

Knowledge Acquisition Session Plan RTOG – Common Data Elements

Session Date: 11/29/00

Session Time: 12:00 – 4:30 p.m.

Session Topic: Radiation Therapy Oncology Group use of common data elements in case report forms

Knowledge Analysts: Bill McCurry – ScenPro, Inc. (Lead); Beverly Meadows – CTEP; Carolyn Pifer, JJ Maurer, Lisa Chatterjee – Oracle

Session Location: RTOG offices, Philadelphia, Pennsylvania

Type of Session:

- Interview ___ Task Analysis ___ Scenario Analysis
___ Concept Analysis ___ Observation ___ Structured Interview
 Other: Presentation

Documentation: KA Session Report, CDE Presentation

General Topic Area

Use of Common Data Elements by the Radiation Therapy Oncology Group

Session Objectives/goals

- To provide a brief overview of the Common Data Elements (CDE) Project to the RTOG clinical trials staff.
- To review and gain feedback regarding the current CDE applications.
- To gather information regarding a user's typical work tasks, tools and systems used.
- To solicit the clinical staff's ideas regarding tools that would assist them in completing their major clinical trials tasks.

Summary

In this session individuals from the Cancer Therapy Evaluation Program (CTEP) and from Oracle presented an overview of the Common Data Elements (CDE) Project to Radiation Therapy Oncology Group (RTOG) staff. RTOG personnel asked questions about the CDE Project and provided feedback on possible CDE-related applications. RTOG personnel also briefly described their organization, their process for creating case report forms, and the technology currently in use at RTOG.

Overview of the Common Data Elements Project

One of the National Cancer Institute's (NCI) goals is to employ computer technology to improve the cancer clinical trials process. Computer technology can be used to reduce paperwork, simplify protocol administration, improve communication, and provide patients with accessible, timely data.

The Common Data Elements (CDE) Project supports NCI's computer technology implementation goal. NCI intends to create a standardized, computer-readable terminology specific to cancer research. Adoption and use of this terminology is intended to provide the cancer research community with the following benefits:

- Consistent and efficient collection of data
- Uniform reporting
- Data analysis across clinical trials using common variables
- Elimination of redundancy and unnecessary data collection
- Data mining opportunities

NCI has formed CDE Development committees to begin creating sets of common data elements specific to cancer types. Each committee includes representatives from NCI and from various cooperative groups. Physicians, statisticians, research nurses, and clinical research assistants have participated in CDE development on these committees. Figure 1 shows the CDE development scheduled in 2000 through 2002.

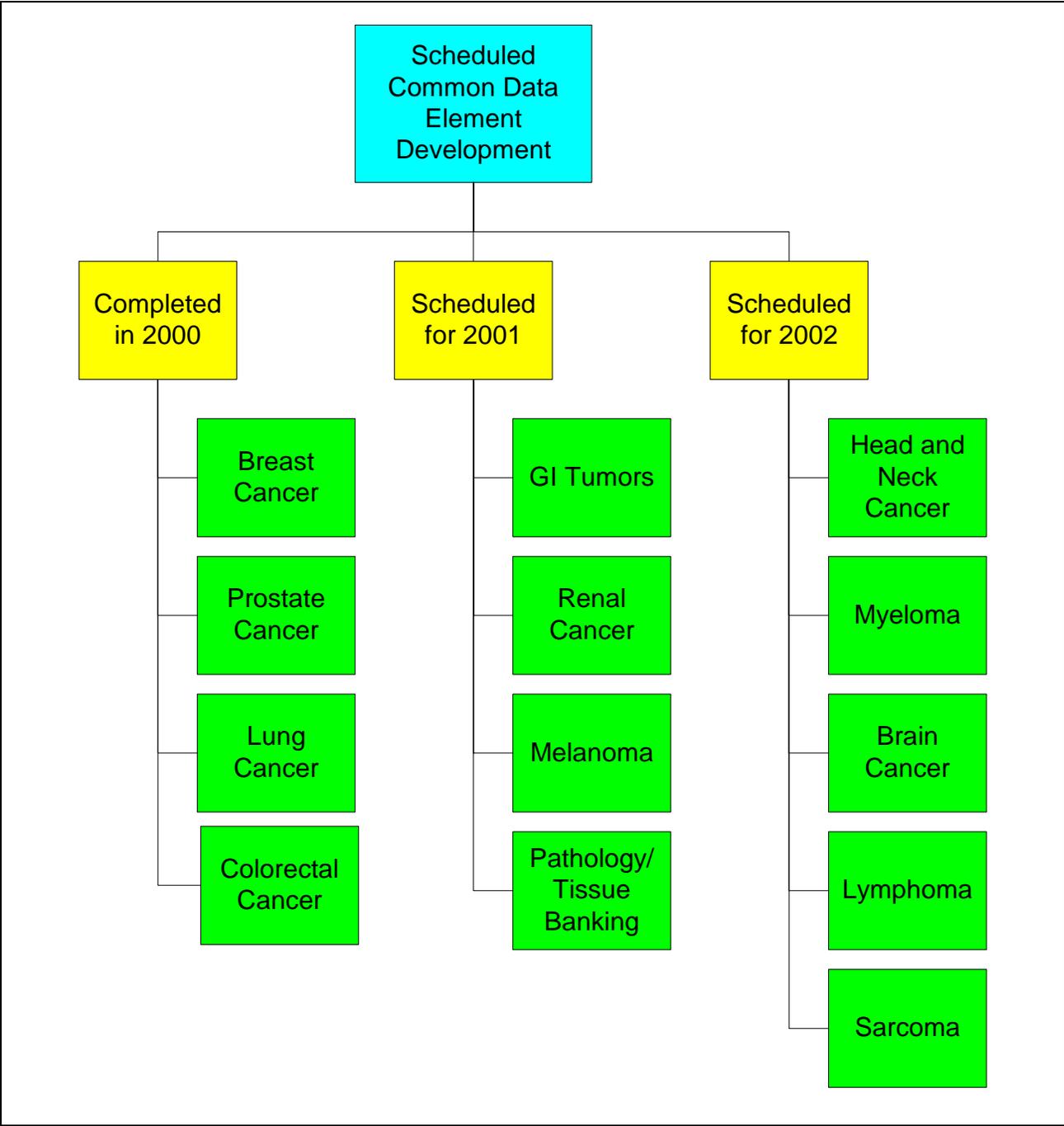


Figure 1: Scheduled Common Data Element Development

The current focus of CDE development is on adult Phase III clinical trials for cancer treatment. Pediatric trials, prevention trials, and Phase I/II trials are not currently within the scope of the CDE Project.

Each common data element is an entity that may be represented in logic that a computer can readily store and manipulate. Characteristics of CDEs include:

- Short CDE name
- Long CDE name (more descriptive than the short name)

- Definition
- Valid values for the CDE (based on standards)
- Instructions for clarification

The Cancer Therapy Evaluation Program (CTEP) at NCI has requested that several cooperative groups develop case report forms in compliance with the existing sets of Common Data Elements. The Radiation Therapy Oncology Group (RTOG) is among those cooperative groups.

RTOG personnel provided CTEP with their case report form information. CTEP staff members then evaluated the degree to which the case report form items complied with the common data elements. The categories of compliance are:

- Exact match: The case report form item and the CDE match word for word.
- Partial match: The case report form item and the CDE are similar but do not match word for word.
- Omission: There is no case report form item that corresponds to the CDE. This is not a problem as long as the cooperative group has no need for the item.
- No match: There is no CDE that corresponds to the case report form item. A new CDE should be created for this item.

CTEP personnel were surprised by the amount of variability in case report form terminology from one cooperative group to the next. RTOG domain experts attributed this variability to the fact that each cooperative group has taken its own approach to protocol development for many years.

Oracle has developed an online repository for CDEs. This online dictionary may be found at the following URL:

http://ciiserver4.nci.nih.gov:85/cde/cde_java.show

Version 1.0 of the CDE Dictionary allows users to browse for CDEs. It includes CDEs for Phase III breast, lung, prostate, and colorectal cancer treatment clinical trials. Version 2.0 of the CDE Dictionary will be released in mid-December 2000. The new version will include updated content, CDE versioning information, a search capability, and content specific to LCBC.

Radiation Therapy Oncology Group Overview

The Radiation Therapy Oncology Group (RTOG) is a multi-institution cooperative group. It was organized in 1968 to perform radiation therapy research and cooperative clinical investigations. RTOG first received National Cancer Institute (NCI) funding in 1971.

RTOG currently participates in more than 30 active clinical trials and accrues about 3,000 patients onto its trials per year. RTOG headquarters and its statistical unit are located at the American College of Radiology offices in Philadelphia, Pennsylvania. The RTOG administrative unit operates from the American College of Radiology headquarters in Reston, Virginia. Figure 2 shows the RTOG organization.

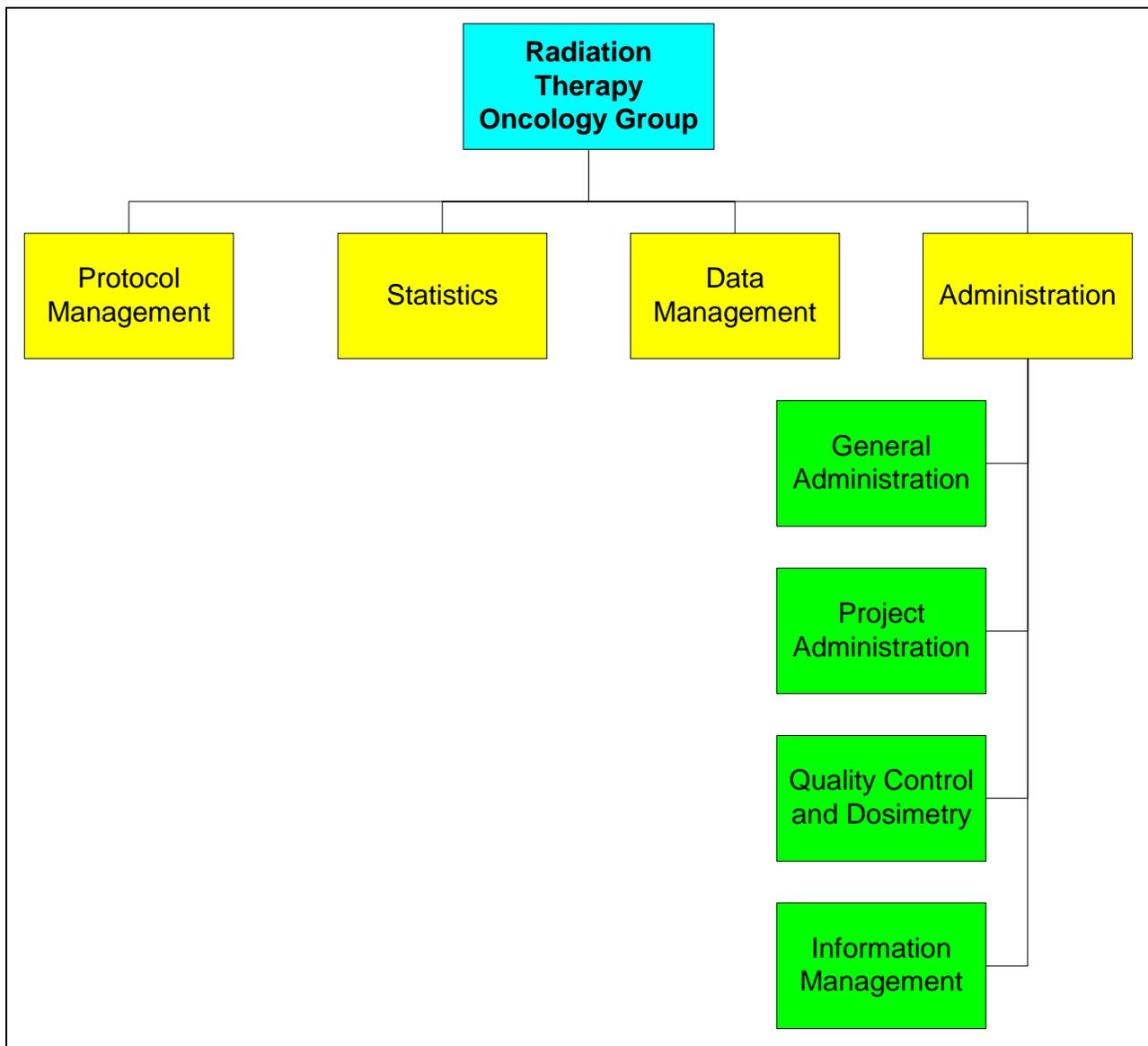


Figure 2: Radiation Therapy Oncology Group Organization

Additional knowledge acquisition would be required to document the tasks and functions of each unit.

RTOG Case Report Form Development Process

A set of case report forms must accompany each clinical trial protocol. The clinicians treating patients on a trial must record and submit all patient information via the case report forms.

Description of the Process

Radiation Therapy Oncology Group (RTOG) creates master case report forms from a data dictionary of over 14,000 elements. The RTOG Data Access and Retrieval Committee (DARC) contains Representatives from each RTOG unit. DARC creates a master case report form for each disease site and treatment modality.

When a Principal Investigator submits a draft protocol, Protocol Managers review the draft. It is then passed to a Data Manager, who pulls the master case report forms appropriate to the protocol. The Data Manager then pulls a set of case report forms from an existing similar protocol. Typically no more than eight or nine forms are created for a protocol. In the view of RTOG personnel, most people will not keep up with more than that number of forms.

The Data Manager and Statistician then discuss analysis elements that must be represented on the case report form. The Data Manager may also need to collect background information to evaluate the information needed for the case report forms.

At this point the Data Manager is ready to revise the case report form content if necessary. The Data Manager may revise existing modules of elements, may create new modules, and may add special instructions to clarify data collection. The Data Manager determines how the modules and instructions should be laid out on each case report form.

Some Data Managers create form content and layouts using MS Word, while others use pen and paper. A Forms Designer translates the case report form content and layout into actual case report form documents using desktop publishing software.

Once the case report forms are drafted, the Data Manager, Statistician, and Principal Investigator must all review and approve the forms. The forms typically undergo three round of review before final approval. The entire case report form development process requires about two to four weeks.

Ideally RTOG personnel would consult the 14,000-element data dictionary of case report form elements at various points throughout this process. In practice, this has not yet become part of the process.

Although certain questions typically in a case report form module, are they not mandatory for every protocol in which the module is used. Most of the questions on a case report form ask for key information that will be analyzed at the close of the study.

There is sometimes value in data analyzing across studies. Such an analysis could compare results for the same agent, or it could compare results across disease sites.

Clinicians in the field are comfortable with the standard case report form templates. They have sometimes asked RTOG to leave unneeded questions on forms and simply cross them out to indicate they are not needed for the study.

Figures 3 and 4 show the RTOG Case Report Form development process.

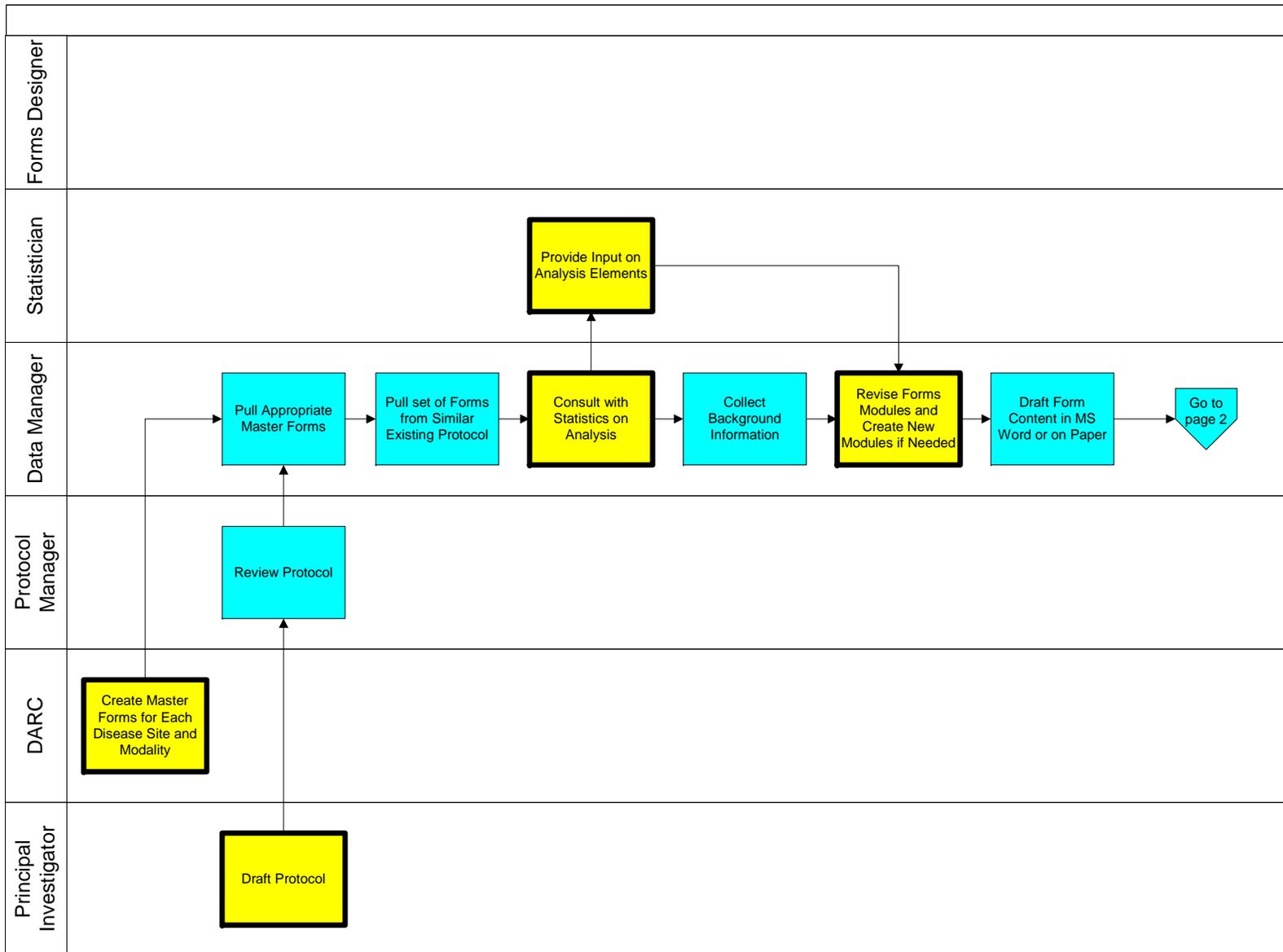


Figure 3: RTOG Case Report Form Development Process - Page 1

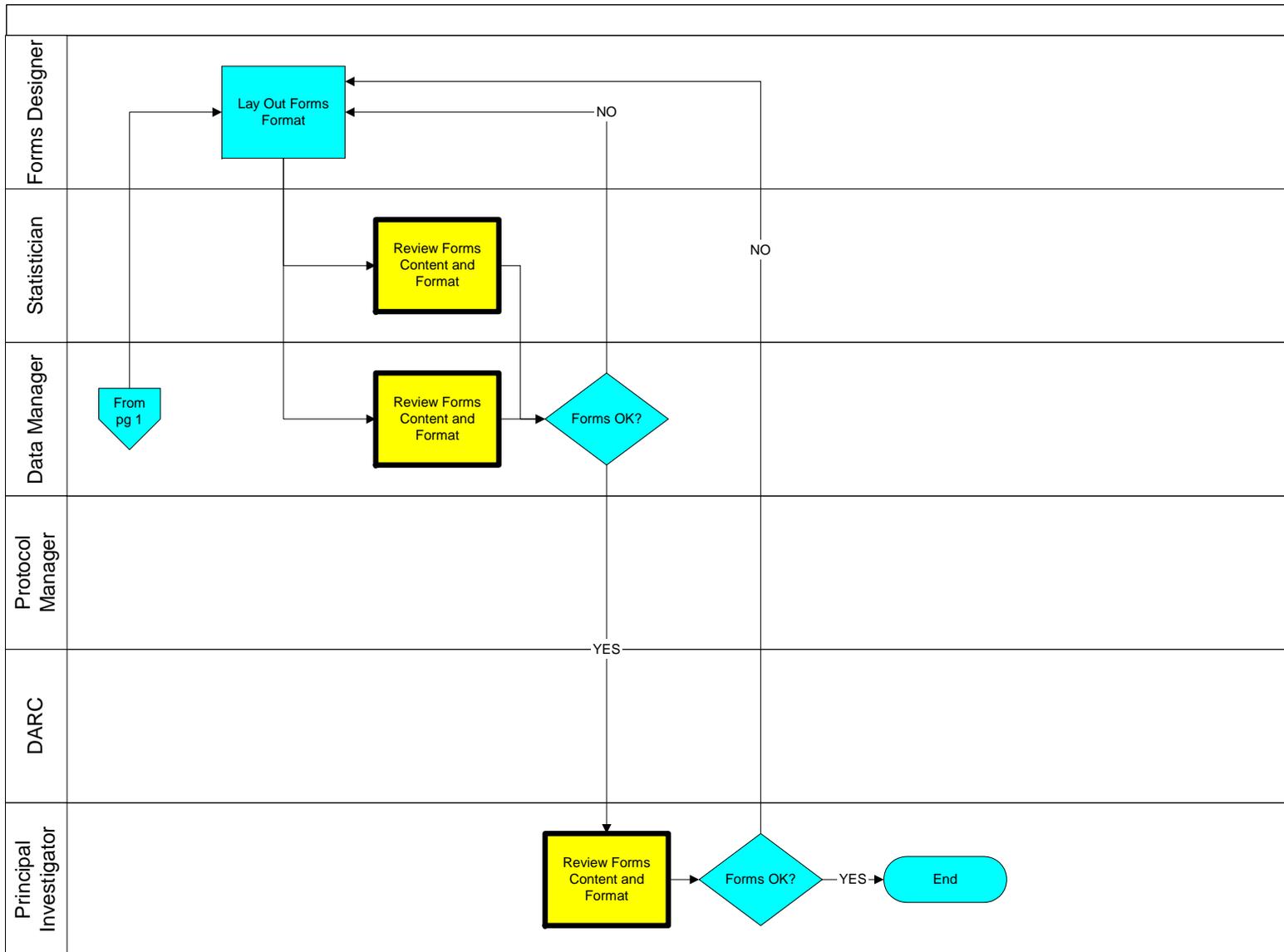


Figure 4: RTOG Case Report Form Development Process - Page 2

The highlighted boxes in Figures 3 and 4 indicate steps in the process that are most likely to be affected by the adoption of Common Data Elements. The step most strongly affected is one of the earliest in the process: “Create Master Forms for Each Disease Site and Modality.” In order to comply with CDE terminology, RTOG would need to review and revise all of its master case report forms so that they conform to CDE wording and valid values. RTOG would also need to suggest new CDEs to cover items for which no CDEs currently exist.

RTOG personnel were uncertain about the process they should follow to suggest new CDEs. The CTEP protocol submission form allows the submitter to identify new CDEs needed for the protocol. However, RTOG personnel need to review CDEs against their master case report form templates. They will not submit protocols as part of that review. CTEP has not yet defined other methods to suggest new CDEs.

Review and Approval of Proposed Common Data Elements

The Cancer Therapy Evaluation Program (CTEP) has defined a process for reviewing and approving new Common Data Elements (CDE). Researchers in the clinical research community may propose new data elements. Members of National Cancer Institute (NCI) disease or special topic committees may also propose new data elements. Once a data element is proposed, review and approval will follow the sequence outlined below:

1. The element is initially designated as a Proposed Data Element.
2. The appropriate disease or special topic committee reviews and may modify the Proposed Data Element.
3. If the committee chair approves, the Proposed Data Element becomes a Draft Data Element.
4. The Draft Data Element is Analyzed, Refined and Approved by an NCI Content Panel.
5. An NCI Harmonization Group validates the Content Panel approval and resolves any issues that may arise.
6. Once the Draft Data Element has been approved by both the Content Panel and the Harmonization Group, it becomes a Common Data Element.
7. Approved Common Data Elements are published as such in the CDE dictionary.

A diagram on page 8 of the attached CDE presentation shows this review and approval process.

RTOG Feedback

RTOG staff members provided feedback on a wide variety of topics during the knowledge acquisition session. A summary of the RTOG feedback follows.

Feedback on the Common Data Elements Process

- RTOG personnel have been trying to find CDEs to see how closely they match RTOG terms. RTOG personnel have been unable to find some of the terms they use. Radiation-specific CDE terms are missing, but RTOG staff are unclear on how to propose new CDEs. They have been hesitant to propose new CDEs.

CTEP staff wants new CDE submissions to come through CTEP. The protocol submission worksheet contains a space for new CDEs that may be used in the protocol. However, there were no instructions in the CDE Dictionary v1.0 on how to submit new CDEs. CTEP is still working out the process for submitting new CDEs.

- When evaluating CDEs, RTOG personnel have been evaluating whether they match RTOG term content. If the meaning was the same for both terms, they did not worry about whether the wording was exactly the same. Some of these people were on the original CDE development committees, and it was not clear to them that RTOG should use exactly the same term as the CDE.
- RTOG personnel maintained that although forms standardization is desirable, people in the field want and need variation.
- RTOG personnel have been trying to match their case report form data elements to the Common Data Elements. CTEP staff clarified that they want case report forms to use not only common data elements but also standard modules as much as possible. RTOG has not been trying to match its forms modules to standard modules.
- In comparing RTOG with CDEs, RTOG personnel thought they could only search for CDEs in the area specific to the disease site. CTEP staff clarified that it is all right to look in other disease site areas for CDEs that will work.
- When CTEP evaluated RTOG's comparison of its terms to the CDEs, CTEP personnel sent feedback via spreadsheet. RTOG staff felt it would have been helpful if CTEP had sent back at least one page with a sample of what was expected. RTOG staff worked from what they thought were example forms, but they still got corrections back from CTEP. Also, RTOG explained that they wanted feedback on paper rather than on spreadsheets.
- CTEP personnel explained that it is acceptable use standard modules on forms other than the form on which the module is usually found. RTOG staff asked that if a term is present on another RTOG form, then CTEP should not classify the term as "omitted." RTOG staff also asked whether another forms submission method is needed to clarify which terms are on which forms.

- The RTOG protocol manual contains RTOG's standard format for protocols. However, protocol authors frequently do not adhere to the standard format. The protocol is as individual as the person writing or amending it. RTOG also finds terminology within individual protocols to be inconsistent. For example, some protocol authors will not upgrade some of the lab test names.
- RTOG data managers are accustomed to putting instructions in the case report form question itself for clarity. They were uncertain how much flexibility they have for this while still remaining consistent with CDEs? CTEP staff indicated that there is a section for instructions in each CDE.
- RTOG sometimes receives supporting information and comments that are not on forms. Most Quality Control/Disometry data are not on forms. These data frequently consist of images with associated reports (e.g., cat scan plus report, MRI plus report, etc.). Quality Control/Disometry reviews and fills out an internal form with containing results for these items. The RTOG database contains information on these and other internal forms.

Feedback on the Common Data Elements Dictionary Browser

- Many RTOG staff members reported that they have not visited the CDE website.
- Some RTOG personnel felt that the CDE browser version 1.0 was not user friendly at all. When they got in CDE website, they got very frustrated. However, they thought that version 2.0 looked more user friendly.
- RTOG users were not yet familiar with CDE sub-headings in version 1.0 of the browser. This made it very difficult to find things. They felt that the search string function found in version 2.0 will help with this major problem.
- RTOG users would like to search for CDEs both by category search and by keyword search. They feel the more search options the better. Search questions would include:
 1. Is the term there among the CDEs?
 2. If the term is there, what are the related items that can also be considered? The relationship could be based on form placement/grouping, or it could be conceptual. For example, if the user is looking for a special way to ask about the toxicity of a drug, he or she would like to see all CDEs related to toxicity. Would like to search for exact match, string, and concept
- Version 2.0 of the CDE browser has only been tested with Netscape Navigator in Windows environment. Some functions will not work properly when using Internet Explorer. However, most RTOG personnel use Internet Explorer. Netscape Navigator is not prohibited at RTOG, so a temporary solution is to load Netscape Navigator for RTOG personnel who need to use the CDE browser. None of the RTOG personnel use Macs, but there may be Mac users out in the field. RTOG users felt that browser independence is more critical than platform independence.

- Some RTOG users want to print the CDE Dictionary, but none have been able to do this. It is possible to move the data to Excel, but RTOG users do not like to download to Excel.
- RTOG personnel felt that the glossary to keep track of acronyms and other terms is a very nice feature in the CDE browser.
- When asked, RTOG users felt it would be helpful to have access to international systems of terms. However, they felt it would be distracting to include these as part of the main set of CDEs. They suggested that access to international terms could be provided via a link or an advanced search capability. They agreed that it is forward-thinking to plan now for international exchange of data.
- Version 2.0 of the CDE browser offers standard CDE Data Forms. RTOG personnel asked whether cooperative groups are required to use these forms. CTEP would prefer that cooperative groups use the standard forms or something similar, but groups may create their own forms as long as they use the CDEs to do so.
- RTOG users would like to be able to flag a CDE in some way whenever they use it in a protocol.

Feedback on Other Common Data Element-Related Tools

- RTOG staff wondered whether downloadable case report forms could be linked to a protocol authoring tool. They felt it would be good for such a tool to prompt the user as to what case report forms are needed.
- RTOG personnel wanted a tool of some kind that would create case report forms!
- The Oracle Discoverer tool would allow users to generate reports showing many data elements at once. RTOG users felt this could be a good method to see drafted and proposed elements, and they felt there was some value to this.
- RTOG personnel would like to be able to track CDEs in a particular protocol. Once they have created a case report form, they would like to be able to track which CDEs are in it, and which elements represent new CDEs that should be proposed.

RTOG Technology Information

RTOG maintains a production database for active protocols and another database for terminated protocols. RTOG stores its case report form data dictionary in the production database, which is a Microsoft SQL Server 7 database. Many of the data elements in this dictionary represent questions that can appear on case report forms.

This RTOG data dictionary contains about 14,000 data elements and about 5,000 response values. The same response values may be used by more than one data element. For example, the response values “Yes” and “No” are used by many different data elements.

The RTOG data dictionary is organized by disease site. Within each disease site blocks such as staging and patient characteristics appear. RTOG has developed a method for finding the standard case report form questions used for a particular situation. The protocol details will drive which questions will be included on a case report form.

All RTOG software has been built in-house. RTOG Initially had six developers when implementing its databases. Four developers now support the database and its users. Database changes are not made often.

The Common Data Elements have not been added to RTOG dictionary, nor have they been mapped directly to elements in the RTOG dictionary.