National Cancer Institute

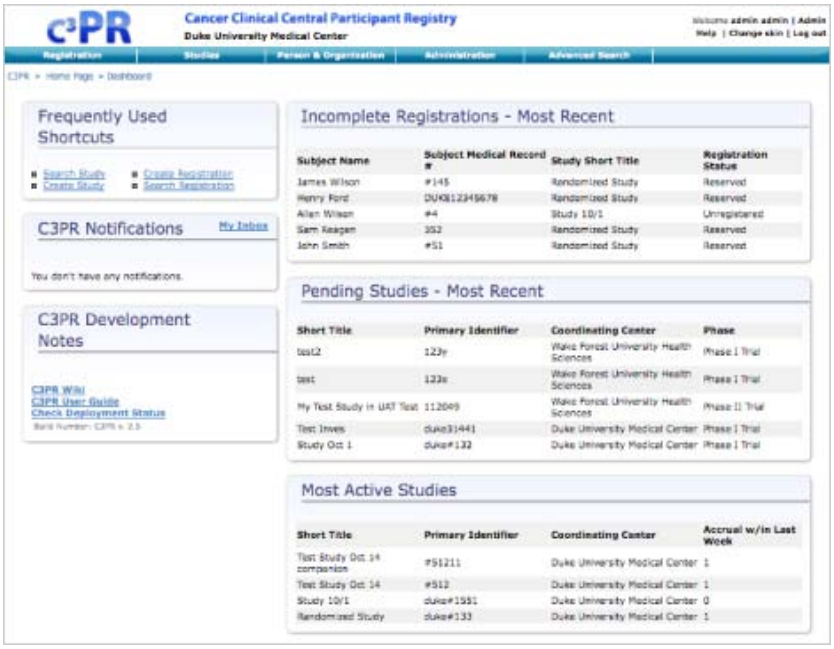
Cancer Central Clinical Participant Registry (C3PR)

Study participant registry

Cancer Central Clinical Participant Registry (C3PR) is a Web-based application for managing clinical trial data across multiple cancer clinical trials and trial sites. It is used to improve clinical trials activation and execution by providing an efficient Web-based clinical trials information management system available for use by multiple cancer research centers, and can support large-scale, geographically dispersed studies. C3PR provides current enrollment statistics and a repository for participant information across studies, sites, systems, and organizations.

Features:

- Manages subject registrations to clinical trials (study open, participant eligible, consent received)
- Stratifies subjects, randomizes to trial arms, registers subjects to companion protocols
- Streamlines registration workflow by provider role-based views to registration data
- Notifies users through email and dashboard of registration events, including accrual thresholds
- Tracks participants across sites and handles single-site and multi-site trials
- Manages study personnel who have access to registry
- Reports data to facilitate generation of NCI Cancer Center Summary 3 and 4 reports
- Facilitates compliance with Federal regulations including 21 CFR Part 11, HIPAA, and Section 508
- Integrates with other clinical systems



C3PR interface

Categories of Use:

- ☐ Biospecimens
- ■ **Clinical Trials Management**
- ☐ Data Analysis & Statistical Tools
- ☐ Data Sharing
- ☐ Genome Annotation
- ☐ Infrastructure
- ☐ Imaging
- ☐ Microarrays
- ☐ Pathways
- ☐ Proteomics
- ☐ Translational Research
- ☐ Vocabularies

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Architecture Overview

- **Application type:** Web-based
- **System requirements:** Minimal system requirements are dependent on the number of patients, protocols, and users planned. Some analysis and testing should be done to establish a performance-based recommendation. Although the application was tested on two servers, it could theoretically be installed on one server with an Internet connection, Database Server with Oracle or Postgres, and an Application Server with Tomcat. Integration of legacy applications in a multi-site setting may require custom enhancement.

Installation and Administration:

- **Skill sets needed:** System administration, database administration, Web application administration
- **Infrastructure needed:** Database (Postgres or Oracle), application container (Tomcat), caGrid (optional, needed for multi-site interactions and deployment as part of the caBIG® Clinical Trials Suite)
- **Long-term administration needs:** Standard database, Web, and system administration

Resources

Tool Overview Page	https://cabig.nci.nih.gov/tools/c3pr#end
Primary Workspace	Clinical Trials Management Systems (CTMS)
CTMS Knowledge Center	https://cabig-kc.nci.nih.gov/CTMS/KC/index.php/Main_Page
CTMS LISTSERVS	https://list.nih.gov/archives/cabig_ctms_cond_sig.html and https://list.nih.gov/archives/cabig_ctms-l.html
caBIG® Tool Inventory	https://cabig.nci.nih.gov/inventory
NCI Center for Bioinformatics Applications Support	ncicb@pop.nci.nih.gov

Key Contributors:

- Duke Comprehensive Cancer Center
- SemanticBits, LLC
- Comprehensive Cancer Center of Wake Forest University
- Mayo Clinic
- Cancer Leukemia Group B (CALGB)
- Coalition of Cooperative Groups
- Lombardi Comprehensive Cancer Center at Georgetown University
- Westat
- Chao Family Comprehensive Cancer Center of University of California Irvine
- NCI Center for Bioinformatics (NCICB)
- NCI Center for Cancer Research (CCR)

Other Clinical Trials Compatibility Framework Components:

- Cancer Adverse Event Reporting System (caAERS)
- Cancer Data Exchange (caXchange)
- LabViewer
- Patient Study Calendar (PSC)
- Cancer Central Clinical Database Connector (C3D Connector)

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