C3PR Vision and Scope

Contents

Introduction

Background

The Cancer Central Clinical Participant Registry (C3PR) is a web-based application used for end-to-end registration of patients to clinical trials. This includes capturing the consent signed date, eligibility criteria, stratification, randomization, and screening. Clinical workflows are enabled by both subject- and study-centric views into the registration process. C3PR can be run in a standalone mode where study definitions, investigators, study personnel, and sites are entered into the system, or C3PR can be run in an integrated mode with the caBIG Clinical Trials Suite (caBIG Suite). C3PR also enables multi-site clinical trials where registration information is entered locally at affiliate sites and the registration is completed by call-out to the coordinating site.

Throughout the development of C3PR, a number of elaborator and adopter sites are actively being engaged to help define requirements and test the application. Our primary elaborators include Duke, Wake Forest, Mayo, Westat, CALGB, UAMS, Baylor College of Medicine, CCR, and the Coalition of Cooperative Groups. Our primary adopters include Duke, Georgetown, Mayo, Baylor College of Medicine, UAMS and Wake Forest with engagement of CCR and CALGB.

C3PR release 1 was developed by Nortel Solutions and released in 2006. Release 2 was developed by Duke Cancer Center in collaboration with SemanticBits, LLC and was released in March, 2008. Version 2.5 was released in September 2008, version 2.5.5 in March 2009, version 2.8 in December 2009, version 2.9 in March 2010, version 2.9.1 (Suite release 2.2.) in September 2010. We are currently in the next phase of

development with releases slated for May, 2011, when c3pr version 2.9.3 will be released along with the Suite version 2.3.

Position

Vision Statement

The vision of the C3PR project is to extend the existing system and underlying database to enable additional capability for the capture and management of:

- Clinical trials participant registration.
- Protocol information.
- Clinical trials registration information across different clinical studies for supporting multi-site trials.
- Information on referring physicians, research sites, and organizations.
- Timely access to information for clinical research staff and physicians.
- Integration with NCI Enterprise services (formerly known as COPPA services)
- Creating Service Oriented Architecture (SOA) services for key c3pr functionalities (Subject Management, Subject Registration, Randomization) to enable integration with external applications and services.

Current functionality includes:

- Management of Registrations, Subjects, Studies, Investigators, Personnel, and Organizations.
- Registration of Subject to Studies, including capturing consent signed date, eligibility, stratification, and randomization.
- Study Amendment.
- System integration through CTMS Suite, APIs, and XML upload/download.
- Secure access to functionality, including authentication, role-based authorization, and grid-based.
- Logging and Auditing through database and application container functionality.
- Exception handling.
- Multi-site support for study definition and registration.

The focus of version 2.9.3 will be to:

- Enhance C3PR to close the gap between current features and what the community needs/wants for adoption of C3PR
- Integrate C3PR with NCI Enterprise Services
- Decompose C3PR into a set of capabilities and services to move towards a pure Service Oriented Architecture (SOA)
- Enhance C3PR to meet CTMS Suite use cases and workflows
- Support previous releases of C3PR

Use cases that we will apply include, but are not limited to:

- NCI Enterprise Services (COPPA) Integration
- Companion Protocols
- Groups of Organizations
- Reporting (Summary 3, Summary 4)
- Hosted Mode
- Basic Science Eligibility Criteria
- Custom Fields
- OPEN Integration
- Call-out Randomization
- RSS Integration
- Legacy Application Integration
- Study Level Authorization
- Groups of Study Personnel
- Eligibility waiver
- Subject Demographic snapshot
- Consent Form Enhancement
- Re-consent
- Consent Withdrawal

Problem Statement

Information that is accessible in a timely manner and clearly understandable for cancer clinical research trials is difficult to capture and present to the multitude of stakeholders that require it: cancer patients and their families struggling with treatment options for their disease, physicians seeking information and trials for their patient community, and researchers who seek technical and scientific knowledge on current trials and historical trial outcomes. Patients who have been diagnosed with cancer and want to understand treatment options that are available to them are confused and frustrated with highly scientific and technical information on clinical trials that do not specifically address their questions. Physicians, who want to help their patients understand their disease and gain access to current trials and therapy options, find it difficult to locate enough information in a user-friendly, timely manner. This prohibits the physician from providing their patients with specific trial options and newly approved therapies. Researchers who conduct clinical trials themselves and often require comparative data for dosing, measurable clinical trial end-points, and model validation encounter difficulty accessing aggregate clinical trials data. This, in turn, limits their ability to advance the science. The development and deployment of a central participant registry, containing requisite information on clinical trials, will provide all groups (patients and their families, community physicians, as well as cancer researchers) to meet their diverse set of informational and data needs.

The caBIG community will be the primary stakeholder for Release 3 of the C3PR application. The below table provides more details:

Stakeholders	**Perspective**

caBIG Community • CTMS workspace • Tissue Banking Workspace • Imaging Workspace • Entire Community	Integration with existing caBIG tools to provide basic participant information between systems and reduce manual entry
Patients/ Patient Advocates	Treatment recipient and beneficiary
Clinical Trial Sponsors • National Cancer Institute; specifically the CCR • NCI funded cancer Cooperative Groups • Other NIH Institutes • Pharmaceutical/ Biotechnology Companies	Funds studies • Holds IND for the study • Responsible to FDA for proper conduct and reporting of the study
Regulatory Agencies • U.S. Food and Drug Administration • NIH Office of Human Research Protection • Data Safety and Monitoring Boards • Institutional Review Boards	• Responsible for participant safety • Regulatory compliance

The table below considers in-scope system end-users:

Type of Users/ Stakeholders	**Role**
Clinical research site personnel • Principal Investigator and other investigators • Research Nurses • Clinical study coordinators • Clinical data managers	Registers participants on study and verify demographic and medical information
NCI Intramural Divisions and Programs • Center for Cancer Research (CCR)	• Final approvers for registration approval • Read access only to all blank

• Division of Cancer Epidemiology and Genetics (DCEG)
• NCI-sponsored cancer Cooperative Groups
  ○ American College of Surgery Oncology Group (ACOSOG)
  ○ Cancer and Leukemia Group B (CALGB)
  ○ Eastern Cooperative Oncology Group (ECOG)
  ○ Gynecologic Oncology Group (GOG)
  ○ National Cancer Institute of Canada – Clinical Trials Group (NCIC-CTG)
  ○ North Central Cancer Treatment Group (NCCTG)
  ○ National Surgical Breast and Bowel Project (NSABP)
  ○ Radiation Therapy Oncology Group (RTOG)
  ○ Southwestern Oncology Group (SWOG)
• The Cancer Trials Support Unit (CTSU)
• NCI (61) Cancer Centers (NCI CC) information.
	eligibility forms for all studies.
	• Host registration and randomization systems.
	• Provides clinical protocol information.
	• Collects and maintains rosters of institutions, investigators, and clinical research site personnel.

Central Registration Office	• Performs audit and quality assurance step • Provides registration reports to Office of Clinical Director • Manages the implementation of protocol randomizations provided by the NCI Biostatistics section into C3PR.
System Administrators	• Assigns roles and access to match the user's privileges. • Verifies approval for user privileges with Deputy Director of Nursing Affairs.

C3PR Release 2.9.3 Overview

Description

C3PR is a web-based application used to manage participants in cancer clinical trials. Research staff will use C3PR as a participant-centric entry point to clinical trial management systems. C3PR provides a central registry for study participants, and it enables the end-user to access participant-centric information that is stored in multiple clinical trial systems. Participants that can be tracked include patients or potential patients, their guardians, family members, and referring physicians. The system also allows tracking other types of participants such as principal investigators, caregivers, referring physicians, and the users of the system.

Going forward, C3PR Release 2.9.3 system will be based on the founding principles of caBIG, including Open Source, Open Access and Federated. C3PR resolves some key issues regarding participant management. Some key functional requirements include the following examples:

- Tracking participant history, which is especially important if the participant had been involved in multiple studies (at a particular site)
- Caregivers have ready access to participant information related to their participation in studies
- Meeting regulatory requirements related to patient registry
- Information on the eligibility of current study participants for future studies is readily available

C3PR provides functionality to resolve these and other issues related to the need for centralized tracking of clinical trial participant information.

The C3PR Release 2.9.3 system will be caBIG Silver Level compatible, will pursue Gold Level compatibility as appropriate and possible, and will leverage the standardized caCORE SDK and Semantic Integration Workbench tools to enhance any model changes. The model will be harmonized with BRIDG. Furthermore, C3PR Release 3 will leverage the caGrid infrastructure for messaging and security. C3PR will meet caBIG CTMS conformance statements as defined by the Composite Architect Team in alignment with the overall strategy of a Service Oriented Architect (SOA).

Features

The key features of the C3PR Release 2 system are categorized as follows: Studies, Subjects, Registrations, Study Personnel, Investigators, Organizations, Security, and Integrations.

Potential Integration Points with C3PR Release 2.9.3

The following applications present a potential integration point for C3PR Release 2.9.3:

- NCI Enterprise Service (COPPA)
- C3PR-to-C3PR integration for multi-site studies
- Patient Study Calendar
- Firebird
- caMatch
- Tissue Banking Systems
- caAERS
- Lab Hub
- Legacy financial and billing systems
- Clinical Trials Management Systems: specifically C3D and non-caBIG (legacy) systems
- caDSR and EVS Integration
- The CTSU Regulatory Support System (RSS)
- Other CS initiatives: CTOM, BRIDG, caGRID, Velos etc.
- OPEN

The integration of these systems will be explored through the elaboration and construction phases.

Types of Data in C3PR Release 2.9.3

The following data types are expected to be handled by C3PR Release 2.9.3:

- Subject Information
- Registration information
- Investigator information
- Study Personnel information
- Study information
- Organization information

Data exposed through services in the CTMS Suite will be leveraged in place of native handling of data in C3PR.

Related Initiatives

C3PR will leverage various initiatives that are ongoing in the cancer clinical trial community. Some of these initiatives may include:

- caBIG: As with version 2, C3PR Release 2.9.3 will be designed in accordance with caBIG design principles and standards. These standards, including vocabularies, data elements, modular architectures, and programming, and data exchange interfaces will provide C3PR with the maximum power and adaptability to meet the needs of the cancer clinical trials community.

- COPPA: being developed by NCI, COPPA is a set of services for managing Persons, Organizations, Protocol Abstractions, and the Correlations between them. COPPA will be fed data by CTEP (and possibly other sources) to be exposed to the community.
- OPEN: being developed by the CTSU. The OPEN software will perform some of the same functions of C3PR, will share many data sources with C3PR, and will be used by many of the same research sites. C3PR will utilize many of the same metadata standards established in the caDSR and potentially have a similar user interface. In addition, there may be opportunities for exchange of data between the two systems. As both systems mature, there may be synergistic opportunities for development and deployment.
- Cancer Central Clinical Database (C3D): C3D is a clinical trials database that provides a large-scale and efficient Internet-based management system available for use by multiple cancer research centers across the country. All participants' Information entered into C3PR is also stored in C3D.
- caBIG Clinical Trials Management Work Space (CTMS WS): The Clinical Trial Management Systems Workspace is developing a comprehensive set of modular, interoperable, and standards based tools designed to meet the diverse clinical trials management needs of the cancer center community. There are a number of Special Interest Groups (SIGs) with which the C3PR developers will need to regularly collaborate with including the System Interoperability and Harmonization SIG, which is working to create a logical, efficient systems workflow for NCI clinical trial management.
- caMATCH: The program's objective is to match potential participants to clinical trials. Currently caMATCH is a small strategic research project that is in partnership with NCI, UCSF, UC Davis, and several patient advocate organizations. C3PR will integrate with the caMATCH program in order to maximize participant's options in finding clinical trials.
- FAIR/FAIRView: The Family and Individual Registry system (FAIR) is an on-line data entry system containing information on families and individuals for the Genetic Epidemiology Branch and the Clinical Genetics Branch. C3PR will leverage the information contained in this system in order to match participants to genetic-based clinical trials.
- Biomedical Research Integrated Domain Group (BRIDG): The BRIDG model defines standard entities, roles, attributes, and activities for the business processes in standard clinical trials. It can be used as a core data standard for managing the workflow in clinical trials and for generating clinical trial software applications that share the same semantics and thus can exchange data more readily. C3PR will leverage the BRIDG model to establish a standards-based data model, which will help maximize the value of data harvested from source systems.
- Clinical Data Interchange Standards Consortium (CDISC): CDISC has established worldwide industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. C3PR will leverage CDISC standards in order to manage data effectively.