Title: Electronic Case Report Form Development

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REVISION HISTORY

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

1. INTRODUCTION AND PURPOSE

Electronic Case Report Forms (eCRFs) are developed to collect and record the data required to answer the research question(s) for a specific protocol, to create the study build in the Rave clinical database management system, and also to serve as a description of the expected content of the final dataset for the study.

The System Variable and Attribute Report (SVAR) Template is the tool that will be used to create the eCRFs. The SVAR is a customizable template used to develop or revise protocol-specific eCRFs. The SVAR Template contains both mandatory and recommended content, and should be used as the basis for developing the protocol-specific eCRFs.

eCRFs should be created to collect data in a consistent manner to assure quality, completeness, and accuracy of the final data sets, and to ensure that data collection is done in compliance with Good Clinical Practice, the standards for National Cancer Institute (NCI) Common Data Elements (CDEs), and federal regulations, including but not limited to 21 CFR Part 11 and the Health Insurance Portability and Accountability Act (HIPAA).

2. SCOPE

This document details the responsibilities of the LAO Site Investigator and designees regarding the creation of eCRFs for new, revised and amended protocol submissions.

3. RESPONSIBILITIES

The LAO Investigator, LAO Site Coordinator, or designee is responsible for drafting the initial version of the eCRFs for each new protocol submission, utilizing the CP-CTNet SVAR Template.

1. The CP-CTNet SVAR Template, including instructions for use of the SVAR, will be posted on the Data Management Auditing and Coordinating Center (DMACC) Portal Gateway. The SVAR Template should be used to create a customized SVAR Workbook which documents all questions and data elements required for each protocol, as well as the Schedule of Forms, which describes which eCRFs will be completed at each visit/event in a protocol-specific logical order.
2. The protocol-specific SVAR Workbook should be submitted in spreadsheet format. Each tab in the SVAR contains questions, their corresponding attributes (e.g., field length, response value, data type), and the following elements:
    - Change Indicator
    - Question Name
    - Data Type
    - Field Length (including decimal places, if applicable)
    - Field Type
    - Valid Values (value and value meaning)
    - Mandatory?
    - Field Help Text
    - MDS Field?
    - MDS Collection Table
    - Site Comments
    - Curator Comments
    - caDSR Public ID: Version
    - csDSR Definition

- caDSR Representation (Value Domain Public ID)

3. The LAOs' responsibilities include:
   3.1. Follow the SVAR Workbook development process as outlined in REFGD03 Data Management Plan (DMP).
   3.2. Confirm that all mandatory or required questions, including those that will be used to collect data for the Minimum Data Set (MDS) reporting, are included in the SVAR Workbook
      - Mandatory questions are organized by modules (i.e., groups of related NCI CDEs). If a protocol does not use a particular module, the mandatory questions for that module do not need to be included in the protocol-specific SVAR Workbook. Please refer to the link below:

        https://wiki.nci.nih.gov/display/CRF2/CRF+Harmonization+and+Standardization.
   3.3. Confirm compliance with the standards for the CDEs. Information regarding these standards is available at https://wiki.nci.nih.gov/display/CRF/Case+Report+Forms+Wiki. DCP's CDE Curator will work with each LAO to ensure all questions and valid values are CDE-compliant.
   3.4. Submit the protocol-specific SVAR Workbook to the DCP Protocol Information Office (PIO) (nci_dcp_pio@mail.nih.gov) with the ***second*** submission of the protocol.
      - The SVAR Workbook should contain the protocol title, version number and date. Each time changes are made to the Workbook, the document should be updated with the current protocol version number and date.

      3.4.1. A SVAR version number and version date must be included in the initial and updated versions of the SVAR Workbook. Apply the following versioning conventions to the SVAR Workbook.

         3.4.1.1. The version date must be current and different from any previous version date for the SVAR Workbook. The version date of the SVAR Workbook is not required to match the version date of the protocol and informed consent.

         3.4.1.2. The version number will change based on the approval status of the SVAR Workbook.

            - The version number for the initial submission of the SVAR Workbook will be v1.0. If the SVAR Workbook is revised before the SVAR Workbook is approved, the version number will be updated to include decimals to indicate a SVAR Workbook revision (e.g., v1.1, v1.2, v1.3, etc.).
            - The version number for the SVAR Workbook will change to whole numbers after the SVAR Workbook is approved. The first submission of the SVAR Workbook after its approval will be numbered as v2.0, the next updated SVAR Workbook would be numbered as v3.0. All subsequent submissions of updates to the SVAR Workbook will continue to use whole, sequential numbers to indicate a new workbook version throughout the life of the SVAR Workbook.

   3.5. The PIO will send either review comments requiring a SVAR Workbook revision/resubmission, or a notice of SVAR Workbook approval to the LAO.
   3.6. The SVAR Workbook will be reviewed by the eCRF Review Team. The PIO will send the review comments requiring a SVAR Workbook revision/resubmission, and/or a notice of SVAR Workbook approval to the LAO. If revision is required, the LAO will revise and

resubmit the SVAR Workbook to the PIO, as needed, until the Workbook is found to be acceptable. Both a clean and a tracked version should be submitted.

- The comments from the eCRF Review Team will be recorded in a Consolidated SVAR Review Document (Appendix I) and/or in the appropriate tab in the SVAR Workbook. Each comment on the Consolidated SVAR Review Document will be tagged with a comment type to identify the reason the SVAR revision or clarification is requested (e.g., "MDS Requirement" would be a tag for a comment regarding a missing MDS variable.)
- For any resubmissions, include a "Response Memo" listing the response to each comment in the Consolidated SVAR Review Document and the SVAR Workbook.
- If any changes to the protocol are made during the submission process, review the SVAR Workbook to determine if parallel changes are needed.

3.7. The SVAR Workbook may also be revised due to protocol amendments, to address administrative issues at the site, and/or to address site errors. Two versions of the updated workbook should be submitted to the DCP PIO; one with tracked changes and a clean version (with no tracked changes). A "Change Memo" listing the revisions should also be sent with the revised SVAR Workbook. Any SVAR Workbook change prompted by a protocol change will require a revised protocol for review.

4. DOCUMENTATION REQUIREMENTS

Each LAO is responsible for maintaining the following documentation in their files:

1. Current CP-CTNet Master DMP and any related documents that reflect the current data collection practices for each protocol.
2. The letter of acceptance from DCP regarding the SVAR Workbooks for each protocol.
3. The approved SVAR Workbook.

5. ADDITIONAL INFORMATION:

Refer to the CP-CTNet Acronym List to see the description for commonly used acronyms in this SOP.

Please send questions and comments to the DMACC at:

DataManagement_CP-CTNet@frontierscience.org

6. REFERENCES

- System Variable and Attribute Report (SVAR) Template

7. APPENDICES

- Appendix 1 - Consolidated SVAR Review Document

Appendix I
Consolidated SVAR Review Document

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Consolidated SVAR Review Document

Review Completed Date:

Protocol Number	**Choose an item.**
Protocol Title	Click here to enter text.
Protocol Version and Date	Click here to enter text.
SVAR Version and Date	Click here to enter text.
Review Outcome	Choose an item.
Review Comments	
Instructions	Please see the SVAR Curator Comments column for all CDE questions and comments. All non-CDE comments are listed on this document. • Text in red font in the Curator Comments column requires site action (tabs with comments are in red). Sites responses should be entered in the Site Comments column. • Cells with black text in the "Curator Comments" column are informational updates/clarifications; struck through text are prior comments that have been resolved. • The cells highlighted in blue provide details such as CDE identifiers, version, and statuses used by the CDE Curator. This content should not be modified by the site. • Comments prefaced with "Curator Note" do not require site action and will be addressed by DCP Librarian once the SVAR is finalized.

General Comments No General Comments ☐

Comment Type	Comment
Mandatory ☐ Recommended ☐	

SVAR Specific Comments No SVAR Specific Commen ☐

Tab Name	Comment Type and Priority	Comment
	Mandatory ☐ Recommended ☐	

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Consolidated SVAR Review Document

Review Completed Date:

Definitions of SVAR comment types:

- General: comments not specific to the study or DCP requirements, such as spelling, formatting, or wording
- Consistency: comments referring to either an internal discrepancy within the SVARs or an external discrepancy between the SVARs and other protocol documents (e.g., the protocol, schedule of forms, or PIO TAC coding letter)
- CDE Compliance: comments addressing CDE noncompliant values in the SVAR, or concerns held by the DCP CDE Contractor.
- Regulatory Compliance: comments addressing regulatory noncompliant items in the SVAR, or concerns held by the DCP Regulatory Contractor.
- Auditing Consideration: comments addressing auditing concerns held by the Data Management, Auditing and Coordinating Center (DMACC).
- DCP Preferred Terminology: comments containing DCP-suggested terminology edits.
- MDS Compliance: comments indicating that data elements for MDS reporting are missing, inconsistent, etc.
- Informational: general comments for information purposes only. No action is required.

Definitions of comment priority:

- Mandatory: comments containing a critical revision that must be made before SVARs can be approved.
- Recommended: comments containing noncritical suggestions that can be addressed in a later submission to DCP.