National Cancer Institute

caBIG® Patient Study Calendar (PSC)

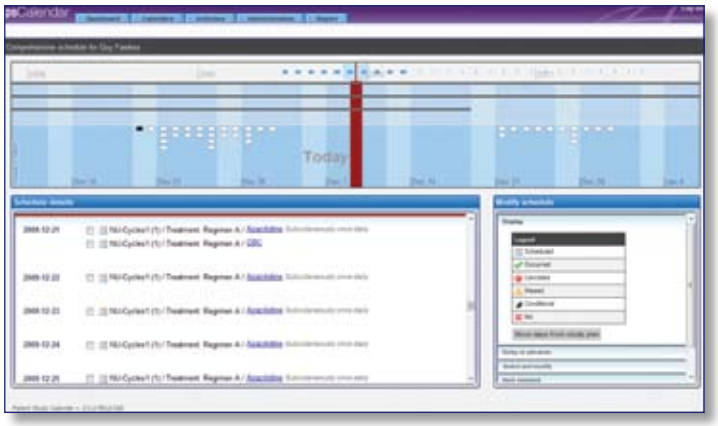
Clinical Study Participant Schedule Management

Managing patient schedules, events, and activities requires acute attention to detail and accuracy to assure that patients receive the best treatment possible and that clinical protocol is followed consistently. In the past, patient study calendar administration has been fragmented and managed through a combination of paper, appointment cards, Microsoft Outlook®, and other proprietary scheduling systems.

The caBIG® Patient Study Calendar (PSC) is an open-source, standards-based software application intended for use by organizations to centrally and consistently manage study participant schedules in clinical trials. PSC is a Web-based application that provides the ability to create, edit, and version study calendar templates to assure treatment consistency and protocol compliance. If PSC is used in conjunction with the caBIG® Clinical Trials Suite, the patient's study calendar can be generated automatically when a patient is registered in the participant registry application, Cancer Central Clinical Participant Registry (C3PR). PSC can also be used as a stand-alone application and patients can be entered manually to generate their study calendar based on the protocol template. Patient coordinators can view patient calendars, export them into Outlook® or iCal®, track patient events and activities as they occur, and reschedule activities as necessary throughout the life cycle of a study. When an event is rescheduled, PSC automatically adjusts the patient's remaining schedule according to the protocol template.

PSC is extremely flexible and accommodates all types of studies (including multi-site studies), and offers the ability to export and share protocol templates with other organizations or sites running separate instances of PSC.

PSC 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 PSC they are selecting from a curated global list. Through this process, errors and inconsistencies are eliminated, and standards are enforced.



PSC 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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Features

- Features a user-friendly dashboard interface
- Creates templates to represent the events and activities within a study
- Manages access to templates within a multi-site environment
- Imports and exports study templates
- Provides future and historical views of patient activities
- Provides aggregate view of all patient activities for a coordinator
- Manages changes to templates based on protocol amendments
- Manages re-consent of patients on a study
- Generates reports using a flexible reporting interface
- Receives Adverse Event notifications from the Adverse Event Reporting System (caAERS) and displays them in the patient calendar
- Provides a link to Lab Viewer from patient calendar
- Receives patient registration from C3PR

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® Central Clinical Participant Registry (C3PR)
- caBIG® Clinical Connector
- caBIG® Integration Hub
- caBIG® Lab Viewer

Resources

Tool Overview Page	https://cabig.nci.nih.gov/tools/PatientStudyCalendar
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
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