National Cancer Institute

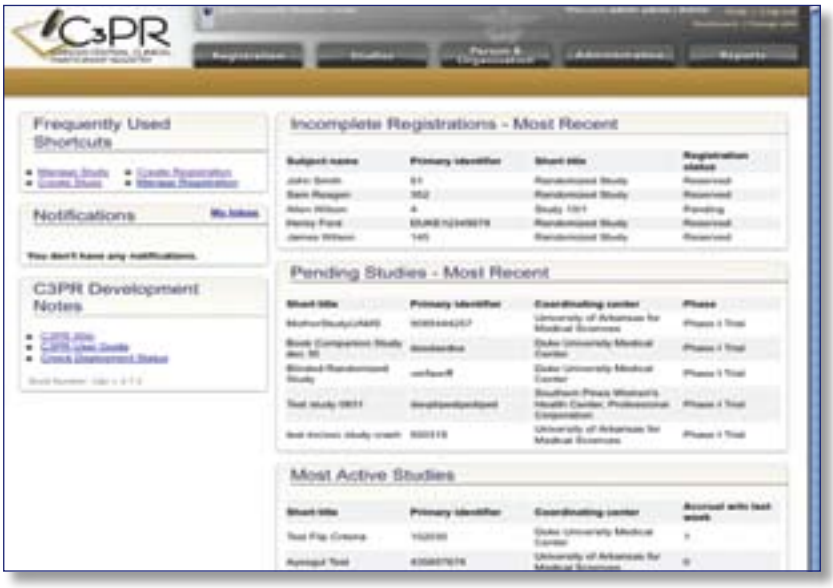
caBIG® Central Clinical Participant Registry (C3PR)

Study Participant Registry

For decades, clinical study sites have used paper and Excel® spreadsheets to track registration information when enrolling patients into clinical trials. Not only does this make the data prone to error and difficult to review, but it also promotes inconsistency and fragmentation, and makes larger-scale, multi-center trials unmanageable.

The caBIG® Central Clinical Participant Registry (C3PR) is an open-source, Web-based system that enables efficient and streamlined registration of participants into clinical trials. It can be used by an individual site or by a multi-institutional organization with geographically dispersed sites. C3PR helps organize and standardize templates for patient registration. Once the informed consent information, inclusion/exclusion criteria, stratification categories, and treatment arms and regimens are entered, reviewed, and approved, the study can be activated for patient accrual. C3PR provides a user-friendly patient registration wizard which walks the study coordinator through the process of enrolling, registering, and randomizing patients. The system tracks screening failures and enrollment statistics and can be configured to alert study personnel when accrual thresholds are met.

C3PR 2.0 has been enhanced to leverage the National Cancer Institute's services-based enterprise architecture. When users select study personnel and participating organizations in C3PR, they are selecting from a curated global list. Through this process, errors and inconsistencies are eliminated, and standards are enforced.



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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Study Participant Registry

caBIG® cancer Biomedical Informatics Grid®

Features

- Features a user-friendly dashboard interface
- Features a workflow-based data entry wizard
- Tracks clinical trial milestones (site initiation, informed consent, eligibility criteria, stratification, and treatment assignment)
- Features an import option for importing study templates
- Includes a companion protocol feature for tracking patients on multiple studies
- Supports protocol amendments, backdated registrations, and re-consent
- Generates e-mail and dashboard user notifications for study events
- Enables error-free study personnel and organization management through the NCI Enterprise "Person" and "Organization" services
- Generates parameterized study and registration reports
- Enables NCI Cancer Centers Branch "Summary 3" Reporting
- Facilitates integration and interoperability with other clinical systems in the caBIG® Clinical Trials Suite

Resources

Tool Overview Page	https://cabig.nci.nih.gov/tools/c3pr
Primary Workspace	Clinical Trials Management Systems (CTMS) https://cabig.nci.nih.gov/workspaces/CTMS/
CTMS Knowledge Center	https://cabig-kc.nci.nih.gov/CTMS/KC
CTMS Forums	https://cabig-kc.nci.nih.gov/CTMS/forums
CTMS LISTSERVS	https://list.nih.gov/archives/cabig_ctms_cond_sig.html https://list.nih.gov/archives/cabig_ctms-l.html
caBIG® Tool Inventory	https://cabig.nci.nih.gov/inventory
caBIG® Support Service Providers	https://cabig.nci.nih.gov/esn/service_providers
NCI Center for Bioinformatics Applications Support	ncicb@pop.nci.nih.gov
caBIG® Product Representative	caBIGproductRep@nih.gov

Technical Specifications

- Database (PostgreSQL or Oracle)
- Application container (Tomcat)
- caGrid (optional, needed for multi-site interactions and deployment as part of the caBIG® Clinical Trials Suite)

Other caBIG® Clinical Trials Suite Components

- caBIG® Adverse Event Reporting System (caAERS)
- caBIG® Clinical Connector
- caBIG® Integration Hub
- caBIG® Lab Viewer
- caBIG® Patient Study Calendar (PSC)

NIH Publication No. 10-7433
Updated December 2009