



CALGB Statistical Center

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CALGB Data Operations

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Objectives

- Understanding the organization of the CALGB Statistical Center
- Contacting Data Coordinators
- Directing questions to the appropriate contact
- Locating training resources at www.calgb.org
- General updates

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CALGB Statistical Center Organization (Durham, NC)

- Data Operations
 - Form development
 - Form submission
 - Clinical review
 - Data entry
 - Data entry
 - Registration
 - Record retention
- Information Systems
 - CALGB Help Desk - (877) 44-CALGB
 - Web site (www.calgb.org)
 - IS Web applications
 - LabTrak, Patient Registration, Reporting System, Secure Mail
- Biostatisticians

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Data Coordinators

- Introduction of Data Coordinators (DCs)
- Contact information
 - Log in to Member Site, click Directory tab
 - Search by last name, or
 - Click the "Whom Do I Contact in Data Operations" link, or
 - Call 919-668-9355, or
 - Refer to the title page of the protocol

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Appropriate Questions for DCs

- Submission of forms/Data Submission Table in the protocol
- Completion of forms
- Amended data

CALGB 30004

5.4 Data Submission: Forms should be submitted to the CALGB Data Management Center (DMC) in compliance with the Data Submission schedule below. There are three options for submitting forms that use the following barcodes and conventions:

- the forms may be faxed to the DMC at 919 416 4500. Please note that the four conventions and the form id ("formap") must appear on the form. Copies must be 100% of the original form size.
- the forms may be mailed to the CALGB Data Management Center, First Union Plaza, Suite 340, 2700 West Main Street, Durham, NC 27705. Please note that the four conventions and the form id ("formap") must appear on the form. Copies must be 100% of the original form size.
- data may be entered electronically by logging onto the CALGB web site and locating the specific web-ready form.

Form	Submission Schedule
C 076 CALGB Respiratory Measurement Form	Within 2 weeks of registration.
C 708 CALGB 30004 Relapsed/Refractory Stratification Form	
C 500 CALGB Prior Therapy Form	
C 409 Respiratory On-study Form CALGB 30004 Confirmation of Rand Pathology report. For patients who were previously completely resected, please submit to document histologic or cytologic recurrence.	
C 841 CALGB Chemotherapy Dose Form	Complete one form per cycle and submit with follow up forms every 2 cycles.
C 666 CALGB Respiratory Follow Up and Response Form	Every 2 cycles until completion of treatment, then q3 months x 4, at time of progression or death.
C 076 CALGB Respiratory Measurement Form	
C 785 CALGB 30004 Adverse Event Form	Submit at the time treatment is terminated.
C 300 CALGB Off Treatment Notice	
C 400 CALGB Long Term Follow Up Form	18 months after treatment is completed, then q6 months.
C 215 CALGB Secondary Malignancy Form	At presentation of secondary malignancy.
C 113 CALGB Notification of Death Form	At death.

5.4.1 Treatment Type Coding:
The Respiratory Follow Up and Response Form (C-666) and various other forms which need to be submitted require specification of treatment type. The following codes for treatment type should be used for this study:

- 1 = Chemotherapy
- 5 = Follow Up (off treatment)

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Appropriate Questions for Study Chairs

- Eligibility
 - Only the CALGB Group Chair or an Executive Officer may approve an eligibility exception.
 - Not Study Chairs, Data Coordinators, or the Registrars.
 - Exceptions are RARE.
- Treatment
- Dose modification
- Other clinical questions
- If you cannot reach your Study Chair, contact the DC

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Appropriate Questions for Help Desk

- Web applications
- Passwords
- CALGB Help Contact Information
 - (877) 44-CALGB
 - calgb-support@calgb.duhs.duke.edu

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Appropriate Questions for the PCO

- The Pathology Coordinating Office (PCO) or other receiving lab
 - Sample procurement
 - Sample submission
- PCO contact information (Ohio State Univ.)
 - www.calgb.org contains hotlink to PCO web site
(does not require password)
 - E-mail: path.calgb@osumc.edu
 - Phone: (614) 293-7073
 - Fax: (614) 293-7967

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AdEERS Questions

- Policy-related, medical questions and administrative issues, contact:
 - AdEERS MD Help Desk: (301) 897-7497
 - AdEERS MD Email: AdEERSMD@TECH-RES.COM
- Technical and training issues, contact:
 - NCI CTEP Help Desk: (301) 840-8202
 - NCI CTEP Email: ncictephelp@ctep.nci.nih.gov

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Training Tab

- Group meeting agendas and presentations posted here prior to the meeting
- Recordings of CRA Orientation and portions of the Group Meeting after the meeting
- New Member Orientation (*currently being revised*)
- IPEC
- Lost to Follow-Up
- IS applications

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E-Form submit

- For any technical issues completing the forms, contact Susan Sutherland at susan.sutherland@duke.edu
- Examples of technical issues

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Lost to Follow-up Policy Update

- Run-in period has passed
 - Patients who were not confirmed as lost will appear on the delinquency list as *alive*
 - Patients who were confirmed as lost will not appear on the delinquency list
- Revised Lost to Follow-Up Form (C-1742)
 - Submit to notify DC patient is lost (instead of follow-up form)
 - Submit every 6 months for 2 years until criteria for lost to follow-up status are met

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AdEERS Clarification

- Submit one AdEERS report per course/cycle.
- Amend existing report if:
 - AEs worsen
 - New AEs occur that require Expedited Reporting

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New Staff Assistant

- Valerie Duke
- 919-668-9355
- valerie.duke@duke.edu
- Call if you need assistance contacting the study DC
- E-mail or call for C-030 Forms

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