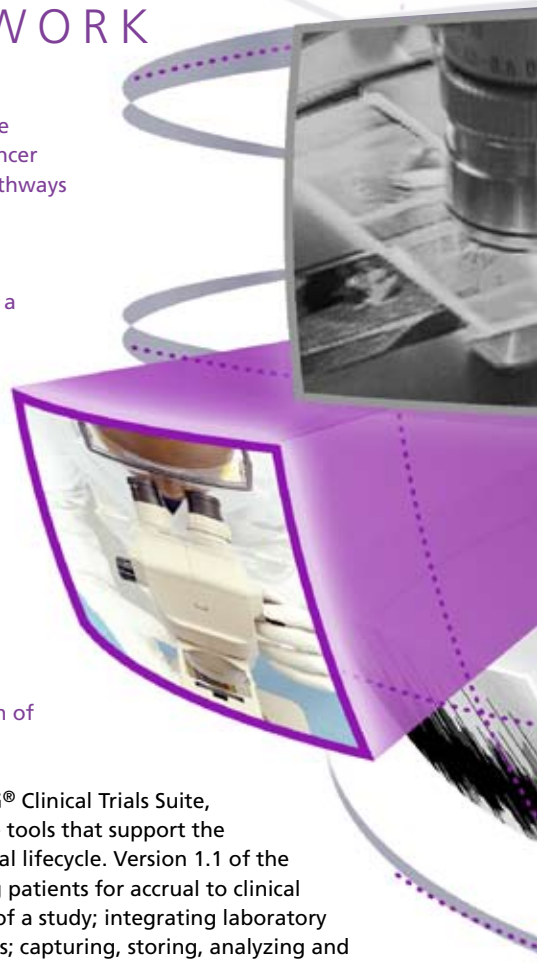
National Cancer Institute

Getting Connected with caBIG®

CLINICAL TRIALS COMPATIBILITY FRAMEWORK



The caBIG® Clinical Trials Compatibility Framework is designed to facilitate electronic clinical research data management and enable the comprehensive sharing and integration of information not only in cancer clinical trials, but in all clinical trials. The Framework provides four pathways to achieving this:

1. Software tools developed by caBIG® (the caBIG® Clinical Trials Suite; see below) that can be adopted either individually or as a bundle to support the execution of trials at one or more sites
2. Guidance to support the adaptation of non-caBIG® systems to be compatible with the caBIG® infrastructure
3. Components to integrate caBIG®-compatible tools (either adopted or adapted) with appropriate caBIG®-compatible Clinical Data Management System (CDMS) selected by the organization
4. Components that facilitate the connection of caBIG® compatible clinical trials systems to the caBIG® grid (caGrid)

Organizations can choose which of these paths, or which combination of these paths, best serves their needs.

The caBIG® Clinical Trials Compatibility Framework contains the caBIG® Clinical Trials Suite, an integrated, stable, and secure collection of interoperable software tools that support the management of study participant information through the clinical trial lifecycle. Version 1.1 of the Suite enables management of tasks such as: screening and registering patients for accrual to clinical trials; scheduling and tracking of patient activities during the course of a study; integrating laboratory results with the patient record; tracking and managing adverse events; capturing, storing, analyzing and routing clinical data in a meaningful manner.

In addition to the software Suite, this bundle also contains components that facilitate the electronic connection of software tools to existing data management systems and to the caBIG® infrastructure. These tools provide security features and access controls to ensure appropriate protection of human subject information and clinical research data.

This document provides an overview of the Clinical Trials Compatibility Framework and its software component, the caBIG® Clinical Trials Suite. It outlines what the Suite is designed to do, its features and benefits, and the requirements for implementing the Suite.

Capabilities and tools included in this bundle

- Adverse event management [Cancer Adverse Event Reporting System (caAERS)]
- Clinical data exchange [Cancer Data Exchange system (caXchange)]
- Study participant calendar [Patient Study Calendar (PSC)]
- Study participant registry [Cancer Central Clinical Participant Registry (C3PR)]
- Virtual clinical data repository [Clinical Trials Object Data System (CTODS)]
- caBIG®-compatible systems architecture [caGrid]
- Integration with caBIG®-compatible clinical data management systems

The Clinical Trials Compatibility Framework is part of the National Cancer Institute's overarching goal to connect the people, institutions, and data in the research community through caBIG®. This collection of tools and capabilities is one of three "bundles" that have been designed to help support and streamline clinical trials, imaging, tissue banking, and integrative cancer research, and to provide the materials needed to join the secure caBIG® data-sharing framework.

Visit https://caBIG.nci.nih.gov/inventory for more detailed information and access to caBIG® resources.

U.S. Department of Health and Human Services

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CLINICAL TRIALS COMPATIBILITY FRAMEWORK

Suite Tools	Description	Benefits
Cancer Adverse Event Reporting System (caAERS)	Enables capture and management, and reporting of adverse events that occur during clinical trials	• Allows local collection, management, and querying of adverse event data (routine and serious) • Supports regulatory compliance
Cancer Central Clinical Participant Registry (C3PR)	Tracks subject registrations to clinical trials	• Provides repository for participant information across studies, sites, systems, and organizations • Provides current enrollment statistics
Cancer Data Exchange (caXchange)	Facilitates automatic capture of clinical laboratory data from laboratory systems and automatic translation and import to caBIG® -compatible clinical trials databases	• Enables translation of multiple source data formats into standards-compliant data • Facilitates the mapping of clinical laboratory data and its transfer to clinical trials systems • Delivers clinical laboratory data in HL7 version 3 format, the emerging standard
Patient Study Calendar (PSC)	Enables clinical trial managers to schedule and manage treatment and care activities for each participant in a clinical trial	• Accommodates epidemiological (and population) studies, observational studies, and interventional studies • Represents study workflow in time, process, and phases • Represents event-driven and date-driven behaviors • Facilitates easy management of the screening process, registration, active monitoring, and long-term follow-up
Data Repository	**Description**	**Benefits**
Clinical Trials Object Data System (CTODS)	Enables storing and sharing of clinical trials data in both identifiable and de-identified form	• Enables data from any Clinical Trials Data Management System (CDMS) or data source to be available to the research community • Provides clinical research partners with identifiable clinical trials data (as permitted) • Provides the broader research community with de-identified clinical trials data (data that have all patient identification information removed)
Infrastructure	**Description**	**Benefits**
Clinical Trials Data Management System Integration (CDMS)	Enables the exchange of data between the Suite and a caBIG® -compatible CDMS	• Provides standard interfaces for interacting with Clinical Data Management Systems (CDMS) • Reduces data entry errors and facilitates clinical trial workflows • Integrates with data collected through the use of Common Data Elements (CDEs)
caGrid	Provides the services backbone for data and message exchange across all tools	• Connects all tools in the caBIG® Clinical Trials Suite • Common identity and security management across tools • Message transport and routing • Secure access, query, and retrieval of data across tools

caBIG®
cancer Biomedical Informatics Grid®

Features

caAERS

- Adverse event (AE) tracking and classification using accepted standards (e.g. CTC 2.0/3.0 and MedDRA 10/11)
- Import of protocol and protocol participant information, and import and export of AE data in common/required formats
- Automated, rules-based assessment of seriousness and reporting requirements (sponsor-level, institution-level and protocol-level rules)
- Ability to submit electronically to the Adverse Event Expedited Reporting System (AdEERS) of the NCI Cancer Therapy Evaluation Program (CTEP)
- Maps to vocabularies and coding systems
- Generates customizable reports and submits to external agencies, including generation of NCI and FDA compliant reports

C3PR

- Manages subject registrations to clinical trials (study open, participant eligible, consent received)
- Stratifies subjects, randomizes to trial arms
- Tracks participants across studies and sites, and handles single-site and multi-site trials
- Manages study personnel who have access to the 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

caXchange

- Enables automatic transfer of clinical data from point-of-care systems, such as clinical chemistry laboratory systems
- Incorporates caXchange Lab Viewer, allowing viewing of clinical laboratory data imported from clinical chemistry and other lab systems
- caXchange Lab Viewer allows search by Medical Record Number (MRN) and date range
- Laboratory results can be selected for loading into clinical trials database
- Automatically flags laboratory result values that may indicate toxicity
- Incorporates caAdapter mapping and translation tool to enable translation of any non-standard source and destination format
- Health Level Seven (HL7) version 2 and comma separated values (CSV) support
- Generates HL7 version 3 messages

PSC

- Creates template to represent activities of a study and applies template to patient to generate calendar
- Applies additional parts of the study template as the patient advances through the study
- Provides prospective and historical views of patient activities
- Manages status of activities: scheduled, occurred, or canceled
- Tracks the history of changes to an activity as well as its ideal date
- Adjusts schedule of activities with delays or advances in calendar
- Generates activity reports by site, study, and patient
- Provides access control to patient calendars within a multi-site environment
- Receives AE notifications from caAERS and displays them in the dashboard
- Provides link to Lab Viewer from patient calendar
- Receives patient registration from C3PR

Features

CTODS

- Based on open standards and standards-based tools designed to enable clinical research partners to share, interpret, and integrate identifiable information as permitted
- Consistent with the Biomedical Research Integrated Domain Group (BRIDG) model that underpins data interchange standards and technology solutions, which enable harmonization between the biomedical/clinical research and healthcare arenas

Features

CDMS

- Automatic registration of patients and data load into CDMS products that use the caBIG® Common Data Elements (CDEs) and standard Case Report Forms (CRFs)
- Retrieval of patient position from any CDMS that meets standard interfaces
- Support for the Cancer Central Clinical Database (C3D) and other conforming CDMS products

caGrid

- Globus-based data services grid
- Index of registered services
- Uniform data query and retrieval across systems
- Message transport and routing between systems
- Federated security and identity management to support controlled access to systems

BUNDLE REQUIREMENTS

The caBIG® Clinical Trials Suite is a series of enterprise applications that must be installed following the minimum hardware and software configuration recommendations. Check the caBIG® tools Web page (https://cabig.nci.nih.gov/tools) for the most up-to-date information on the system requirements outlined below. This Suite is designed so that end users can access the applications from a standard internet web browser.

SUPPORTING SOFTWARE

- Apache Ant
- Apache Maven
- Apache Service Mix
- Apache Tomcat
- Java SE Development Kit (JDK)
- MySQL Database, Oracle Database or
- PostGreSQL Database
- caBIG®-compatible Clinical Data Management System (CDMS)

RESOURCES

- Specific tool information: https://cabig.nci.nih.gov/tools
- caGrid information: https://cabig.nci.nih.gov/workspaces/Architecture/caGrid
- Overview of caBIG®: http://cabig.cancer.gov
- Detailed information about caBIG®, including training, compatibility, etc: https://cabig.nci.nih.gov
- For general information about "Getting Connected with caBIG®": https://cabig.nci.nih.gov/getting_connected

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