the study.
- For the database lock the PI will be required to provided sign offs for the study CRFS.
- After closeout, DMACC will be manage the end-of-study data management tasks including the posting data to the Cancer Data Access System (CDAS).

7. SECURITY

- All organizations must establish adequate security procedures to maintain the accuracy, reliability, integrity, availability, and confidentiality of all study participant data and other study-related data.
  - Each staff member recorded on the Delegation of Tasks Log (DTL) will have a unique username and password for the appropriate systems. Passwords must not be shared.
  - Participant names should not be included in any email correspondence. If protected health information (PHI)/personally identifiable information (PII) data must be included in correspondence, measures should be taken to encrypt the emails and/or files containing this information.

8. RECORD RETENTION

- Clinical records for all participants, including SVAR worksheets, all source documentation (containing evidence of study eligibility, history and physical findings, laboratory data, results of consultations, etc.), as well as Central Institutional Review Board (CIRB) records and other regulatory documentation will be retained by the Investigator in a secure storage facility in compliance with Health Insurance Portability and Accountability Act (HIPAA), Office of Human Research Protections (OHRP), FDA regulations and guidance, and NCI/DCP requirements, unless the standard at the site is more stringent.
- The records for all studies performed under an Investigational New Drug (IND) will be maintained, at a minimum, for two years after the approval of a New Drug Application (NDA). For NCI/DCP, records will be retained for at least three years after the completion of the research.
- NCI will be notified prior to the planned destruction of any materials. The records should be accessible for inspection and copying by authorized persons of the FDA. If the study is done outside of the United States, applicable regulatory requirements for the specific country participating in the study also apply.

9. REVIEW OF THE MASTER DATA MANAGEMENT PLAN:

- The NCI/DCP and DMACC will review the DMP annually to evaluate the currency, adequacy and effectiveness of the procedures described in the plan, and update as necessary.
- The DMP also will be updated as required by the NCI/DCP and DMACC to incorporate any necessary procedure changes.
- The DMACC will notify the LAOs of the revised, approved DMP, including a link to the document. This version will supersede all other DMPs and will be applied to all protocols. The LAOs will distribute the DMP to the AOs.

Please send questions and comments to the DMACC at:
DataManagement_CP-CTNet@frontierscience.org

10. RESOURCES

- NCI/DCP website for CP-CTNet
  https://prevention.cancer.gov/major-programs/cancer-prevention-clinical-trials-network-cp-ctnet
- Protocol Information Office (PIO) Instructions and Tools
  https://prevention.cancer.gov/clinical-trials/clinical-trials-management/protocol-information-office/pio-instructions-and-tools/cp-ctnet-instructions-forms
- Cancer Data Standards Repository (caDSR)
  https://wiki.nci.nih.gov/display/caDSR/caDSR+Wiki

  Cancer Data Standards Repository (caDSR) CDE Browser
  https://cdebrowser.nci.nih.gov/CDEBrowser/
- FDA: CFR - Code of Federal Regulations Title 21
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62

11. APPENDICES

- None