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caAERS Introduction and History

History:

The caAERS application development project began on December 1, 2006. The goal of this project is to develop and to deploy an adverse event reporting system that is nationally scalable with a robust architecture to meet the needs of the caBIG? Community. caAERS is a product of the NCI Center for Bioinformatics and its partners. Visit the [caAERS project web site](#) or more information.

Description of caAERS:

The Cancer Adverse Event Reporting System (caAERS) is an open source, web-based 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 CTC 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, the CTEP AdeERS reports, and the NCI-DCP SAE form. 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. caAERS can be deployed as a stand-alone application or as an integrated module within the caBIG? Clinical Trials Suite CCTS).

caAERS Release History

Below is listed the recent release history of caAERS.

- caAERS v1.0 - 8 March 2008

- caAERS v1.1.2 - 1 May 2008
 - caAERS v1.1.3 - 7 July 2008
 - caAERS v1.2.1 - 9 July 2008
 - caAERS v1.3 - 31 July 2008
 - caAERS v1.5 - 25 September 2008
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New Features and Updates

This is an announcement of the caAERS 1.5 release, which is a major milestone release included in the caBIG® Clinical Trials Suite 1.1 release. The new and improved functionality within this release is focused on supporting the usage of caAERS as a single repository for all adverse events, support of services allowing real-time data exchange between caAERS and other clinical trial management systems, expanded support of FDA and NCI adverse event reporting requirements, and significant improvements to the user interface by utilizing web 2.0 design principles.

The following new features and enhancements have been implemented since the previous production release:

1. Adverse event entry:

Significant improvements have been made to the adverse event entry support in caAERS. These improvements are designed to better facilitate caAERS usage as a single source of truth for all adverse events.

- caAERS now supports a single point of entry for adverse events, regardless of whether or not they are serious. This single entry point is designed to better harness the utility of the caAERS rules engine and provide a simpler interface for users.
- Support of solicited adverse events.
- Support of evaluation period types. These are phases in a study to which solicited adverse events can be associated. By default, each study created is pre-initialized with three evaluation period types "Baseline", "Treatment", and "Follow-up".
- Support of cycle/course annotation during adverse event entry.
- Support of evaluation periods. These are the specific dates, usually cycle-centric, around which adverse events are evaluated for reporting. Each evaluation period can be associated with an evaluation period type to allow any solicited adverse events to be pre-initialize in the adverse event entry screens.
- Support of assigning seriousness reasons to individual adverse events. Previously, seriousness could only be assigned to a collection of adverse events.
- Support for adverse event grading with CTCv2.0.
- Support of MedDRA configuration for "Other, specify" adverse event terminology.

2. Adverse Event Reporting: Significant improvements were made to the adverse event reporting capabilities of caAERS to better support user, regulatory, and sponsor requirements.

- CTEP improvements:
 - ◆ Removed "expected" as a required field.

- ◆ Hardened the caAERS-to-AdEERS submission
- ◆ Removed fields from the user interface that are not appropriate for CTEP reporting.
- DCP improvements:
 - ◆ Added the ability to associate seriousness criteria to each adverse event.
 - ◆ Updated the "DCP SAE Report" template to reflect changes made by DCP including addition of new fields, renaming of fields, and removal of fields.
 - ◆ Update the caAERS data model and user interface to include the following new fields: personnel title, personnel address, time of event onset, location of subject at event onset, formulation, lot #, still taking concomitant medication?, concomitant medication start date and stop date, autopsy performed?, and cause of death.
 - ◆ Corrected and improved the mapping of data elements to the report fields during report generation.
- FDA reporting requirements:
 - ◆ Implemented an exportable PDF version of page one of the MedWatch 3500A form.
 - ◆ Added the following two fields to the caAERS data model and user interface required for MedWatch report completion: event abated after use stopped or dose reduced?, and event reappeared after reintroduction?.
 - ◆ Implemented the necessary data element mapping to populate the MedWatch 3500A form.
- Report Definitions and Rules Engine:
 - ◆ Mandatory fields for report definitions now support a "not-applicable" option to prevent display of the field in the user interface. This provides a configurable method to ensure only relevant fields are displayed in the user interface.
 - ◆ Mandatory fields for report definitions are now selectable through a drop-down function rather than a check box.
 - ◆ Updating of the rules to support FDA, DCP, and CTEP reporting.
 - ◆ Addition of an editable display name for each report definition to allow for better user configuration without the need for additional programming.
- Adverse Event Reporting:
 - ◆ Previously, Patient Details, Pre-existing Conditions, Concomitant Medications, and Prior Therapies were all separate page. This flow has been streamlined to combine these pages into one Patient Details page.
 - ◆ This flow has been updated to allow for better integration with the new single Adverse Event Entry flow and the updated Manage Report page.
- Manage Reports:
 - ◆ The Manage Report page has been updated to be evaluation period centric. From that manage report screen, users can view the status of reports, summaries of adverse events, directly access any evaluation period or adverse event report, and initiate export, submit, and amend activities.

3. Data Sharing and Integration:

- Support for creating & updating subjects via messaging and web services.
- Support for updating subjects via xml import.
- Support for creating & updating studies via messaging and web services.
- Support for updating studies via xml import.
- Support for creating & updating research staff via messaging and web services.

- Support for creating & updating research staff via xml import.
- Support for creating & updating investigators via messaging and web services.
- Support for creating & updating investigators via xml import.
- Implementation of a lab message consumer.
- Implementation of Alerts message panel for handling Lab messages.
- Implementation of Hotlink configuration changes for CCTS.
- Implementation of an adverse event query API.
- Support for multiple concurrent versions of MedDRA.
- Support for CTCv2.0 adverse event grading descriptions.
- Support of "happy.jsp" which provides configuration feedback when installed as part of CCTS.

4. Installation / Configuration

- Support for changing the SYSTEM_ADMIN password during installation.
- Addition of "user id" to support changing users' email addresses.
- Made caAERS Installer agnostic of version changes to caaers-core jar during the installation process.
- Foreign Key constraints added to the Database to ensure integrity of data.

5. General Usability

- Updated user guide
- Updated administration guide
- Updated installation guide
- New application look and feel.
- Updated and redesigned buttons.
- Improved support for Internet Explorer v7 browser.
- Improved use of color.
- Centered layout.
- Improved navigation tabs to ease application navigation.
- Use of light-views and pop-ups to improve the user experience and reduce page refreshes.
- Updated page instructions.
- Updated field level help.
- Error messages are displayed in a bigger font, along with an icon.
- Error messages summary (displayed on top of the page) is in a box.
- Rewriting of error messages to be clearer.
- Added "Begin Typing Here" to all autocompleter fields.
- Added confirmation for all deletes.
- Phone # format is displayed everywhere a FAX or PHONE number is asked for.
- Addition of "please select" to all drop-down lists, with default set to "please select".
- Change date fields to separate MM-DD-YYYY fields.

Existing Features: For a list of features currently implemented in caAERS, refer to earlier versions of the Release Notes (available at: [\[1\]](#))

Bugs Fixed Since Last Release

A number of bugs were fixed as part of this iteration, including the following:

- CAAERS-94 show all does not have a close button
- CAAERS-41 Duplicate study agents allowed in Create/edit study flow
- CAAERS-40 Duplicate treatment assignments can be created in 'Create studies' flow
- Removed duplicate error messages.
- CAAERS-264 Require hospitalization information only if grade > 2 in Enter AEs tab
- CAAERS-142 Use StudySubjectIdentifier as Participant Identifier, in AdEERS communication
- CAAERS-50 script 10/47 not working in Oracle.
- CAAERS-28 NullPointerException thrown from Auditing framework while deleting study.
- CAAERS-40 Duplicate treatment assignments can be created in 'Create studies' flow
- CAAERS-279 Invalid dates allowed in Enter AEs
- CAAERS-297 AdEERS error when submitting AE report with radiation information

Known Issues

As of the writing of these release notes, there are no known issues which will impact the functioning of the application.

Documentation and Support

The [CTMS Knowledge Center](#) is the primary source of documentation and support for production releases of caAERS:

Through this site, you can obtain all installation, administration, and user documentation. Additionally, this is the appropriate forum to report bugs and issues. You can also access the caAERS development team through this site.