



Statistical Center Update

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CALGB Statistical Center**

*CRA Committee: General Session
2010 Summer Group Meeting*

Objectives

- Patient withdrew - What do I do?
- At treatment end - What do I send?
- Delinquency list - What did I miss?
- IS Applications update

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Withdrawal of Consent

What did the patient withdraw consent for?

- Further treatment
- Sample submission
- Clinical follow-up (e.g., CT scans, blood draws)
- Clinical and survival follow-up

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Further Treatment

Submit:

- End of treatment data (indicate pt refusal as reason for end of treatment)
- Clinical follow-up data (CTs, blood draws) until study endpoint (e.g., progression, relapse)
- Survival data

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Sample Submissions

Submit:

- Signed statement from patient or patient's physician withdrawing consent for further sample collections
- All treatment, AE, and follow-up data as required by protocol.

NOTE: When a patient withdraws consent for sample use/collection, no sample previously submitted can be used.

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Clinical Follow-up

Submit:

- Signed statement from patient or patient's physician withdrawing consent for clinical follow-up
- Survival data per protocol requirements

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Survival Follow-up

- Submit signed statement from patient or patient's physician withdrawing consent for (clinical and) survival follow-up
- If patient has already reached end of clinical follow-up, then patient only needs to withdraw consent for survival.
- No future data should be submitted.
- Previously submitted data or data required prior to withdraw of consent may be queried for.

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Non-compliant Patients

- A patient's refusal to comply with follow-up visits or requirements is not considered to be an implied withdrawal of consent for follow-up.
- Institutions must follow the Confirmation of Lost to Follow-up procedure (section 8.1.2.6) for a non-compliant patient who has not specifically withdrawn consent for follow-up.
- P&P Section 8.1.2.5

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Example Withdrawal of Consent Statement

- "I, [Patient initials, CALGB ID], withdraw my consent to be followed with respect to clinical status/survival status on CALGB study # XXX."
 - Patient signature/date (Patient signature, except initials, can be redacted from submitted copy.)
- "[Patient initials, CALGB ID] withdrew consent to be followed with respect to clinical status/survival status on CALGB study # XXX."
 - Physician signature/date

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Summary

- Be specific- what did the patient withdrawn consent for?
- A signed statement from patient or physician may be required
- Contact the data coordinator for protocol-specific data submission requirements.

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Post-treatment Follow-up

- Protocol-specific depending on study objectives
- In general, studies require clinical follow-up until study endpoint is met (e.g., relapse, progression)
- Studies require survival follow-up for protocol specified time

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Patient Never Started Treatment

- Protocol specific- check with data coordinator if unsure
- Randomized study (Phase II or III)
 - Relapse or progression
 - New malignancy
 - Survival
- Non-randomized study (Phase I or II)
 - Submit C-300 with “Treatment never started” marked
 - No additional data is required

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New Data Submission Schedule Template

Form*		Submission Schedule
Baseline		
C-1911	80802 On-Study Form	Within one month of registration
C-2000	Solid Tumor Evaluation Form	
Report	Baseline CT/MRI report	
Report	Pathology report to confirm HCC diagnosis	
C-1922	CALGB 80802 Imaging Form*	
Sample Submission		
C-1442	Pharmacogenomic Submission and Quality Assurance Form	Submit form to PCO with samples and to the CALGB Statistical Center.
C-1928	80802 Sample Submission Form	
Treatment		
C-1912	80802 Treatment Form**	Each cycle (q 3 weeks) during protocol treatment.
C-1913	80802 Adverse Event Form***	
C-1914	80802 Follow-up and Response Form	Every 2 cycles (q 6 weeks) during protocol treatment.
C-2000	Solid Tumor Evaluation Form	
C-1922	CALGB 80802 Imaging Form* CT/MRI reports	
Follow-up (Post-treatment)		
C-1914	Follow-up and Response Form	Every 3 months for 1 year, then every 6 months for 2

Use CALGB Remarks Addenda (C-260) if additional comments are necessary or additional writing space is needed. If patient never starts treatment, submit Baseline data, a C-1912 80802 Treatment Form to report reason for ending treatment, and Follow-up (Post-treatment) data.

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Delinquency Data

- All delinquent data lists and reports cover all patients that still require follow-up on CALGB-coordinated studies
- Delinquent data lists and reports are not based on protocol-specific form submission requirements.

Delinquent Data

- Delinquent data lists and reports are based on the CALGB minimum data submission requirements, which state that institutions must submit current data
 - Every 6 months for 2 years after patient registration
 - At least annually thereafter while follow-up is required

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Sample Delinquent Data List

Pt ID	Clinical Fup Date	Clinical Fup Status	Survival Date	Survival Status	Delinquent Data	New Survival Status**	New Survival Date**
12345	08/15/2007	In Follow-up	11/28/2007	Alive	Both		
23456	04/02/2008	Terminated	04/20/2008	Alive	Survival	_____	_____
34567	01/02/2008	In Follow-up	06//01/2010	Alive	Clinical		
45678	04/04/2007	In Follow-up	07/29/2007	Alive	Both		

** If only survival data are delinquent, survival date and status may be updated by completing these columns and returning this list to CALGB Data Operations. DO NOT complete these columns for patients still in clinical follow-up.

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Survival Delinquency

- If only survival data are delinquent the current status and date may be submitted on the delinquency report
- Data should also be submitted on:
 - Study-specific follow-up form
 - C-400 Long-term Follow-up Form (if allowed per protocol)
 - C-113 Notification of Death
 - C-900 Survival Data Form

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Clinical Data Delinquency

- Need updated disease information
 - CT/MRI/PET scan
 - CBCs, Plts, bone marrow
 - Protocol specific requirements
- Survival information is usually not enough
 - E.g., Survival date is 6/1/2010, but clinical date is 1/2/2008

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Lost Patients

- Patients who cannot be contacted, but have been "lost" for less than 2 yrs will still appear on the delinquency list with a status of Alive
- When all requirements (see C-1742) have been met, the patient status will be changed to Lost.
- Patient will appear in the Lost Patient section of the delinquency list, but do not count towards institution's overall delinquency

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IS Updates

- Query Tracking System (QTS)
- caAERS
- OPEN

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Resources

- Withdrawn consent- P&P section 8.1.2.5
- Patient never received treatment- P&P section 8.1.2.3
- Delinquency lists- 2.10.2
- Lost to follow-up- 8.1.2.6

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