



Routine Adverse Events Reporting System (RAERS) Overview

Konnie McCauley
Information Systems Help Desk
CALGB Statistical Center
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Objectives

- Define purpose of RAERS
 - Advantages of RAERS over paper-based system
 - RAERS features
- Describe CRA use of RAERS
 - List Roles - Lead CRA, CRA, and DC
 - Define tasks each role can do
 - Show briefly how to create an AE report and enter an expected and other adverse event
- List availability of training, resources, and support

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What is RAERS?

- A CALGB Web Application designed to replace paper Adverse Event (AE) forms
- Implemented to make report submission and approval faster and more accurate
- Addresses common problems with paper form system
 - Invalid selection of codes
 - Volume of paper AE forms to process
 - Missing AE data (gaps)

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RAERS Is...

- HIPAA compliant
- Easily accessed
- Easy to use

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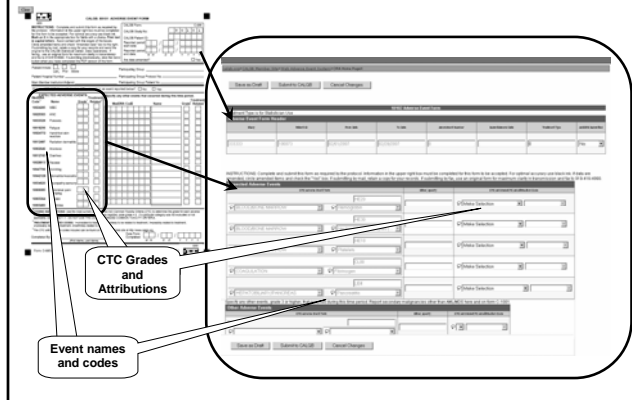
Advantages of RAERS

- No need to look up CALGB/SWOG codes
- Grading criteria built in and specific to the adverse event
- Electronic forms – no need to process paper which can be lost or be destroyed, electronic forms are easy to query and search
- Gaps and overlaps are clearly identified
- Prompts you if you attempt to enter invalid data

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Paper and Electronic Forms



Key Features

- Application lets users save draft records
- RAERS displays the codes and CTC versions for a study on the screen
 - Codes are new CALGB codes, MedDRA
- Procedure updates from paper AE forms to RAERS
 - CRAs use RAERS to complete and submit AE reports electronically
 - DCs use RAERS to review and correct reports or request changes

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CRA Roles

- CRA
 - View existing AE reports
 - Create a new AE report
 - Save, modify, delete drafts
 - Print AE reports
 - Submit AE reports for DC review
 - Amend reports
- Institutional roles (CRA and Lead CRA)
 - CRAs can work with only the patients associated with the CRA's institution
 - Lead CRA can use RAERS the same as a CRA and can work with patients in associated institutions

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DC Role

- DC
- Reviews reports and requests needed corrections
- Approves and submits reports to the CALGB database
- Corrects or amends records from the CALGB database

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CRA RAERS Home Page

Text boxes for study-patient combination search

List of Draft Reports

Links to view or print each Draft Report

Status for each Draft Report

View	Print	Study No.	Patient ID	Event Date	Event Date	Submission Date	Trackout Type	AE/PTI	AE/PTI	Status
View	Print	111111	100001	01/15/2007	01/22/2007	02/09/2007	0	No		Submission Correction Requested
View	Print	111111	100019	07/31/2006	01/29/2007	01/29/2007	0	No		Submission Correction Requested
View	Print	111111	100019	12/01/2006	12/31/2006	01/29/2007	0	No		Submission Correction Requested
View	Print	333333	100095	01/01/2007	01/31/2007		0	No		Draft
View	Print	111111	100001	01/01/2007	01/31/2007	01/09/2007	0	No		Submission Correction Requested
View	Print	111111	100001	01/01/2007	01/31/2007	03/09/2007	0	No		Draft

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Creating a New Report

Electronic reports for this study.

Category provided

Event name provided

CALGB Code filled in

Choose the severity (CTC grade)

Indicate extent this AE is related to treatment

View	Print	Study No.	Patient ID	Event Date	Event Date	Submission Date	Trackout Type	AE/PTI	AE/PTI	Status
View	Print	10102	Adverse Event Form	11/01/2006	11/09/2006		0	No		Draft
View	Print	10102	Pre-Existing Conditions Form	10/01/2006	10/31/2006	01/12/2007	0	No		Submitted

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Completing Report Fields – Expected Adverse Events

Category provided

Event name provided

CALGB Code filled in

Choose the severity (CTC grade)

Indicate extent this AE is related to treatment

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Choosing Severity (CTC Grade)

Grades match this adverse event

The screenshot shows the 'Expected Adverse Events' section of a form. A callout box with the text 'Grades match this adverse event' points to the severity dropdown menu for the first event, which is currently set to 'E1'. Other events in the list also show 'E1' or 'E2' in their severity dropdowns.

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Choosing Attribution

Choose the attribution from the drop-down menu

The screenshot shows the 'Expected Adverse Events' section of a form. A callout box with the text 'Choose the attribution from the drop-down menu' points to the attribution dropdown menu for the first event, which is currently set to 'Drug'. Other events in the list also show 'Drug' in their attribution dropdowns.

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Completed Expected Adverse Event

The screenshot shows the 'Expected Adverse Events' section of a form. A callout box with a black oval around it points to the first event row, which is now completed. The event name is 'MUSCULOSKELETAL/JOINT', the severity is 'E1', and the attribution is 'Drug'. The 'Expected Adverse Events' section is now empty.

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Entering Other Adverse Events

Other Adverse Events

The screenshot shows the 'Other Adverse Events' section of a form. A callout box with a black oval around it points to the event name dropdown menu, which is currently set to 'MUSCULOSKELETAL/JOINT'. Other dropdowns for severity and attribution are also visible.

Choose category, event name, severity, and attribution from drop-down menus.

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Submitting the Report to CALGB

The screenshot shows the RAERS system interface. At the top, there are three buttons: "Save as Draft", "Submit to CALGB", and "Cancel Changes". The "Submit to CALGB" button is circled in red. Below the buttons, there is a table with columns for "Event ID", "Event Name", "Event Date", "Event Time", "Event Location", "Event Status", and "Event Type". The table contains one row of data. Below the table, there is a section for "Expected Adverse Events" with a dropdown menu showing "BLOODSUGAR MAINTAIN" and a "Possible" status.

- **Submit to CALGB** – sends report to assigned DC.
- **Save as Draft** – saves report in draft folder to be completed and submitted later
- **Cancel Changes** – retains report with header information, but cancels all adverse event selections

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Status of RAERS

- End-users at Duke and Christiana are testing RAERS
- Test started May 23, will end on August 15

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Training, Resources, and Support

- Training planned for all users
- Documentation
 - *User's Guide: Routine Adverse Events Reporting System (RAERS) (Coming soon)*
- Help Desk support

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Summary

- RAERS provides a more accurate and efficient means for viewing, creating, submitting, and reviewing reports for a patient on a study by allowing you to:
 - find reports by searching a study number and patient identifier.
 - work with reports based on your role.
 - create, save, modify, view, print, and delete reports.
 - amend existing reports in RAERS.

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