Title: Electronic Case Report Form Development

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Version: Interim 1.0
Version Date: April 27, 2020
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## REVISION HISTORY

<table>
<thead>
<tr>
<th>Version</th>
<th>Effective Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim 1.0</td>
<td>XXX-XX-2020</td>
<td>Original version of document.</td>
</tr>
</tbody>
</table>


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 protocol submissions as well as the development and maintenance of related eCRF documents.

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 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 (i.e., 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
3. The LAOs’ responsibilities include:


3.2. Confirm that all mandatory or required questions, including those that will be used to collect data for Minimum Data Set (MDS) reporting, are included in the SVAR workbook.

   - Mandatory questions are organized by modules (i.e., groups of related NCI Common Data Elements (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](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](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 Division of Cancer Prevention (DCP) Protocol Information Office (PIO) ([nci_dcp_pio@mail.nih.gov](mailto: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 revision’s version number and date.

3.5. The PIO will distribute the SVAR workbook to the eCRF Review Team (DCP study staff, DCP regulatory contractor, CDE Curator, and DMACC, who will review the data items for consistency with the protocol, regulatory requirements, CDE and database requirements. The eCRF Review Team will return review comments to the PIO for distribution to the DCP study staff for final comment and/or approval. The PIO will send either review comments requiring a SVAR revision and resubmission or a notice of SVAR approval to the LAO. The LAO can submit the requested eCRF revisions by revising the SVAR workbook and submitting both clean and tracked versions of the SVAR to the PIO.

3.6. Revise the SVAR workbook based on comments received from the eCRF Review Team, as needed, until the workbook is found to be acceptable.

   - 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. 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 re-submissions, include a “Response Memo” listing the response to each comment in the Consolidated SVAR Review Document.

   - 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. Each SVAR submission (for each protocol) must be assigned a unique version date. In addition to the version date, a version numbering schema must be used. The version number and date must be updated with each document change made both before (revisions) and after protocol approval (amendments). Whole, sequential, and continuous version numbering is to be used throughout the life of the protocol, (i.e., do not renumber documents after protocol
approval). These numbering conventions apply to both the protocol and SVAR documents. Please refer to the Revision or Amendment Submission Checklist for DCP Chemoprevention Studies.

4. The SVAR workbook may also be revised due to protocol amendments, to address administrative issues at the site, or to address site errors. Two versions of the updated workbook should be submitted; 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 change prompted by a protocol change will require a revised protocol for review which should be included in the email sent from the PIO to the eCRF Review Team.

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

• None

7. APPENDICES

• Appendix 1 - Consolidated SVAR Review Document
Appendix I
Consolidated SVAR Review Document

NCI-DCP CP-CTNet

Consolidated SVAR Review Document

Review Completed Date:

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>Choose an item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Title</td>
<td>Click here to enter text</td>
</tr>
<tr>
<td>Protocol Version and Date</td>
<td>Click here to enter text</td>
</tr>
<tr>
<td>SVAR Version and Date</td>
<td>Click here to enter text</td>
</tr>
<tr>
<td>Review Outcome</td>
<td>Choose an item</td>
</tr>
<tr>
<td>Review Comments</td>
<td></td>
</tr>
</tbody>
</table>

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 back 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 □

<table>
<thead>
<tr>
<th>Comment Type</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory</td>
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</tr>
<tr>
<td>Recommended</td>
<td>□</td>
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</table>

SVAR Specific Comments
No SVAR Specific Comments □

<table>
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<tr>
<th>Tab Name</th>
<th>Comment Type and Priority</th>
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<tbody>
<tr>
<td></td>
<td>Mandatory</td>
<td>□</td>
</tr>
<tr>
<td></td>
<td>Recommended</td>
<td>□</td>
</tr>
</tbody>
</table>
NCI-DCP CP-CTNet

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.