National Cancer Institute

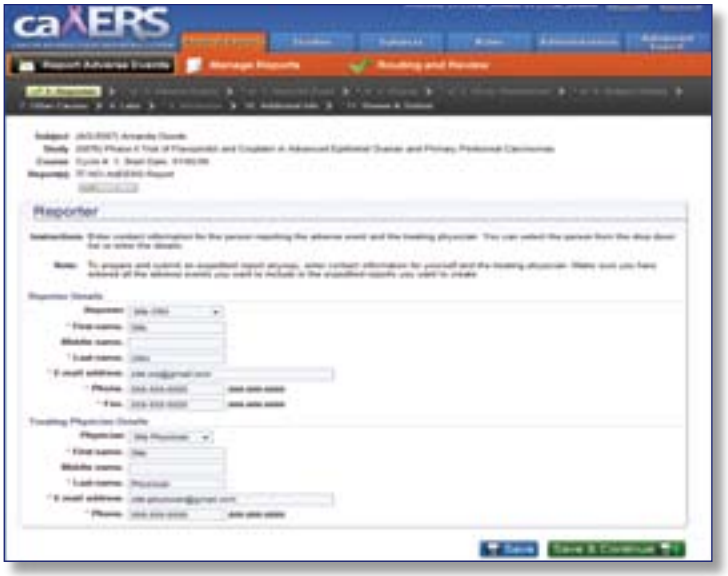
caBIG® Adverse Event Reporting System (caAERS)

Adverse Event Management and Reporting

Adverse event tracking and reporting is a process that is typically handled on paper Case Report Forms (CRFs) as well as additional, supplemental paper forms to collect the detail necessary to comply with regulatory and sponsor-reporting requirements. These reports are time-sensitive, as they are the source of data used in safety surveillance and pharmacovigilance.

The caBIG® Adverse Event Reporting System (caAERS) is open-source, standards-based software that is used to manage the collection and reporting of adverse event data obtained during clinical trials. caAERS facilitates NIH, FDA, IRB, and sponsor regulatory compliance and reporting, and supports local collection, management, and querying of adverse event data. caAERS provides a simple, user-friendly interface for building study templates to collect patient adverse events, and a step-by-step wizard guides the user through the detailed process of collecting the necessary information to produce regulatory reports. The built-in, configurable rules engine helps determine whether adverse events are routine or should be expedited, and automatically generates the due date. caAERS provides import features for importing rule sets, as well as studies, patients, and adverse event dictionaries such as Common Terminology Criteria for Adverse Events (CTCAE) and the Medical Dictionary for Regulatory Activities (MedDRA). An advanced search tab enables users to build queries using drop-down lists and text search features.

caAERS can be used as a stand-alone adverse event reporting and tracking application or in conjunction with the caBIG® Clinical Trials Suite, in which case it receives patient registration information when a patient is registered to a study in the patient registration system (C3PR).



caAERS interface

Categories of Use

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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

caBIG® Adverse Event Reporting System (caAERS)

Adverse Event Management and Reporting

caBIG® cancer Biomedical Informatics Grid®

Features

- Features a user-friendly dashboard interface
- Features a workflow-based data entry wizard
- Features an automated rules engine to facilitate compliance with regulatory, sponsor, protocol, and institution requirements
- Generates study-level prompts for collection of solicited adverse events
- Enables electronic report submission to the NCI Cancer Therapy Evaluation Program (CTEP) Adverse Event Expedited Reporting System (AdEERS)
- Facilitates use of customizable reports using NCI, FDA, EMEA, and ICH-compliant report templates such as the MedWatch 3500A
- Uses standards-based vocabularies and coding systems (e.g. CTCAE, MedDRA)
- Populates forms by previously entered data to save time and minimize data entry errors
- Enables customized adverse event routing, review, and submission notifications and workflow
- Leverages an advanced search tab to query, analyze, and export nearly all data elements captured
- Features a configurable and secure user access that can interface with enterprise single sign-on (SSO)
- Facilitates integration and interoperability with other clinical systems in the caBIG® Clinical Trials Suite

Resources

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

- 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

- Central Clinical Participant Registry (C3PR)
- caBIG® Clinical Connector
- caBIG® Integration Hub
- caBIG® Lab Viewer
- caBIG® Patient Study Calendar (PSC)

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