

Knowledge Acquisition Session Report NCI – DCP Protocol Information Office

Session Date: 4/11/00

Time: 2:00 p.m. – 4:00 p.m.

Session Topic: PIO Information Processes and Procedures

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Organization: Protocol Information Office, NCI Division of Cancer Prevention

Session Location: Rockville, MD

Type of Session:

Interview Task Analysis Scenario Analysis
 Concept Analysis Observation Structured Interview
 Other:

Documentation: KA Session Report , Updated Evaluate Documents process map (April 12, 2000), Updated System Requirements list (April 12, 2000), CCOP Administrative Database Schema.

General Topic Area

Division of Cancer Prevention – Protocol Information Office: Information Processes and Procedures.

Session Goals

To elicit information related to DCP-PIO processes, system requirements, and existing data sources.

Report Summary

This report focuses on PIO (Protocol Information Office) processes and information system requirements. In the KA session, the PIO validated a model of the steps common to the two distinct clinical trial processes managed in the Division of Cancer Prevention (DCP). These processes include daily PIO responses to protocol questions from within DCP. PIO asked for a web-based query tool that would allow users to answer protocol-related questions. The Community Clinical Oncology Program (CCOP) supports these clinical trial processes by providing the PIO with CCOP funding and patient accrual information. PIO also validated the Evaluate Documents process map, which depicts protocol-related tasks as they relate to the new system. Oracle plans to provide a web-based user interface for the new system. NCI Office of Informatics servers will house the system. Domain experts requested that the system track studies turned down by CCOP so that patterns of decision making in the cancer centers can be tracked. PIO personnel also requested the incorporation of existing data into the new system. Two of those existing data sources are Microsoft Access databases created and maintained by Information Management Systems (IMS), and another is the Clinical Chemoprevention Study Associates (CCSA) database.

DCP Processes

Major Steps of a DCP Study

The Protocol Information Office (PIO) reviewed and validated a model of the eight major steps that are common to both the Community Clinical Oncology Program (CCOP) processes and the Contracts processes. The model is depicted in Figure 1.

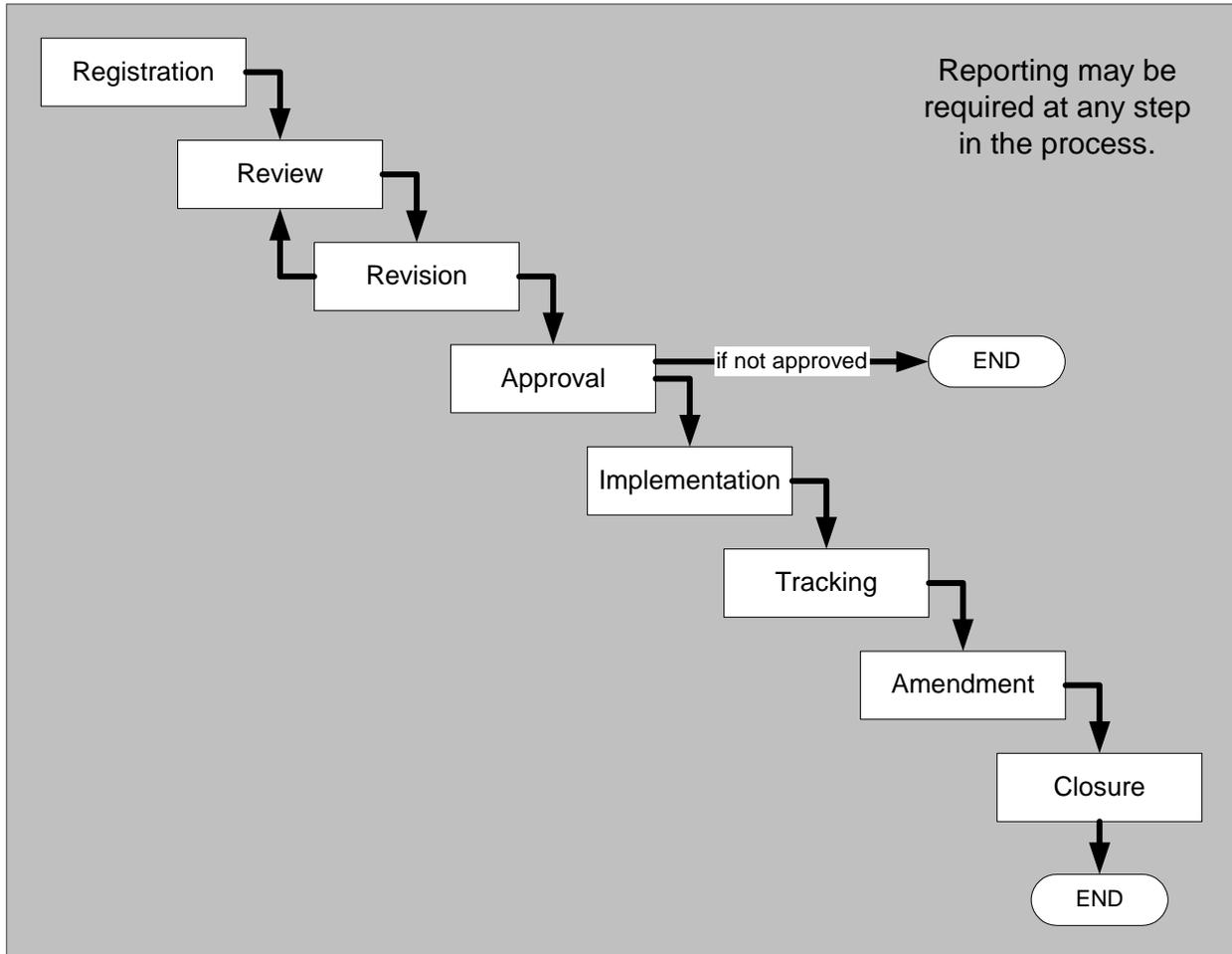


Figure 1: Major Steps of a DCP Study

PIO personnel made modifications to the process model to more accurately describe the DCP processes. First, the steps of review and revision may repeat one another any number of times before moving on to Approval. Second, the process ends if the study is not approved. Finally, PIO may be required to report on the status of a study at any point in the process.

The Evaluate Documents Process Map

During the KA session, PIO reviewed and validated a process map that details the new system's procedures for working with documents. Oracle has named this the Evaluate Documents process

map. Oracle made the following modifications to the process map based on input obtained during the KA session:

- For documents inappropriate for a Division of Cancer Prevention (DCP) study, the Protocol Specialist forwards the document to Cancer Therapy Evaluation Program (CTEP).
- The system must consider a variety of issues to determine whether to forward a document to Clinical Chemoprevention Study Associates (CCS).
- DCP uses the terms “Agent Expert” and “Medical Monitor” rather than “Drug Monitor” and “Disease Monitor”.
- CCS tracks IRB approvals for Contract studies, while CCOP annually tracks IRB approvals for CCOP studies.
- CCS handles all of the FDA functions such as submitting protocols to the FDA for approval and preparing/correcting the FDA document packet.
- PIO personnel highlighted the following information as significant to Contracts Project Officers:
 - Whether Protocol is the IND filing Protocol
 - Status of the FDA Document packet
 - Whether Protocol or Amendment is new

DCP Internal Queries to the PIO – As Is

The PIO may respond to study-related questions from within the DCP at any point in the steps of a study. The PIO receives two queries a day on average from within the DCP. Program Directors and Project Officers ask most of the questions. Queries are usually submitted via email, phone, or in person.

Most questions focus on the status of a given protocol. The inquirer usually knows the Principal Investigator’s name, the agent, the institution involved, the study organ site, or the project officer’s name. PIO may require anywhere from a couple of minutes to an hour of research to answer a particular question.

DCP Internal Queries to the PIO – To Be

When the new system is implemented, the PIO anticipates they will receive more internal inquiries because of their improved access to information. A web-based query system accessible by Program Directors and Project Officers would free the PIO staff of this time consuming task.

The CCOP Program Analyst's Role in the Process

Cynthia Whitman is a Program Analyst within the Community Clinical Oncology and Prevention Trials Research Group. The Program Analyst manages the flow of administrative and financial clinical study information. Ms. Whitman maintains the CCOP Administrative database. She enters quarterly patient accrual information gathered by the CCOPs into this database. She forwards patient accrual information to PIO personnel to assist them in tracking the progress of studies.

Ms. Whitman also forwards non-DCP related studies to the Cancer Therapy Evaluation Program (CTEP) for review. These studies are usually treatment trials generated by non-cooperative group institutions (i.e., Wake Forest and M.D. Anderson).

In addition, Ms. Whitman tracks the credits awarded in CCOP studies. The DCP uses credits as a form of currency in CCOP studies. The volume of data management involved in a study determines the amount of credits awarded. Credits are awarded in three categories:

1. Treatment Credit
2. Cancer Control Credit
3. Cancer Control Follow-up Credit

Ms. Whitman and the Protocol Review Committees determine how many credits a Prevention and Control study will receive. Then PIO works with the Protocol Review Committees to assign the number of credits awarded to a protocol. Ms. Whitman receives this agreement and enters the information into the CCOP Administrative database.

System Requirements

MoSCoW List

The Protocol Information Office (PIO) reviewed Oracle's prioritized list of the high-level functional and non-functional requirements for the new system. This list prioritized requirements into those the system Must Have, Should Have, Could Have and Won't Have. Lisa Chatterjee emphasized this as a prioritization tool.

Lisa Chatterjee modified the MoSCoW list based on PIO's input. The table below shows modifications as well as notes about individual items. The changes are reflected in the April 12 version of the MoSCoW list.

Changes and Notes for the April 10, 2000 MoSCoW List	
Item	Changes/Notes
<u>Must Have</u>	
ID 10: Enable complete abstraction of Concept/Protocol which includes abstraction of following elements: <ul style="list-style-type: none"> • General Information like Study Types, Eligibility Criteria • Study Participants • Study Agents, INDs, and IND Holders • Study Diseases • Study Therapies • Study Funding • Study Sub-groups • Study Accruals • Comments • Milestones 	<ul style="list-style-type: none"> • Change: Study Accruals should include both planned and actual • Note: Linda Parreco would like to capture both race and gender of accruals • Note: Linda Parreco is willing to forego the abstraction of Study Sub-groups if that frees resources for other requirements
ID 60: Standardize decision-making processes for approval/disapproval. This will be accomplished using checklists.	Note: Defining the business rules makes this a complex requirement.
ID 80: Provide clarity with CTEP around definition of cancer prevention, control.	Note: DCP and CTEP are in the process of defining the end points that will clarify this.
<u>Should Have</u>	
ID 180: Provide tracking of FDA submissions.	Change: Could Have: Provide tracking of FDA submissions. This is currently done by CCS. Explore mechanisms for CCS to enter this data into the DCP system.
<u>Could Have</u>	
ID 210: Send updates to PDQ	Change: Won't Have
ID 220: Web-based FAQs about concept and protocol development and submission process.	Note: It may be a better for internal DCP resources to address this requirement.
ID 240: Tools to compose concept/protocol documents	Note: There was discussion about moving this item to the Won't Have category, but it was not moved.
<u>Won't Have</u>	
ID 290: Web-based Investigator's Handbook	Note: It may be a better for internal DCP resources to address this requirement. An Investigator's Handbook currently exists on the CTEP website.

Changes and Notes for the April 10, 2000 MoSCoW List (continued)	
Item	Changes/Notes
Won't Have (continued)	
ID 300: Web-based RFA forms and tables	Note: It may be a better for internal DCP resources to address this requirement.
ID 310: System Calendar	Note: There may be off-the-shelf software that will meet this need.

During the discussion, Lisa Chatterjee clarified that the new system would have a web-based user interface, would be an Oracle database, and would likely be stored on an NCI Office of Informatics server.

Transient Studies

Occasionally, another Division within the National Cancer Institute will approve a study previously rejected by CCOP. Domain experts stated that tracking these studies would highlight patterns of decision-making at the cancer centers.

Existing Data Sources

The Protocol Information Office (PIO) primarily uses information stored in three existing data sources: the Protocol Review System (PIO refers to this as the IMS database), the CCOP Administrative Database, and the CCS Database.

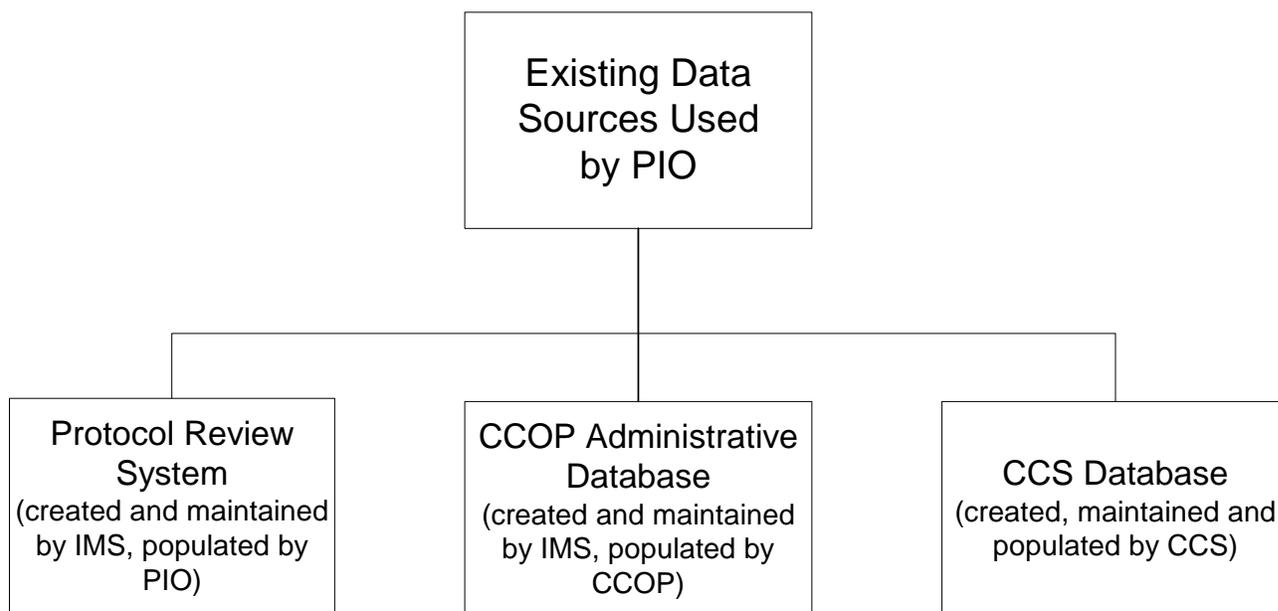


Figure 2: Existing Data Sources Used by PIO

Information Management Systems (IMS) built and maintains the Protocol Review System and the CCOP Administrative Database. Clinical Chemoprevention Study Associates (CCS) built, maintains and populates the CCS database. More KA is needed to determine whether the data contained in these databases overlaps the data in the Cancer Therapy Evaluation Program (CTEP) Protocol Authorization and Tracking System (PATS).

Protocol Review System (referred to as IMS database by PIO)

The Protocol Review System provides protocol review information related to Community Clinical Oncology Program (CCOP) studies. PIO uses this Microsoft Access database to perform data maintenance and reporting on CCOP studies.

Data Maintenance Types

- Cancer Control
- Special Cancer Control
- CTEP
- Addresses

Report Types

- Reports
- Letters
- Frequency Tables

PIO personnel will obtain a copy of this database schema.

CCOP Organizations

The CCOP Administrative Database contains CCOP administrative and funding information. To put the role of this database into context, a brief explanation of the CCOP organizations follows.

The Community Clinical Oncology Program is designed to conduct cancer research in community settings, to improve clinical oncology in community settings, and to coordinate community-based oncology with NCI cancer research. CCOP includes several types of organizations. Figure 3 shows the CCOP organizations, their definitions and their roles.

The Community Clinical Oncology Program (CCOP)

- The overall program designed to:
- conduct cancer research in communities
 - improve clinical oncology in communities
 - coordinate community-based oncology with NCI cancer research

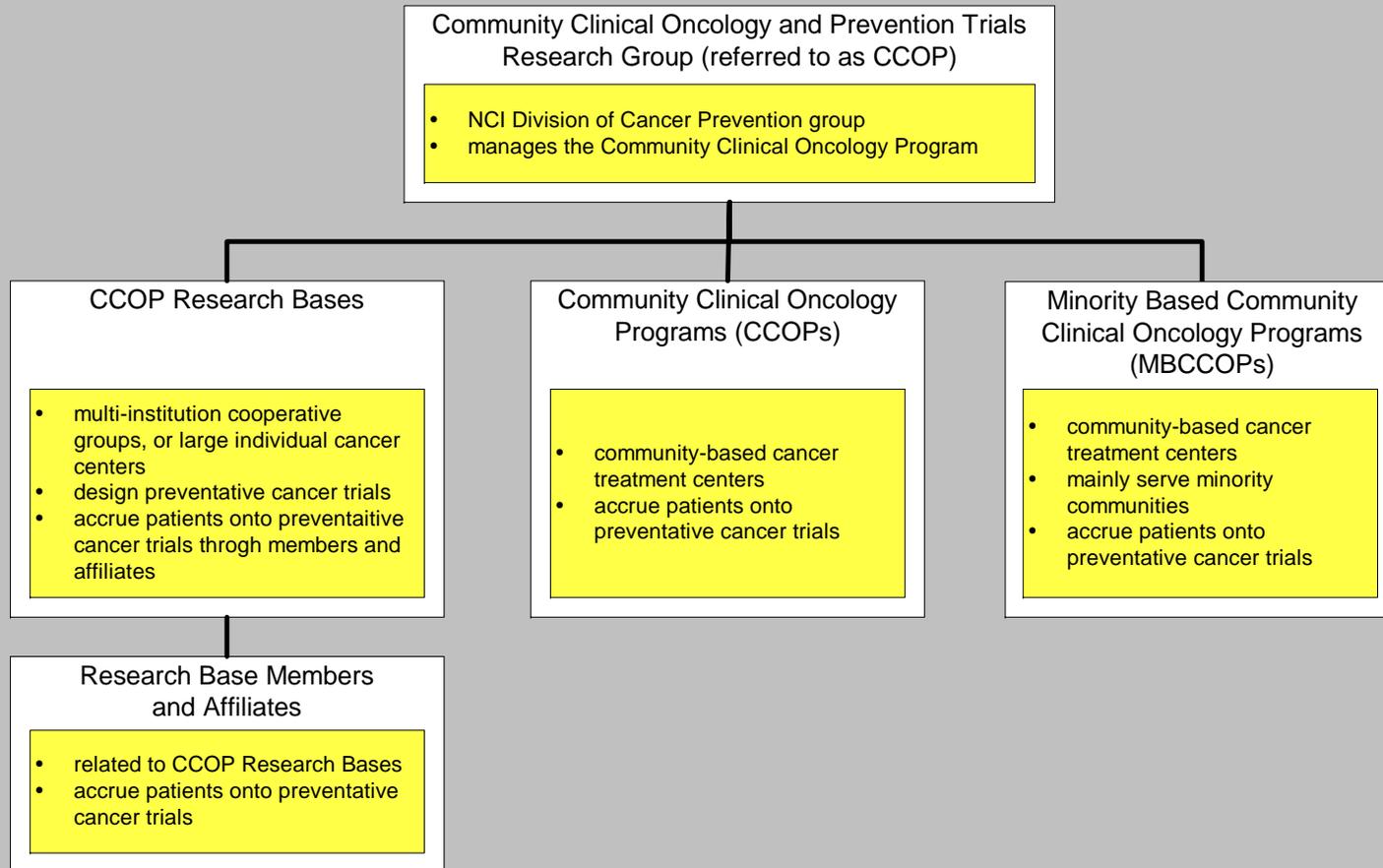


Figure 3: Components of the Community Clinical Oncology Program

Community Clinical Oncology Prevention Trials Research Group

The Community Clinical Oncology Prevention Trials Research Group manages the Community Clinical Oncology Program. It is a group within the NCI's Division of Cancer Prevention, and it is often referred to as CCOP.

CCOP Research Bases

CCOP Research Bases are either multi-institution cooperative groups (i.e., Southwest Oncology Group) or large individual cancer centers (i.e., M.D. Anderson Cancer Center). These organizations design clinical trials for cancer prevention. They also may accrue patients onto trials themselves (if they are cancer centers) or through their members and affiliates.

Research Base Members and Affiliates

The cancer center members and affiliates of the multi-institution Research Bases accrue patients onto CCOP-sponsored preventative cancer trials.

Regular Community Clinical Oncology Programs

Regular Community Clinical Oncology Programs (CCOPs) accrue patients onto CCOP-sponsored preventative clinical trials. These are community-based cancer centers that have joined the overall CCOP program.

Minority Based Community Clinical Oncology Programs

Minority Based Community Clinical Oncology Programs serve minority communities and accrue patients onto CCOP-sponsored preventative clinical trials. These are minority community-based cancer treatment centers that have joined the overall CCOP program.

CCOP Administrative Database

The CCOP Administrative Database provides information related to CCOP protocol funding and administration. The CCOP Program Analyst (Cynthia Whitman) populates this database via a disc sent quarterly from the CCOP organizations.

The CCOP Administrative Database stores administrative information related to CCOP studies and CCOP organizations:

- Name of organization
- Name of clinical trial
- Name of Principal Investigator
- Affiliates and components that make up a Research Base
- Patient accrual information by protocol and by organization

The database also houses information about credits awarded to CCOP protocols. Ms. Whitman crosschecks the data with the PATS system to ensure accurate reporting. During the KA session, Ms. Whitman provided the schema of this database.

CCS Database

Clinical Chemoprevention Study Associates (CCS) created, maintains and populates a database that stores protocol administration data related to contracts, grants, and FDA regulatory issues. PIO identified this data as being critical to the new system, but PIO is not able to access this information directly. Donya Bhageri serves as liaison between CCSA and the DCP PIO.

PIO Head Linda Parreco will conduct a site visit to CCS during the week of April 17, 2000. She will attempt to obtain information about the CCS database, including the database schema.

Entries for Domain Dictionary

Agent Expert: Performs a function similar to a Drug Monitor in CTEP processes. Additional KA needed.

CCOP Research Base: An individual cancer center or a multi-institution cooperative group that develops preventative cancer trials for the Division of Cancer Prevention's Community Clinical Oncology Program. The Research Base may also accrue patients for those trials themselves (if a cancer center) or through members and affiliates (if a cooperative group).

CDUS (Clinical Data Update System): CTEP database designed to replace all monitoring methods except CTMS monitored Phase I studies.

Credits: A credit is a form of currency used within the DCP for CCOP studies. Credits are commensurate with the amount of data management involved in a study. There are three types of credits:

1. Treatment Credit
2. Cancer Control Credit
3. Cancer Control Follow-up Credit

MBCCOP: Minority Based Community Clinical Oncology Program. A community-based cancer treatment center that serves a minority community and is part of the Division of Cancer Prevention's Community Clinical Oncology Program.

Medical Monitor: Performs a function similar to a Disease Monitor in the CTEP process. Additional KA needed.

MoSCoW List: An acronym used to represent the categorization of a requirements list: Must Have, Should Have, Could Have, and Won't Have.

Program Analyst: A position in the Chemopreventive Agent Development Research Group of the Division of Cancer Prevention at the NCI. The Program Analyst manages the flow of administrative and financial clinical study information.

Protocol Review System: A Microsoft Access database that provides protocol review information related to Community Clinical Oncology Program studies to the Division of Cancer Prevention Protocol Information Office. PIO uses this database to perform data maintenance and reporting on CCOP studies.

RFA: Additional KA needed.