National Cancer Institute

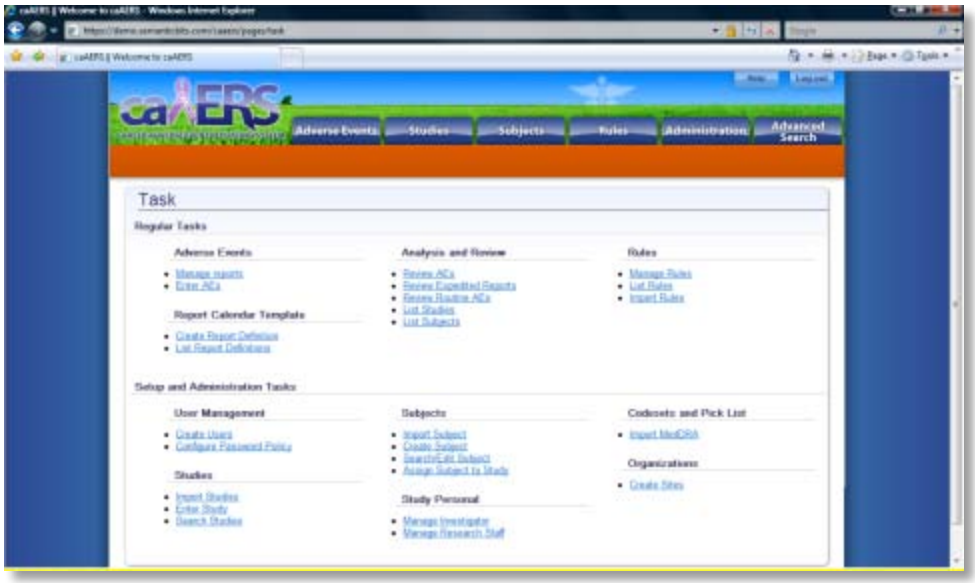
Cancer Adverse Event Reporting System (caAERS)

Adverse event manager

The Cancer Adverse Event Reporting System (caAERS) is an open-source software tool that is used to collect, process, and report adverse events that occur during clinical trials. This tool supports regulatory compliance and allows local collection, management, and querying of adverse event data, whether routine or serious.

Features:

- Adverse event (AE) tracking and classification using accepted standards (e.g. CTC 2.0/3.0 and MedDRA)
- Import of protocol , participant, research staff, and investigator information using user interface or exposed services 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
- Capable of capturing all AEs, including serious, routine, and solicited adverse events.
- Redesigned user interface utilizing Web 2.0 principles



caAERS 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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caBIG® cancer Biomedical Informatics Grid®

caAERS: Adverse event manager

Architecture Overview

- **Application type:** Web Application - remote application with data uploads/downloads through Web interface, services, and/or messaging; Enterprise System/Infrastructure - Server/Network Dependent

Installation and Administration:

- **Skill sets needed:** Ability to install and administer the Apache Tomcat Application Server, ability to create and administer PostgreSQL or Oracle database, ability to create and work with XML files to support import and export functionality
- **System requirements:** Firefox 2.0 or higher or Internet Explorer 7; Mac OS X 10.4, Windows XP, or Linux; 2 GB RAM, 36 GB Disk Space, JDK 5.0 or higher, Apache Tomcat 5.5.23 or higher, PostgreSQL 8.1.9 or higher or Oracle 10g Release 2 or higher

Resources

Tool Overview Page	https://cabig.nci.nih.gov/tools/caAERS#tools
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/index.php/Main_Page
CTMS LISTSERVS	https://list.nih.gov/archives/cabig_ctms_cond_sig.hml 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:

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- City of Hope National Medical Center & Beckman Research Institute
- Comprehensive Cancer Center of Wake Forest University
- Mayo Clinic Comprehensive Cancer Center
- Robert H. Lurie Comprehensive Cancer Center of Northwestern University
- SemanticBits, LLC

Other Clinical Trials Compatibility Framework Components:

- Cancer Central Clinical Participant Registry (C3PR)
- Cancer Data Exchange (caXchange)
- Clinical Trials Object Data System (CTODS)
- Patient Study Calendar (PSC)

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