



CALGB Statistical Center Update

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CALGB Group Meeting, June 2009

For CALGB Participants Only

Objectives

- IS Application Updates
- RECIST Implementation
- CTCAE v.4 Implementation
- CRA Orientation
- QuickLinks on www.calgb.org
- E-submit
- Data submission tips

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Specimen Tracking System

- Replaces LabTrak for tracking specimen submissions
- Training for beta testers taking place
- System release date is dependent on the results of the beta test

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caBIG Cancer Adverse Event Reporting System (caAERS)

- New system for reporting expedited and routine AEs
- Beta testing will begin soon
- Active Phase II studies
- Site selection for testing in progress

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Oncology Patient Enrollment Network (OPEN)

- New system for patient registration
- Beta testing to begin soon with Study 140503
- Other studies to follow

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RECIST Implementation

- New criteria to be discussed by Nathan Hall, MD, PhD
- Developing new forms to collect measurements
- Check protocol to determine which RECIST version is being used on each study.

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CTCAE v.4 Implementation

- New criteria to be discussed by Dr. Chen and Ann Setser
- Depending on implementation schedule, new forms may be released
- Check protocol to determine which CTCAE version is being used on each study.
- Until official release continue using appropriate CTC version.

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CRA Orientation Online Training

Now available on the training section of the CALGB website.

Cancer and Leukemia Group B
Tomorrow's Cancer Treatments Today

Home | Member Site | Studies | IS Applications | Directory | Resources | **Training** | Policies | Funding | www.calgb.org

Monday June 22, 2009

CALGB Web Search
[Search Box] Search

CALGB Site Navigation
[Site Navigation] Site Navigation

Web Site Help
All documents require Adobe Acrobat PDF software. Download Adobe Acrobat Reader for free

CALGB Training
The CALGB is committed to providing its members with the education and training to enhance and support clinical research studies.

Resources available include:

- Training events
 - CALGB Summer Group Meeting - June 25-27, 2009
- Online training
 - Getting Started
 - Orientation Programs for New CALGB Members
 - **CRA Orientation Online Training**
 - New Member Orientation
 - Study Chair Workshop - coming soon

Training FAQs

- How are the training topics chosen?
- I have an idea for a training topic. Whom do I contact?
- If I have a question or comment about a policy, whom do I contact?
- I have trouble with the CALGB Online Training system. Whom do I contact?

CRA Orientation Online Training

- Provides core information about CALGB policies and procedures to all new CRAs and oncology nurses, regardless of their specialty
- Must have a CALGB Participant ID and Web applications password to enroll
- Certificates of completion may be submitted to SoCRA as proof of continuing education
- See the June CALGAB CRA Perspective article and the training section of the CALGB website for more information

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Quick Links on CALGB website

The screenshot displays the CALGB website interface with several key sections highlighted:

- Quick Links:** A sidebar menu containing links such as "Updated List of Studies with Termination of Patient Follow-Up (05/2009)", "Electronic Submission of CALGB Data Forms (09/25/2007)", "CALGB Approved Transplant Centers (09/2007)", "Data and Safety Monitoring Board (DSMB) Statements (12/2008)", "CALGB Accrual Data and Protocol Listing (11/2008)", "Common Toxicity Criteria MedDRA Codes v3", "Common Toxicity Criteria MedDRA Codes v2", "CALGB Participation in Intergroup Protocols", "CALGB Status Sheets (05/15/2009)", "List of Supplied Agents for CALGB Protocols (10/16/2008)", "TeleForm Instructions", "CALGB Approved Institutional Cytogeneticists (12/15/2008)", "DCP Protocol Credit Assignment", "List of Credentialed Surgeons for CALGB 140503 (03/23/2009)", and "2009 Executive Committee Conference Call Schedule".
- Studies FAQs:** A section titled "Studies FAQs" with questions like "Why can't I cut and paste material from CALGB studies on the web site?", "Where can I get an Investigator's Brochure when I submit a CALGB protocol to my IRB?", "How soon after registration does treatment need to begin in CALGB trials?", and "I can't reach a Study Chair with a should I cor".
- Common Forms:** A list of forms including "A-006 CALGB Patient Transfer Form", "Patient Race and Ethnicity Form", "C-113v4 CALGB: Notification of Death", "C-215v4 CALGB: Secondary Malignancy Form", "CALGB: Remarks Addenda", "C-300v5 CALGB: Off Treatment Notice", "C-400v4 CALGB: Long-Term Follow-Up Form", "C-560v3 CALGB: Prior Therapy Form", "C-1001v2 CALGB: New Primary Cancer Form", and "C-1742v2 CALGB: Confirmation of Lost to Follow-up Form".
- Recent Stud:** A section titled "Recent Stud" listing "IMPENDING CALGB 1003 for prev of 6 after ASCT" and "CALGB 3040 30605 ERLG LETTER: IMM ACTION RE (05/27/2009)".
- CALGB Past Postin:** A section titled "CALGB Past Postin".

E-submit Update

- E-submit usage has increased since November meeting.
- Thanks to those who completed the E-submit User Survey.
- See the June CALGAB Training article for results
- Overall, results were very positive.
- Some issues were identified that we are working to resolve.

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Data Submission Tips

- Date fields
 - 1-part date field (true date)
 - Enter entire date in one field
 - Used when entire date is required
 - 3-part date field
 - Enter each part of date into three separate fields
 - Used when entire date may not be known or is not required.
- Print and proofread forms prior to submission.
- Number flow sheets continuously throughout study.

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Summary

- Beta testing underway for new IS Applications (Specimen Tracking, caAERS, OPEN)
- RECIST 1.1 and CTCAE v.4 to be implemented soon. Updates to implementation process will follow.
- Online CRA Orientation is now available. See the Summer CALGAB and the training section of the CALGB website.
- Quick Links on CALGB website provide easy access to helpful tools.
- E-submit usage has increased. We are working to resolve issues so E-submit is even easier.

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**Cancer and Leukemia Group B
Summer Group Meeting
2009 Chicago, IL
June 25-27**