



Introduction to CALGB Statistical Center and Data Processing

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*CRA Committee: New CRA Session
2010 Summer Group Meeting*

Objectives

- Understanding the organization of the CALGB Statistical Center
- Describe frequently used protocol sections
- Directing questions to the appropriate contact
- Form completion and submission guidelines
- Describe the flow of data at Data Operations

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
 - Patient Registration, Reporting System, Secure Mail, Specimen Tracking System
- Biostatisticians

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Frequently Used Protocol Sections

- Title Page
- Eligibility Criteria
- Required Data
- Registration/Data and Sample Submission
- Treatment Plan

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Frequently Used Protocol Sections

- Dose Modifications
- Ancillary Therapy
- Criteria for Response, Progression and Relapse
- Removal of Patients from Protocol Therapy
- Adverse Event Reporting (AER)

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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 Teleform barcode and enclosures:

- the forms may be faxed to the DMC at 919-419-4990. Please note that the four cornerstones and the form id ("bitmap") 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 3100, 4209 West Main Street, Durham, NC 27709. Please note that the four cornerstones and the form id ("bitmap") 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-660 CALGB Prior Therapy Form	
C-849 Respiratory On-study Form	
C-849 CALGB 30004 Confirmation of Rerol 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 OR Treatment Notice	
C-800 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 (RR treatment)

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Data Coordinators Contact Info

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 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 or protocol coordinator

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Appropriate Questions for the CALGB 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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Directing questions to the correct study team member will get you an answer more quickly and accurately!

Completing a Form

Before submitting forms:

- Check data on forms against supporting documentation.
- Check forms to ensure data are consistent with previously submitted data.
- Retain copies of submitted forms.
- Do not staple in TeleForm barcodes.



Completing a Form

- Leading and trailing zeroes are **required**.

Example: Value = 70; Enter

- Round to the nearest number that will fit in the boxes. Example:

– Lab report states value is < 0.01

– Boxes on the form are .

– Enter data on form as .
and note the actual value on a flow sheet or
C-260 Remarks Addenda.

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Completing a Form

- Value is 1.2 and boxes are .

– Type 0 1 “period” 2 0 .

- Leave fields blank if not applicable.

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Completing a Form

- Preferred method of completion and submission is electronic
- Use a black ballpoint pen to print text.
- Fill in all boxes (including dates) in top, right section of forms.
- Right justify patient ID and study number.
- Leave fields blank if they are not applicable.
- Do not add boxes or decimal points and do not use < or >.
- Submit all pages of multi-page forms.

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Amended Data

- Make a copy of data to be amended to retain a record of data originally submitted.
- Mark an "X" in the "Are Data Amended?" box located in upper, right corner of the form.

CALGB Form:	C-300
CALGB Study No:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
CALGB Patient ID:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Are data amended?	<input checked="" type="checkbox"/> Yes



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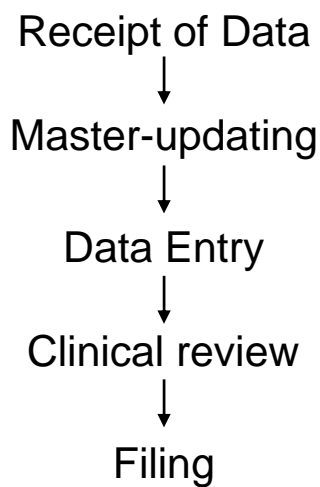
Amended Data

- Cross out incorrect data. Do not use White-out.
- Write correct data to the side and circle. Initial and date the correction.
- Keep a copy and resend to CALGB Statistical Center, Data Operations.
- ***Do not E-submit amended data.***

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Overview of Data Flow at CALGB Data Operations



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Communications Center Staff



- Stamps date of receipt on all pages
- Copies and mails most data to the study chair
- Passes data along to data technicians

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Data Technicians



- Sort data into study bins
- Put data in patient ID order to prepare for master-updating

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Master-Updating

- Quick update of survival and clinical statuses and dates
- Survival – date last known alive or date of death
- Clinical
 - Whether a clinical endpoint (progression, relapse, recurrence) has been met
 - Date last known to have not met a clinical endpoint or date clinical endpoint met
 - Date of last CT, X-ray, MRI
 - Date of last bone marrow biopsy or peripheral blood counts

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Master-Updating

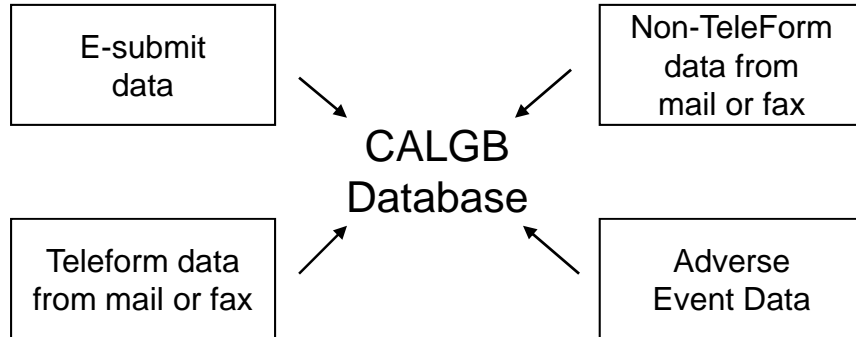
- Data are used to generate delinquency lists
- Data are provided to DSMB for monitored studies
- Data may be used for interim analyses

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Data Entry

Data technicians sort data by type of entry:

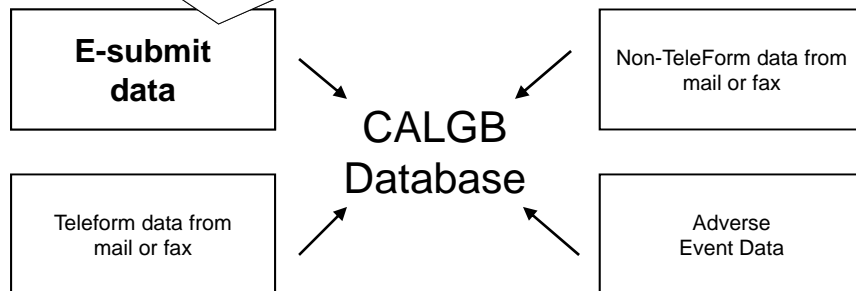


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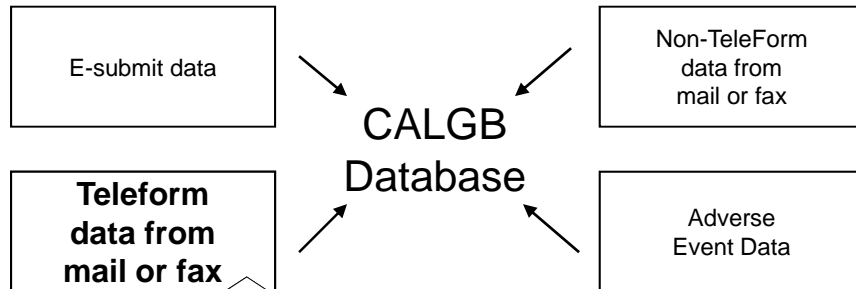
Data Entry

- E-submit data are entered quickly (within 24 hrs of receipt)
- Very little manual verification required



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Data Entry



- Data are scanned into TeleForm Verifier
- Manual verification performed to ensure correct data are exported to database

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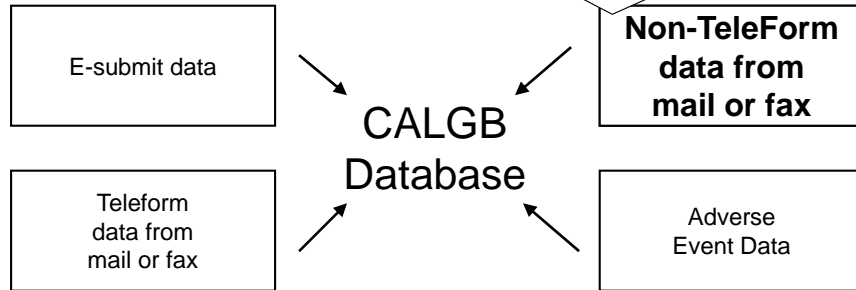
TeleForm Scanner



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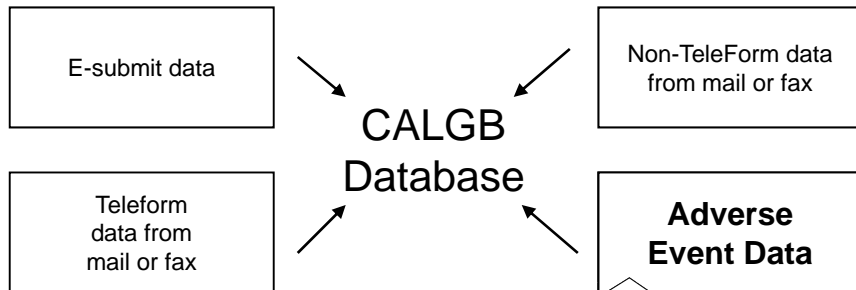
Data Entry

Data are manually entered



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Data Entry



Data are manually entered using application designed for adverse event data

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Clinical Review

Data coordinators:

- Ensure master-updating and data entry are correct
- Review each case for eligibility
- Ensure required data have been submitted
- Review treatment and adverse event data for completeness and accuracy
- Review response and follow-up data against measurement forms, lab reports, and scan reports
- Review other data per study requirements

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Clinical Review

Data coordinators:

- Make corrections to data as needed and send corrections to site if necessary
- Query for:
 - Missing data
 - Incomplete data
 - Data clarifications



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Filing

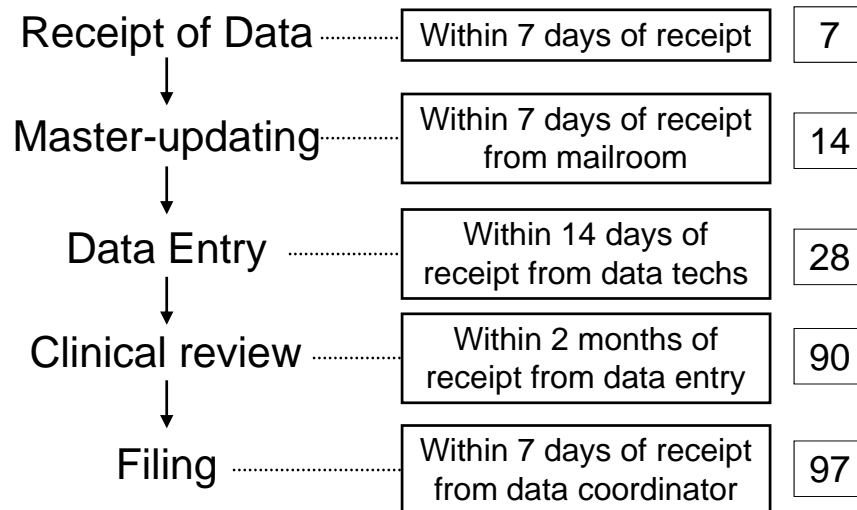


- File room clerk files data by study in individual patient charts
- Data are kept FOREVER!
- We are currently in the process of scanning very old data to make room

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Data Processing Timelines



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CALGB Security Measures

- Guided by Health Insurance Portability and Accountability Act (HIPAA) principles
- Applications use 128-bit level encryption with Secure Socket Layer (HTTPS)
- CALGB systems are separated from the general Internet by the Duke University Health System (DUHS) network firewall
- Traffic is monitored by DUHS and CALGB

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CALGB Security Measures

- Access to the Statistical Center is controlled by magnetic key cards
- Access to the Data Operations file room is controlled by magnetic key card and is limited to even less staff



CALGB Security Measures

- Data are not removed from the CALGB Statistical Center offices except for:
 - Audits
 - Copies of data sent to study chairs
 - Copies may be provided to pharmaceutical sponsors
 - Data electronically submitted to NCI
- Data are either mailed or submitted electronically in a secure manner

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Summary

- Answers to many frequently asked questions can be found in the protocol.
- Be sure to contact the correct person to receive a timely response.
- Electronic data submission is the preferred method.
- Submitted data go through many steps before reaching the data coordinator.
- CALGB has many security measures in place to protect both electronic and paper data.

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