Release Notes

caAERS
Version 1.7
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Contents

1.0 caAERS Introduction and History

2.0 Release History

3.0 New Features and Updates

4.0 Bugs Fixed Since Last Release

5.0 Known Issues

6.0 Documentation and Support

1.0 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 Knowledge Center web site for more information:

CaAERS Knowledge Center

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).

2.0 caAERS Release History

Below is listed the recent release history of caAERS.

caAERS v1.5

-- 25 September 2008

caAERS v1.5.1

-- 10 October 2008

caAERS v1.6

-- 26 November 2008

3.0 New Features and Updates

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

- Added Hosted Mode support through refinement of roles and permissions.
    - Required for multi-site studies accessing a common caAERS system (i.e. Cooperative Group studies).
    - This includes updates to content filtering based upon the user's organization, the role of the

organization on the study (i.e. study site or coordinating center), and the user's assignment to the study.

- Added ability to define AE's that are expected for a study.
    - ♦Required by many sponsors and institutions for purposes of proper AE reporting.
- Updated study service and xml import to support creation and update of new study elements (i.e. expected AEs, solicited AEs, evaluation period/epoch)
- Added business rule validations to investigator and research staff data entered into the

system via XML import or message and Excel import.

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    - ♦This is a critical improvement to ensure the integrity of data entered into the

system via imports and messaging meets the same requirements as data entered via the user interface.

- Added a warning message when users navigate away from the AE flow without saving their changes.
    - ♦Helps prevent unsaved data from being lost.
- Added the ability to add several of the same "Other, Specify" AE terms, provided that the MedDRA term

or verbatim text describing the event is unique.

- Added logic in the submission to AdEERS so that "Investigation Agent(s) Administered" = "YES" if investigation agents are included on the report. The flag is set to "NO" otherwise.

4.0 Bugs Fixed Since Last Release

- Fixed issue when ?Begin? tab was selected while in enter AE flow.
    - ♦Issue resulted in a screen error indicating an invalid Study and Subject.
- Updated caAERS to AdEERS message to include "Primary Anatomic Site of Disease"
    - ♦This was added as a required element to the AdEERS message on 12/29/2008.
- Updated caAERS user interface to support "Administration Delay" and "Dose Modification"

changes made to the AdEERS Beta system on 10/3/2008.

- Dose Modified and Administration Delay fields are no longer tied together in the AE reporting flow.
- A duplicate study exists exception was fixed by re-associating the study to the active session

as tabs are switched in the flow.

5.0 Known Issues

- caAERS is not yet approved for use by CTEP for expedited reporting to AdEERS.

Piloting activities are in process that will address this within the next several releases.

- Some pages are incompatible with the Internet Explorer v.6 browser. Plans to

support this browser are being evaluated. Use of Internet Explorer v7 and Firefox v2.0 and up are supported. The use of Internet Explorer v.6 with this version of caAERS is NOT recommended.

- When submitting expedited reports to AdEERS, decimals are not allowed in any values and will result

in submission errors.

- In the Capture AE tab, the "Save & Back" button does not save. The user should first click the "Save"

button and then go back.

- In the Capture AE tab, the "Save your data" warning does not appear if you click on the "Begin" tab and any changes made on the page will not be saved. The user should first click the "Save" button and then navigate to the "Begin" tab.

6.0 Documentation and Support

The CTMS Knowledge Center is the primary source of documentation and support for production releases of caAERS:

CaAERS Knowledge Center

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.