NCI CDISC
Communication Plan

Version 8/19/2019

I.   Introduction

The use of Clinical Data Interchange Standards Consortium (CDISC) standards is required for data submissions to the US Food and Drug Administration (FDA). CDISC submissions to the FDA require the use of controlled terminology and datasets formatted according to Study Data Tabulation Model (SDTM). Collecting clinical data using Clinical Data Acquisition Standards Harmonization (CDASH) facilitates this submission process.

The FDA has mandated sponsors whose studies start after Dec 17, 2016, must submit their clinical study data sets in the Study Data Tabulation Model (SDTM) standard format. For INDs, the requirement applies for studies that start after Dec. 17, 2017. SDTM provides a standard for organizing and formatting data to streamline the process in collection, management, analysis and reporting. The Clinical Data Interchange Standards Consortium (CDISC) is a global nonprofit standards development organization with a worldwide team of staff and volunteer experts across the medical community. CDISC provides data standards to streamline clinical research, one of which being SDTM. CDISC is also developing Clinical Data Acquisition Standards Harmonization which establishes a standard way to collect data in a similar way across studies and sponsors so that data formats and structures provide clear traceability of submission into the SDTM. To support the FDA mandate of submitting clinical study stat sets to the FDA in the SDTM format, the NCI is transitioning their current Network Rave Data Standards (NRDS) Initiative, led by the Cancer Therapy Evaluation Program (CTEP) into the CDISC implementation.

The NCI is working in collaboration with CDISC to ensure data is collected in the CDASH format for the Oncology Patient Enrollment Network (OPEN) System, Clinical Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS) and the Clinical Data Update System (CDUS). According to the FDA Study Data Technical Conformance Guide, section 4.1.2 (SDTM General Considerations), it is recommended that sponsors implement the collection of data in a format that is harmonized with SDTM such as CDASH.

Per the NCI, all CTEP-sponsored Investigational New Drug (IND) studies activated on or after 01/01/2020 must be CDISC-compliant. The Cancer Trials Support Unit (CTSU) is supporting the NCI's CDISC implementation efforts by developing a CDISC-Compliant Rave Global Library (GLIB) Architect Loader Specification (ALS) file containing CDASH and SDTM variables. The Lead Protocol Organizations (LPOs) will use this ALS file in building their own Rave CDISC-compliant GLIBs for all studies.

II.   NCI CDISC Stakeholders

Lead Protocol Organizations (LPOs)

- ABTC - *Adult Brain Tumor Consortium*
- Alliance
- AMC - *AIDS Malignancy Consortium*
- CCR - *Center for Cancer Research*
- CCTG - *Canadian Cancer Trials Group*
- COG - *Children's Oncology Group*

- ECOG-ACRIN - *Eastern Cooperative Oncology Group-American College of Radiology Imaging Network*
- NRG - *National Surgical Adjuvant Breast and Bowel Project (NSABP), Radiation Therapy Oncology Group (RTOG), Gynecologic Oncology Group (GOG)*
- PBTC - *Pediatric Brain Tumor Consortium*
- SWOG - *formerly the Southwest Oncology Group*
- Theradex*

National Clinical Trials Network (NCTN) / Experimental Therapeutics Clinical Trials Network (ETCTN) Research Sites

- Investigators and associates

National Cancer Institute

- CBIIT
- CCCT
- CTEP
- CTIS*

- CTSU*
- DCCPS
- DCP
- DCTD

* Contractor to the NCI

III. Goals and Objectives

a. Goals

The goal of NCI CDISC Communication Plan is to ensure appropriate, consistent, effective, and timely communications among all NCI CDISC working groups and stakeholders, across all CDISC project related activities. The term NCI CDISC working group covers any committee, working group, sub group or focus group instituted to support the NCI CDISC efforts in the CTEP program. A description of each working group is available in section IV (Communication Vehicles) of this document.

b. Objectives

Primary objectives of the NCI CDISC Communication Plan include:

i. Support the NCI implementation of CDISC
ii. Maintain effective communication between the NCI and all stakeholders in order to sustain a high level of trust in the NCI CDISC efforts
   a) Encourage participation and collaboration
   b) Communicate changes to project stakeholders
   c) Provide mechanisms for two way feedback from end-users

c. Expectations

These expectations are applicable to members of all NCI CDISC working groups, stakeholders, and stakeholder organizations. Stakeholders will be determined as per the member listings specified on

the NCI CDISC Wiki. Project communications (i.e., meeting minutes and email communications) will clearly specify project action items, deliverables, timelines and Stakeholder roles and responsibilities.

    i. Project Decisions

        a) All stakeholders must be actively included in discussions related to any corresponding action items, concerns, considerations, decisions, deliverables, and discussion items.

        b) Key decisions that impact components of the NCI CDISC efforts (e.g., project deliverables, level of effort, outcomes, resourcing considerations, timelines) require documented feedback and agreement from each stakeholder; at minimum, a documented confirmation of acknowledgment and understanding from each stakeholder is required if consensus is not achieved.

        c) For decisions requiring formal vetting, the NCI CDISC voting process must be followed. Refer to the NCI CDISC Voting Guidelines for information on this process.

    ii. Meetings

        a) WebEx meetings will be recorded and available to all stakeholders.

        b) Agendas and prompt minutes should be distributed to all stakeholders.

        c) All stakeholders must be invited to all scheduled (routine and ad hoc) meetings related to any action items, concerns, considerations, decisions, deliverables, discussion items, and status updates   (unless personnel related).

        d) Stakeholders have the option to decline participation in a scheduled meeting; the stakeholder must communicate this decline to the NCI PM if known in advance of the scheduled meeting.

    iii. Email communications

        a) A NCI CDISC listserv will be created, maintained, and used for as the email distribution listing for all NCI CDISC working groups; this document will be available on the NCI CDISC Wiki.

        b) The NCI PM, along with all stakeholders must be copied on all email communications related to said group's action items, concerns, considerations, decisions, deliverables, discussion items, and status updates (unless personnel related).

        b) Emails sent to a subset of stakeholders will be forwarded by the NCI PM to all stakeholders.

IV. Communication Vehicles

a. NCI CDISC Broadcast/ Newsletters

All NCI CDISC Stakeholders will be emailed an NCI CDISC Broadcast/ Newsletter on a monthly and as-needed basis; the NCI CDISC listserv will be used for this distribution.

The Broadcast/ Newsletter will include the following:

    i. NCI CDISC Committee updates

    ii. Updates from all active NCI CDISC working groups

    iii. NCI CDISC status/milestones/upcoming timelines

      iv. NCI CDISC changes made and upcoming

b. NCI CDISC Wiki

The NCI CDISC Wiki will provide a centralized location to maintain NCI CDISC newsletters, communications, documentation, and updates from the NCI CDISC working groups. The NCI CDISC Wiki will be accessible to all NCI CDISC stakeholders.

c. NCI CDISC Working Groups

Each meeting will be held via a virtual web session, and the frequency of meetings will be adjusted based on the need though the life of the project. Each meeting will have an agenda, presentation and minutes that will be posted to the NCI CDISC Wiki.

      i. NCI CDISC Committee

      This group serves as an oversight committee for the NCI CDISC implementation and maintenance. The group will be comprised of NCI and LPO stakeholders.

      ii. NCI CDISC Integration Focus Group

      This group will review the IT impact analysis and determine how to move forward from an integrations perspective with CDASH/SDTM related activities. This group will be comprised of NCI and NCI contractor subject matter experts (SMEs) for OPEN, CTEP-AERS, the Data Mapping Utility, the caDSR and CDISC. The frequency of the meetings may decrease as the project moves forward. This group may move into a hibernation phase, activated by the NCI as needed for activities related to maintenance for the NCI CDISC implementation.

      iii. NCI CDISC Harmonization Working Group

      This group will review and harmonize non-standard content with CDISC. The harmonized content will be vetted across the LPOs into draft CDISC standards and submitted to CDISC for standardization. This group will be comprised of NCI and LPO stakeholders.

      iv. CDISC Policy/Governance Working Group

      This group will identify requirements to guide decisions on the adoption and usage of the standardized CDISC CDEs for the NCI CDISC stakeholders and will be comprised of NCI and LPO stakeholders.

      v. CDISC Validation Working Group

      This group will review tools for CDISC Validation and propose recommendations to the NCI and will be comprised of NCI and LPO stakeholders.