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## Project Summary

The Cancer Adverse Event Reporting System (caAERS) is an open source, standards-based, web application for documenting, managing, reporting, and analyzing adverse events (AEs). The system operates as both a repository for capturing and tracking routine and serious AEs and as a tool for preparing and submitting expedited AE reports to regulatory agencies.

Currently, caAERS works with cancer prevention and therapeutic trials and can accommodate a range of intervention types, including investigational and commercial agents, radiation, surgery, and medical devices. Adverse events can be coded in caAERS using either CTCAE or MedDRA.

To help organizations stay in compliance with AE reporting regulations, the caAERS application comes loaded with a full complement of industry-standard AE reports, including the FDA MedWatch 3500A form,

## CaAERS

the CTEP AdEERS reports, the NCI-DCP SAE form, and CIOMS. In addition, the caAERS system features a powerful, state-of-the-art rules engine, which can capture a range of sponsor, institution, and protocol-level reporting requirements.

Using these rules, caAERS can automatically determine if an adverse event requires expedited reporting and when and to whom the report must be submitted -- for any of an organization's trials. The business rules used by caAERS can be authored within the application itself or imported from a library of approved rule sets. caAERS also features an advanced email-based alert system that can be customized along a number of dimensions (message content, recipients, delivery times) to ensure that notifications and reminders are sent out as needed. Also included as part of caAERS is an easy-to-use report template generator, which allows users to build and customize reports.

caAERS can be deployed as a stand-alone application or as an integrated module within the caBIG Clinical Trials Suite (CCTS).

caAERS version 1 was released March 6, 2008. We are currently in the next phase of development with releases slated for the end of September, 2008 and March, 2009.

See our [Vision and Scope Document](#) for more information.

## Submit Feedback

We have set up two pages where you can easily submit feedback and ask questions.

- [Process and Technical Questions - caAERS](#)
- [caAERS Bug Reports](#)

## Project Team

caAERS is a highly collaborative project made up of domain and technical experts from SemanticBits, Wake Forest Cancer Center, Mayo Clinic, Cancer and Leukemia Group B (CALGB), NCI-CBIIT, and SAIC. Email can be sent to the entire team by using the listserv: [caersappdev-general@gforge.nci.nih.gov](mailto:caersappdev-general@gforge.nci.nih.gov) or [caersappdev-general@gforge.nci.nih.gov](mailto:caersappdev-general@gforge.nci.nih.gov).

Team	Members
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CaAERS

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SAIC	<ul style="list-style-type: none"> <li>• Nancy Roche (Technical COTR) rochenv@mail.nih.gov</li> <li>• Peter Yan</li> </ul>

## Installation and Demos

### Installation

The current production version of caAERS can be installed through a graphical wizard-like installer. It requires some software be installed, such as Java and Tomcat. See our Installation Guide for more information. All historical caAERS releases are also available.

Alternatively, you can review the current and historical caAERS releases or checkout and build caAERS from source:

- Subversion repository: <https://gforge.nci.nih.gov/svnroot/caaersappdev/trunk/>
- Subversion module: ?
- User name: ?
- Password: ?
- Prerequisites: Java 1.5, Tomcat

### Demonstration Site

Go to our demonstration site and login to a fully functional version of caAERS.

- Username:
  - ◆ The demo Username is: SYSTEM\_ADMIN (in capital letters).
- Password:
  - ◆ The password is: system\_admin (in lower case letters).
- Submitting Reports to AdEERS:
  - ◆ When caAERS is used to submit a report to AdEERS, the report currently goes to the AdEERS Staging site, [https://capps-ctep.nci.nih.gov/openapps\\_10gbeta/gadeers\\_main\\$.startup](https://capps-ctep.nci.nih.gov/openapps_10gbeta/gadeers_main$.startup)

Demo version of caAERS - data

## caAERS Releases

caAERS Version	Release Date	Release Type	Release Comments
caAERS v1.0	03/08/2008	Production	First production release of caAERS
<u>caAERS v1.1.2</u>	05/01/2008	Production	Period release to fix critical issues identified by user community
<u>caAERS v1.1.3</u>	07/07/2008	Production	Period release to fix critical issues identified by user community
<u>caAERS v1.2.1</u>	07/09/2008	Beta	Messaging consumer for creation and update of study, investigator, and research staff
v1.2.1 - application	07/09/2008	Alpha	Iteration build

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<a href="#">caAERS v1.3</a>	07/31/08	Production	Iteration release containing new AE functionality, messaging support, and bug fixes
<a href="#">caAERS v1.5</a>	09/25/08	Production	End-of-Period release containing significant new functionality, improvements in existing functionality, and bug fixes.
<a href="#">caAERS v1.5.1</a>	10/10/08	Production	Period release to fix critical issues, primarily related to Oracle 10g and Internet Explorer v7 support
<a href="#">caAERS v1.6</a>	11/26/08	Production	Iteration release containing new functionality and bug fixes
<a href="#">caAERS v1.7</a>	01/09/09	Production	Iteration release containing new functionality and bug fixes

## Documentation

- Installation
  - ◆ [v1.6 Quick Start Installation & Configuratin Guide](#)
  - ◆ [Installation Guide](#)
- User Guide
  - ◆ [v1.7 End User Guide](#)
  - ◆ [v1.6 End User Guide](#)
  - ◆ [v1.5 End User Guide](#)
- Administration Guide
  - ◆ [v1.6 Administration Guide](#)
  - ◆ [v1.5 Administration Guide](#)
- [Training Module](#)
- [Use Case Document](#)
- [Requirements Specification](#)
- [Architecture Guide](#)

## Project Planning

We engage in Agile project development, where we focus on time-boxed iterations that result in a deployable, testable application at the end of each iteration. As part of the iterative development, we actively engage with stakeholders on a regular basis. This section describes our project plan and meeting schedule.

## Project Management

In line with our Agile development methodology, we have adopted a modified version of [Scrum](#).

## CaAERS

The caAERS v1.5 project management plan, communications plan, risk management plan, and project schedule are available in the caAERS source control repository. To view or download a copy of any of these documents, please go to the following location:

[https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/docs/Management/caAERS\\_1.5/?root=caersappdev](https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/docs/Management/caAERS_1.5/?root=caersappdev)

## Meetings & Communications

### All-hands Calls

In a project as highly collaborative as caAERS, frequent and open communication amongst all stakeholders is critical to success. In line with this, we have weekly All-hands calls that are mandatory for funded adopters and elaborators but open to anyone.

#### Teleconference Information

*When:* every Thursday 12:00-1:00 EST

*Phone:* 1-800-857-4816

*Passcode:* 72114

*Web:* <http://ncicb.centra.com/>

*Meeting ID:* caAERS Project

#### Agendas and Meeting Notes

Month	1st Thursday	2nd Thursday	3rd Thursday	4th Thursday	5th Thursday
March			<u>3/20</u>	<u>3/27</u>	
April	<u>4/3</u>	<u>4/10</u>	<u>4/17</u>	<u>4/24</u>	
May	<u>5/8</u>	<u>5/15</u>	<u>5/22</u>	<u>5/29</u>	
June	<u>6/5</u>	<u>6/12</u>	<u>6/19</u>		
July	<u>7/3</u>	<u>7/10</u>	<u>7/17</u>	<u>7/24</u>	<u>7/31</u>
August	<u>8/7</u>	<u>8/14</u>	<u>8/21</u>	<u>8/28</u>	
September	9/4	9/11	9/18	9/25	

## Face-to-face Meetings

We hold a number of closed face-to-face meetings for team building, planning, and hashing out use cases. These include:

- [2008 Kickoff 4/15-4/17](#)

## Daily Scrums

In alignment with Scrum methodology, we hold daily Scrum meetings that last approximately 15 minutes. Each member of the technical team describes:

1. What they worked on yesterday
2. What they plan to work on today
3. Any obstacles that they are facing or foresee

## Teleconference Information

*When:* daily 9:30-10:00 ET

*Phone:* 1-800-857-4816

*Passcode:* 85706

## Listservs

There are two listservs used for the caAERS project. To subscribe to these and/or search past messages, see the following links:

- [caaersappdev-general](#)
- [caaersappdev-technical](#)

## Project Collaboration

caAERS is a highly collaborative project involving stakeholders from our funded adopter and elaborator community, caBIG, NCI, and the larger cancer research community. In order to uphold the caBIG philosophy of open development, we engage in collaborative development of use cases and requirements through this wiki. The following sections are used to interactively develop use cases and requirements, as well as keep all stakeholders abreast of current development.

## Use Cases

There is a use case template available when you create a new document. Or, you can view the current [caAERS Use Case document](#).

To view Use Cases currently ready for review, currently in progress, or planned for future development, see the [caAERS Use Cases](#).

## Requirements

There is a requirements template available when you create a new document.

Requirements we are currently working on:

- TBD

Requirements we have already developed:

- TBD

## Cancer Adverse Events Reporting System (caAERS) Knowledge Base

The Knowledge Base was created to address questions and issues related to the CTMS Knowledge Center as

they arise as well as to provide a historical reference of questions and issues that have previously been addressed. For the caAERS project, this knowledge base includes a set of articles that answer related questions and issues that users encounter. Topic areas include:

- *Using Tool in Research* - Ask questions or provide examples of real-life applications. How has the tool contributed to real-life problem solving in biomedicine?
- *Installation and Configuration* - Questions, tips, and lessons learned related to the set-up, installation, and configuration of the tool; Include the environment/operating system you were working with, the problem or situation you encountered, and any build/install/run tip and/or work-around that might benefit others.
- *Architecture and Integration* - Questions, tips, and lessons learned related to interoperability with other systems and tools, including caGrid. Include an overview of the architecture being worked with, and your questions or advice to others working with the same tool or dependent software, including any step-by-step instructions useful to people integrating similar tools and systems.
- *Data Migration* - Questions, tips, and lessons learned related to migrating data from a legacy system or tool to this tool.
- *Workflow* - Observations or questions about the tool in actual use, introducing end users to the tool, integrating the tool into existing workflows, or using it with other applications.
- *Data Sharing and Security* - Questions, tips, and lessons learned related to data sharing or security specifically with respect to this tool.
- *Documentation* - Post comments to existing documentation and/or provide input for new documentation. If you are commenting on existing documentation, please reference document you are commenting on.
- *Other Questions and Comments* - If your question or observation doesn't fit elsewhere, put it here!

The Knowledge Base can be browsed by article (below) or searched on through the search box (left).

## **Using Tool In Research**

## **Installation and Configuration**

## **Architecture and Integration**

## **Data Migration**

**Workflow**

**Data Sharing and Security**

**Other Questions and Comments**