



# Statistical Center Update

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*For CALGB Participants Only*

## Objectives

- Forms
- Pre-registration
- Current IS Projects
- Drug Shipments
- CALGB Studies 40502 and 40503

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*Slide 2*

## "E-Submit"

- E-submit is the preferred method of submission for data forms.
- 63% of forms were submitted electronically May-August 2008.
- If submitting electronically, **do not** fax or mail the forms too.
- **Do not** E-Submit amended data.

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*Slide 3*

## C-1820 AE Addendum Form

- Submit when additional pages are needed for an AE form.
- Use same reporting period dates as study-specific AE form.
- Enter page numbers. Count the study-specific AE as page 1.
- Do not submit instead of study-specific AE form.

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*Slide 4*

## Other Form Items

- C-1742 FAQs posted under CRA Resources on CALGB website
- Use the correct version of the CTC. Some studies still use CTC v.2. Correct MedDRA codes are on the CALGB website.

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*Slide 5*

## Pre-registration

### Allows:

- Pre-study samples to be submitted to assess eligibility (10603 and 80405) or treatment (10501)
- Majority of registration data to be collected so patient can be randomized quickly (140503)
- Sample submission (9665)

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*Slide 6*

## Pre-registration

Will be used on:

- 30506: Risk assessment (stratification factor)
- 30702: Genome-guided therapy

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## Pre-registration

- Not used for all studies.
- Available online.
- Must be completed prior to registration/treatment assignment.
- Separate pre-registration provided.
- Check data submission schedule for patients who do not proceed to registration.

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*Slide 8*

## Current IS Projects

- Specimen Tracking System
  - Demo available at IS Kiosk
    - Friday: 1:00 p.m. – 3 p.m.
    - Saturday: 9 a.m. – 12 p.m.
- caAERS
- Query Tracking
- Clinical Data Management System (CDMS)

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*Slide 9*

## Drug Shipments from the Pharmaceutical Management Branch (PMB)

- Contact the data coordinator when transferring a patient to a new physician or site.
- Coming soon: Ability to provide FedEx or UPS account information to expedite drug shipments.
- Will be collected at registration for studies that do not already require expedited shipment.

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*Slide 10*

## 40502 and 40503 C.S. Consents

If patient answers YES to *“My specimen may be used for the research described above” (Model Consent question #1)*, register patient to the correlative science companion.

- 150714 is the C.S. companion to 40502.
- 150605 is the C.S. companion to 40503.

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*Slide 11*

## 40502 and 40503 PG Consents

If patient answers YES to *“My specimen may be used for the genetic research described above” (Model Consent question #2)*, register patient to the pharmacogenomic companion.

- 60704 is the PG companion to 40502.
- 60605 is the PG companion to 40503.

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*Slide 12*

## 40502 and 40503 Kits

- For samples shipped to Park Laboratory (Janet Scott):
  - **Kit includes:** 4 CellSave tubes for CTCs  
*NOTE: Fill tubes completely.*
  - **Site provides:** EDTA (purple top) tubes for CECs
- The 40503 kit also includes 4 CPT tubes for Proteomics. *(These samples are shipped to the PCO.)*

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*Slide 13*

## 40502 and 40503 Kits

- 40503 Kit instruction sheet is available as a handout and will be posted on web site.
- 40502 Kit instruction sheet coming soon.
- Order starter supply of kits when submitting protocols to IRB.

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*Slide 14*

## 40502 and 40503 Samples

Prior to shipping CTC and CEC samples to Park Laboratory at UCSF:

- Alert Janet Scott and Eddie Sosa by:
  - Fax: (415) 476-8218
- OR**
- Email: [jscott@cc.ucsf.edu](mailto:jscott@cc.ucsf.edu) and [sosae@cc.ucsf.edu](mailto:sosae@cc.ucsf.edu)
- Especially important for samples shipped on Friday
- CRA will receive a reminder phone call from Statistical Center Data Coordinator after registration (*until protocol amendment*)

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*Slide 15*