



# Form Development and Data Flow

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## Objectives

- Introduce
    - Form Development Team
    - Types of CALGB Forms
  - Review NCI Reporting Guidelines
  - Outline Form Development Process
  - Explain Data Flow
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## Form Development Team

- Study Chair/Co-Chair
  - Protocol Editor
  - Statistician
  - Data Coordinator
  - Quality Assurance Director
  - Form Designer
  - Forms/Database Developer
  - Protocol Information Specialist
  - Web Operations Manager
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## Form Types

- On-Study Data Forms
    - Generic or protocol specific
  - Follow-Up Data Forms
    - Generic or protocol specific
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## Types of On-Study Data

### Study Specific

- Pre-existing Conditions
  - Prior Therapy
  - Specimen Routing
  - On-Study
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### Generic

- Disease specific Staging
- Disease specific Tumor Measurement

## Types of Follow-up Data

### Study Specific

- Dosage or Treatment
- Adverse Event
- Response/Follow-up
- Specimen Routing

### Generic

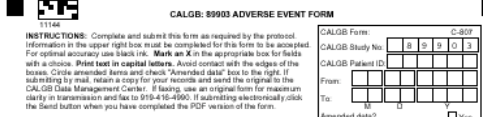
- Disease Specific Tumor Measurement
  - Off-Treatment Notice
  - New Primary Cancer
  - Death
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## **NCI Reporting Guidelines Impact on Forms**

- Common Terminology Criteria Adverse Events (CTCAE) version 3
  - Adverse Event Expedited Reporting System (AdEERS)
  - Clinical Data Update System (CDUS)
  - Common Data Elements (CDE)
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## **Common Terminology Criteria for Adverse Events (CTCAE)**

- Reported on
    - Pre-existing Conditions Forms
    - Adverse Event Forms
    - Severe Adverse Event reports (AdEERs or Medwatch)
  - Designated as an 8 digit MedDRA Code
  - CTCAE Version 3 used on all studies opened after October 1, 2003
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**CALGB 89903 ADVERSE EVENT FORM**

**INSTRUCTIONS:** Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. For optimal accuracy use black ink. Mark an X in the appropriate box for fields with a choice. Print text in capital letters. Avoid contact with the edges of the boxes. Circle amended items and check "Amended data" box to the right. If submitting by mail, retain a copy for your records and send the original to the CALGB Data Management Center. If faxing, use an original form for maximum clarity in transmission and fax to 919-416-4960. If submitting electronically click the Send button when you have completed the PDF version of the form.

## Attribution Codes

1 = Unrelated

2 = Unlikely

3 = Possible

4 = Probable

5 = Definite

\*The CTC with MedDRA codes included can be found on the CALGB homepage at <http://www.calgb.org>

Completed By: \_\_\_\_\_ Date Completed: \_\_\_\_/\_\_\_\_/\_\_\_\_  
(Print or Type Name)

Form: C-807 Version 2.0 07/01/2002 Page 1 of 1

# AdEERS Reporting for Serious Adverse Events

Consider:

- Is event expected or unexpected?
- Grade or severity?
- Agent suspected of causing event?
- Investigational or commercial agent?
- Phase I, II, or III?

## AdEERS Reporting Requirements for Serious Events

- Investigators sends AdEERS report to:
  - CALGB Central Office
  - Institutional Review Board (IRB)
- CALGB Central Office reviews and forwards to:
  - Study Chair
  - NCI
  - CALGB Statistical Center, Data Operations

## AdEERS Report

<b>Adverse Events (CTC)</b>			
Category	Adverse Event	Grade	Hospitalization/ Prolongation of Hospitalization
INFECTION/FEBRILE NEUTROPENIA	Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC <1.0 x 10 <sup>6</sup> /L, fever ≥38.5 degrees C)	3	Yes
BLOOD/BONE MARROW	Platelets	4	Yes
<b>Attribution for Adverse Events</b>			
Attribute to	Febrile neutropenia (fever of unknown origin)	Platelets	
CYTARABINE(63878)	Probable	Probable	
RITUXIMAB (C2B8 ANTIBODY)(68745)	Unrelated	Unrelated	
VP-16-213(141540) NonHodgkin's lymphoma NOS	Probable Unrelated	Probable Unrelated	

## **Clinical Data Update System (CDUS)**

- Full CDUS Reporting
    - Phase I/II Studies, NCI distributed agents
    - Patient, treatment, adverse event, and response information
  - Abbreviated CDUS Reporting
    - Phase III Studies
    - Phase I/II Studies using non-NCI agents
    - Non-treatment studies >100 patients
    - Limited to administration and patient demographics
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## **NCI Common Data Elements (CDE)**

- NCI CDE Data Dictionary
    - Phase III Cancer Trials
    - Promote use of Common Terminology
      - Facilitate data sharing
      - Facilitate data mining
      - Improve efficiency of data collection
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## Form Development Process

Initial Protocol Review

Preliminary Form Review-revision

Author Review/Field Testing-revision

Activate and post protocol

## Initial Protocol Review

- The Protocol Editor:
  - Schedules a conference call
- The Data Coordinator:
  - Creates the data submission schedule
  - Selects appropriate generic forms
- The Data Coordinator and Form Designer:
  - Begin to create study-specific forms

Initial Protocol Review

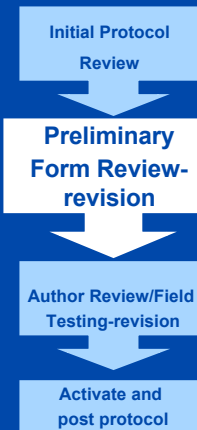
Preliminary Form Review-revision

Author Review/Field Testing-revision

Activate and post protocol

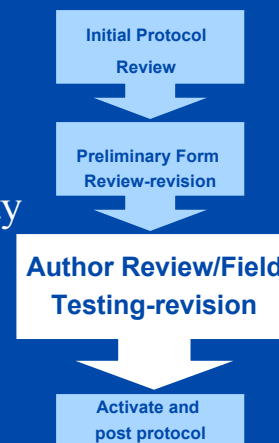
## Preliminary Form Review

- Study Chair and Statistician ensure:
    - Data required to satisfy protocol objectives are included
    - Data items are consistent with protocol
    - Multiple choice listings include all data values
    - Appropriate spacing provided for data values
    - Instructions and data items are clear
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## Author Review/Field Testing

- Study Chairs, Statisticians, Quality Assurance, CRAs, and Nurses review forms for:
    - Content
    - Format
    - Clarity
    - Feasibility/Usability
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## Keys to Successful Form Development

- Communication
  - Focus
  - Consistency/detail
  - Get it right the first time
    - Amendments
    - Multiple form versions
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## Data Flow to the Study Chair

- Confirmation of registration
  - Patient data including lab reports
  - Eligibility evaluations
  - Case evaluations
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## Data Flow at the CALGB Statistical Center

- Data Coordinator
    - Supports registration
    - Clinically reviews all patient data
    - Queries institutions for data that is:
      - Delinquent
      - Incomplete
      - Incorrect
      - Inconsistent
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## Study Chair Resources

- [www.calgb.org](http://www.calgb.org)
  - [www.ctep.info.nih.gov/](http://www.ctep.info.nih.gov/)
  - Protocol Editor
  - Statistician
  - Data Coordinator (919) 286-0045
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