

Knowledge Acquisition Report CDE Compliance Review Tools

Session Date: July 25, 2001

Session Topic: Create Case Report Form Template Use Case Text Description

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Information Sources:

Previous Knowledge Acquisition Efforts with:
CTEP PIO Representatives (July 17 and July 24, 2001)

General Topic Area

This report documents Use Case text derived from sessions with CTEP PIO Representatives regarding steps required to create a Case Report Form Template

Use Case: Create Case Report Form Template

Primary Actor: CDE Manager

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

- CDE—common data element
- CRF—case report form
- SBR—standards based repository

Stakeholders and Interests:

- CDE Manager—to create a CRF template that encourages CRF Creators to use CDEs
- CRF Creator—to quickly and easily create a CRF that supports the needs of the clinical trial
- CDE Coder—to quickly and easily determine whether each element in a CRF is a CDE

Preconditions:

1. Approved and submitted common data elements are stored in the SBR.
2. CDE Manager has knowledge of typical CRFs, history of CRF submissions, and/or expert input on CRF creation.

Trigger: CDE Manager decides that a new CRF template is needed.

Main Success Path:

1. CDE Manager identifies the CRF template to be created.
2. CDE Manager accesses the SBR extension.
3. CDE Manager identifies in the SBR all the CDEs that will provide content for the new template.
4. CDE Manager organizes the CDEs into modules within the CRF.
5. CDE Manager saves the module and form organization information in the SBR extension.
- 6.

Postconditions:

1. Form and module organization is saved in the SBR extension.

Extensions:

Variations:

Use Case: Distribute CRF Template and Review Sheet

Primary Actor: CDE Manager

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CEP—Concept Evaluation Panel

CRF—case report form

CTEP—Cancer Therapy Evaluation Program

PIO—Protocol and Information Office

Stakeholders and Interests:

CDE Manager—to make the CRF template accessible to those who need it.

CRF Creator—to access the CRF template when creating a CRF.

CTEP Concept Evaluation Panel—to provide protocol/CRF creators everything they need to quickly create a protocol that can be reviewed and approved rapidly.

CDE Coder—to access the CRF template during the CDE compliance review.

Preconditions: CRF template has been created.

Trigger: CDE Manager decides to distribute a new CRF template.

Main Success Path:

1. CDE Manager runs a report containing the module names, CDE long names, CDE short names, and valid values.
2. CDE Manager saves the report into a spreadsheet.
3. CDE Manager adds the following columns to the spreadsheet:
 - CDE Match: Exact
 - CDE Match: Partial
 - CDE Match: Not Used
 - New CDE Terms
 - CTEP Comments
4. CDE Manager saves the CRF Review Sheet on the hard drive of her computer.
5. CDE Manager forwards the CRF Review Sheet to the PIO.
6. CDE Manager forwards the CRF Review Sheet to the CDE Coder.
7. PIO Protocol Specialist stores the CRF Review Sheet on the CTEP local area network.
8. CTEP Concept Evaluation Panel generates the CRF template spreadsheet from the SBR extension (note: this part of the process will be implemented shortly).
9. CTEP Concept Evaluation Panel forwards the CRF Template spreadsheet to the CRF Creator along with other concept approval materials (note: this part of the process will be implemented shortly).

Postconditions:

1. CRF Review Sheet has been created.
2. The Concept Evaluation Panel and CRF Creator have access to the CRF template spreadsheet.
3. The CDE Coder has access to the CRF Review Sheet.

Extensions:

Variations:

Use Case: Create Case Report Form

Primary Actor: CRF Creator

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

SBR—standards based repository

Stakeholders and Interests:

CDE Manager—to encourage CRF Creators to use CDEs

CRF Creator—to quickly and easily create CRFs that support the data collection needs of the clinical trial

Creating Organization's Review Boards—to approve CRFs that support the needs of the clinical trial and that adhere to the organization's standards

Preconditions: CRF template has been distributed.

Trigger: CRF Creator receives a new protocol.

Main Success Path:

1. CRF Creator reviews the protocol.
2. CRF Creator reviews CRFs from previous similar protocols.
3. CRF Creator reviews any standard CRFs used by her organization.
4. CRF Creator searches the SBR extension for appropriate CRF templates.
5. CRF Creator downloads appropriate CRF templates from the SBR extension.
6. CRF Creator reviews the CRF templates.
7. CRF Creator searches the SBR extension for additional CDE information.
8. CRF Creator contacts the CDE Manager with any questions.
9. CDE Manager answers CRF Creator's questions.
10. CRF Creator drafts the CRFs for the protocol (both content and layout).
11. The CRF Creator's organization conducts its internal reviews on the CRFs.
12. The CRF Creator's organization approves the CRFs.

Postconditions: The CRFs for a protocol have been created.

Extensions:

Variations:

Use Case: Submit Protocol and Case Report Forms

Primary Actor: Creating Organization's Protocol Manager

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

CTEP—Cancer Therapy Evaluation Program

PIO—Protocol and Information Office

Stakeholders and Interests:

PIO Protocol Specialist—to receive the protocol and its CRFs

CRF Creator—to ensure that the CRFs are safely delivered to CTEP

Creating Organization's Protocol Manager—to deliver the protocol and its CRFs safely to CTEP

Preconditions: Protocol and CRFs created and approved by the creating organization.

Trigger: CRF Creator's organization has approved a protocol and its CRFs.

Main Success Path:

1. Protocol Manager begins collecting all protocol and CRF materials for submission.
2. CRF Creator saves the approved CRF (content and layout) in an Adobe .PDF file.
3. CRF Creator forwards the CRFs to the Protocol Manager.
4. Protocol Manager packages all protocol and CRF materials for submission to CTEP.
5. Protocol Manager sends the protocol submission package to CTEP.
6. CTEP PIO Protocol Specialist receives the protocol submission package.

Postconditions: The protocol and its CRFs have been received by CTEP.

Extensions:

Variations:

Use Case: Log In Protocol and Case Report Forms

Primary Actor: PIO

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

CTEP—Cancer Therapy Evaluation Program

CTEP-ESYS—Cancer Therapy Evaluation Program Enterprise System

PIO—Protocol and Information Office

Stakeholders and Interests:

PIO Protocol Specialist—to verify that all protocol submission elements are present and log them into CTEP-ESYS

CDE Manager—to determine whether submitted CRFs require a CDE compliance review

CDE Coder—to receive any CRFs which should be reviewed for CDE compliance

Preconditions: Protocol submission package received by PIO.

Trigger: PIO Protocol Specialist begins reviewing the protocol submission package.

Main Success Path:

1. PIO Protocol Specialist verifies that all parts of the protocol submission package are present.
2. PIO Protocol Specialist logs the protocol submission into CTEP-ESYS.
3. PIO Protocol Specialist abstracts information from the protocol into CTEP-ESYS.
4. CDE Manager briefly reviews the protocol information and determines whether a CDE compliance review is needed.
5. PIO Protocol Specialist prints copies of the CRFs.
6. PIO Protocol Specialist forwards the hard copy CRF documents to the CDE Coder and CDE Manager.

Postconditions:

1. The protocol and its CRFs have been logged into CTEP-ESYS.
2. CDE Manager has determined whether a CDE compliance review is needed.
3. CDE Coder and CDE manager have copies of the CRFs.

Extensions:

Variations:

- 4a. CDE Manager determines that no CDE compliance review is needed for this protocol.
Process ends.

Use Case: Review CRF for CDE Compliance

Primary Actor: CDE Coder

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

PIO—Protocol and Information Office

Stakeholders and Interests:

CDE Coder—to determine whether the CRF elements match CDEs and to record details when CRF elements do not match CDEs

CDE Manager—to educate CRF Creators about CDE use and to identify new CDEs that need to be added to the SBR

CRF Creator—to have the CRF elements accepted as either CDE matches or new CDEs

Preconditions:

1. The CDE Coder has access to the CRF Review Sheet.
- 2.
3. CRF documents have been received from PIO.
4. CDE compliance review is required.

Trigger: CDE Coder receives CRF documents from PIO.

Main Success Path:

1. CDE Coder quickly reviews all CRFs for the protocol and becomes familiar with them.
2. CDE Coder selects a CRF from the set for the protocol.
3. CDE Coder determines whether a CRF Review Sheet exists for this CRF.
- 4.
5. For each element on the CRF Review Sheet, the CDE Coder looks on the CRF and does the following:
 - a. If the element appears on the CRF, place an X in the “Exact Match” column in the Review Sheet.
 - b. If a variation of the element appears on the CRF, place an X in the “Partial Match” column in the Review Spreadsheet. Then key the text of the CRF element and its values into the “Comments” column of the Review Sheet.
 - c. If the element does not appear on the CRF, place an X in the “Not Used” column in the Review Sheet.
6. For each “Not Used” item on the CRF Review Sheet, the CDE Coder may recall whether whether that element appeared on another CRF for this protocol. If it does, the CDE Coder keys that information into the “Comments” column on the CRF Review Sheet.
7. CDE Coder reviews the CRF to find all elements that do not appear on the CRF Review Sheet.
8. CDE Coder keys the text of each new CRF element and its values into the “New CDE Terms” column of the Review Sheet.
9. CDE Coder saves the CRF Review Sheet.
10. CDE Coder emails the CRF Review Sheet to the CDE Manager.
11. CDE Coder selects the next CRF from the set and continues until all CRFs with templates have been evaluated.

Postconditions:

1. Matches, new elements, and comments have been noted.
2. CRF Review Sheet has been completed for the protocol.

Extensions:

2a. CRF template does not exist for the CRF. No review is conducted for that CRF, and CDE
Coder selects the next CRF from the set.

Variations:

Use Case: Approve CRF for CDE Compliance

Primary Actor: CDE Manager

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

PIO—Protocol and Information Office

SBR—standards based repository

Stakeholders and Interests:

CDE Manager—to educate CRF Creators about CDE use, to identify new CDEs that need to be added to the SBR, and to approve CRFs for CDE compliance.

CRF Creator—to have the CRF elements accepted as either CDE matches or new CDEs.

PIO Protocol Specialist—to receive CDE compliance approval so that overall protocol review may proceed.

Preconditions: CRF Review Sheet has been completed for the CRF.

Trigger: CDE Manager receives CRF Review Sheet from CDE Coder.

Main Success Path:

1. CDE Manager selects a CRF for review.
2. CDE Manager prints the CRF Review Sheet for the CRF.
3. CDE Manager compares hard copy CRF to hard copy CRF Review Sheet. This is frequently done away from the computer (while on travel, waiting for meetings, etc.).
4. CDE Manager notes any coding or comments with which she disagrees.
5. CDE Manager keys coding and comment changes into electronic CRF Review Sheet.
6. CDE Manager searches SBR extension for CDEs to suggest as alternatives to unacceptable CRF elements.
7. CDE Manager keys additional comments into CRF Review Sheet.
8. CDE Manager makes some formatting changes to the CRF Review Sheet to make it a cleaner document.
- 9.
10. CDE Manager saves the CRF Review Sheet.
11. CDE Manager selects the next CRF for review.
12. Once all CRFs have been evaluated, CDE manager calculates statistics for the protocol's set of CRFs.
13. CDE Manager keys the CRF statistics into a Stat Report.
14. CDE Manager keys new CDE information into a New Element Sheet (used for all CRFs in this protocol).
15. CDE Manager sends all CRF Review Sheets, the New Element Sheet, and the Stat Report to the CRF Creator.
16. CDE Manager determines whether the CRFs are approved for CDE Compliance.
17. CDE Manager requests CRF revisions from CRF Creator, if necessary.
18. If approved, CDE Manager notifies PIO of CDE compliance approval.

Postconditions:

1. CRF Review Sheets, the New Element Sheet, and the Stat Report sent to the CRF Creator.
2. CRF revisions have been requested, if needed.
3. PIO notified of CDE compliance approval, if granted.

Extensions:

Variations:

Use Case: Revise Case Report Forms

Primary Actor: CDE Creator

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

PIO—Protocol and Information Office

SBR—standards based repository

Stakeholders and Interests:

CDE Manager—to encourage CRF Creators to use CDEs

CRF Creator—to quickly and easily create CRFs that support the data collection needs of the clinical trial

Creating Organization's Review Boards—to approve CRFs that support the needs of the clinical trial and that adhere to the organization's standards

PIO—to receive revised CRFs so that overall protocol review may proceed.

Preconditions:

1. CRF Review Sheet and New Element Sheets have been sent to the CRF Creator.
2. CDE manager has requested revision of CRFs.

Trigger: CRF Creator receives CRF revision request from CDE Manager.

Main Success Path:

1. CRF Creator evaluates CRF revision request
2. CRF Creator contacts the CDE Manager with any questions.
3. CDE Manager answers CRF Creator's questions.
4. CRF Creator searches the SBR extension for additional CDE information.
5. CRF Creator drafts the revised CRFs (both content and layout).
6. CRF Creator's organization conducts its internal reviews on the revised CRFs.
7. CRF Creator's organization approves the revised CRFs.
8. CRF Creator saves the approved, revised CRF (content and layout) in an Adobe .PDF file.
9. CRF Creator sends the revised CRFs to the PIO Protocol Specialist.
10. PIO Protocol Specialist receives the revised CRFs.
11. CRF Creator completes the New Element Sheet by providing information such as description, valid values, and instructions.
12. CRF Creator saves the completed New Element Sheet.
13. CRF Creator sends the completed New Element Sheet to CDE Manager.

Postconditions:

1. Revised CRFs submitted to PIO Protocol Specialist.
2. Completed New Element Sheet sent to CDE Manager.

Extensions:

Variations:

Use Case: Review Revised Case Report Forms

Primary Actor: PIO

Scope: Case Report Form Compliance Review Tools

Level: User Goal

Acronyms Used:

CDE—common data element

CRF—case report form

CTEP-ESYS—Cancer Therapy Evaluation Program Enterprise System

PIO—Protocol and Information Office

SBR—standards based repository

Stakeholders and Interests:

CDE Coder—to determine whether the CRF elements match CDEs and to record details when CRF elements do not match CDEs.

CDE Manager—to educate CRF Creators about CDE use and to identify new CDEs that need to be added to the SBR.

CRF Creator—to have the CRF elements accepted as either CDE matches or new CDEs.

PIO Protocol Specialist—to receive approval of CDE compliance so that overall protocol review may proceed.

Preconditions:

Revised CRFs submitted to PIO Protocol Specialist.

Completed New Element Sheet sent to CDE Manager.

Trigger: PIO Protocol Specialist receives revised CRFs.

Main Success Path:

1. PIO Protocol Specialist logs receipt of revised CRFs into CTEP-ESYS.
2. PIO Specialist prints revised CRFs.
3. PIO Protocol Specialist forwards hard copy revised CRFs to CDE Coder.
- 4.
5. CDE Coder compares revised CRF to original CRF and CRF Review Sheet.
6. CDE Coder notes any problems or concerns on hard copy revised CRFs.
7. CDE Coder forwards revised CRFs to CDE Manager.
8. CDE Manager reviews CDE Coder's notes.
9. CDE Manager compares revised CRF to original CRF and CRF Review Sheet.
10. CDE Manager notes any problems or concerns with revised CRFs.
11. CDE Manager searches SBR extension for CDEs to suggest as alternatives to unacceptable CRF elements.
12. CDE Manager reviews the completed New Element Sheet.
13. CDE Manager saves the completed New Element Sheet on her computer.
14. If question exist, CDE Manager contacts CRF Creator by phone or email to resolve questions.
15. CDE Manager determines whether the CRFs can be approved for CDE Compliance.
16. If approved, CDE Manager notifies PIO Protocol Specialist of CDE compliance approval.
17. If not approved, CDE Manager requests further CRF revisions or more data on elements.

Postconditions:

1. Additional CRF revisions have been requested, if needed.
2. PIO Protocol Specialist notified of CDE compliance approval, if granted.
3. Completed New Element Sheet stored on CDE Manager's computer.

Extensions:

Variations: