



CALGB Routine Adverse Events Reporting System

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Objectives

- Give an overview of the CALGB Routine Adverse Event (AE) Reporting System
 - Define the roles and requirements for CRAs using the system
 - Explain the features of the application that are parallel with the paper form processes
 - Outline the system functions, including those that will provide an advantage over the paper form process
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Common Issues with Paper Forms

- Invalid selection of codes
 - Medical Dictionary for Regulatory Activities (MedDRA)
 - Common Terminology Criteria (CTC)
 - Volume of paper forms to process
 - Missing AE data (incomplete forms)
 - Missing forms (gaps)
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The Routine AE Reporting System

- Web Application (application that can be used over the Internet using your web browser, such as LabTrak and Patient Registration in CALGB)
 - Task is to replace paper form processing
 - Implemented to make report submission faster, more efficient, and more accurate
 - Procedure updates from paper forms to the Routine AE Reporting System
 - CRAs will use the system to submit routine AE data
 - Data Operations will use the system to review reports, request changes, and correct reports
 - Target release date: later in 2006
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HIPAA Compliance

- Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements restrict access to protected health information (PHI)
 - You are required to log in with CALGB participant ID and password (same as other CALGB Web Applications at www.calgb.org)
 - Your role at an institution or on a study determines your access permissions
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Access and Log In

- Login page will be accessible from www.calgb.org where you access other CALGB Web Applications such as LabTrak and Patient Registration
 - CALGB participant ID is required to use the Routine AE Reporting System
 - What you can do in the application is determined by your CALGB participant identifier (ID)
 - Obtain a CALGB participant ID prior to using the application (www.calgb.org)
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CRA Tasks

- Functions you will use in the application
 - View existing reports
 - Create a new report
 - Save and modify drafts
 - Submit reports
 - Amend reports
 - Institutional roles (CRA and Lead CRA)
 - CRA can work with patients at the same institution
 - Lead CRA can use the application the same way as a CRA and can work with all patients in the member network
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Creating Electronic AE Reports

- Types of reports
 - Baseline events (pre-existing conditions)
 - Adverse events
 - All forms generally follow the same structure in the application
 - Form ID information and form-specific questions
 - Expected and additional adverse events
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Printing and Submitting Reports

- Print blank form or unsubmitted reports any time if desired
 - Submit the report when it is complete
 - Print submitted reports for your records, but no fax or mail submission is required
 - Print a copy of the submitted report for auditing purposes (printable view automatically opens)
 - Data Operations reviews the submitted report and may request changes to the report
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Summary

- The Routine AE Reporting System provides a more accurate and efficient means to process reports for a patient on a study.
 - Your institutional roles in CALGB determine access and functions available in the system.
 - The application will be accessible with other CALGB Web Applications at **www.calgb.org**
 - You can create and submit baseline and adverse event reports electronically and take advantage of automated features in the electronic forms.
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Resources

- Web address of the Routine AE Reporting System provided upon the release of the application
 - Online help from links on menu at the left
 - Application contact (after release): CALGB Help Desk, 877-44-CALGB
 - First-time registration to use CALGB Web Applications
 - Complete the *Roster Update Form* at www.calgb.org to obtain a participant ID and password
 - Contact the CALGB Help Desk to get a password for CALGB Web Applications
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