



Statistical Center Update

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Objectives

- Describe the CALGB implementation plan for:
 - CTCAE v. 4
 - OPEN
 - RECIST 1.1
- Overview of RECIST 1.1

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CTCAE V4 Implementation

- CTCAE v.4 will be used on all studies activating after Nov. 1, 2009
- We are identifying which currently active and closed studies to convert
- Adverse event forms for studies using CTCAE v.4 will have "CTCAE V4" in parentheses in the form title.
- Protocols will say to use the "Active version" of the CTCAE

CALGB: 30506 ADVERSE EVENT (AE) FORM (CTCAE v.4)

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OPEN Implementation

- 140503 and 40601 are the pilot studies for OPEN
- Look for conversion of these two studies early next year
- Active studies and studies in development will be converted soon after
- Registration worksheets and protocols template changes are in progress

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RECIST 1.1 Implementation

- Solid tumor protocols activating after Nov 1, 2009 will use RECIST 1.1
- Currently active studies will not convert to the new criteria.
- Studies using RECIST 1.1 will require the submission of the C-2000 Solid Tumor Evaluation Form.

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Measuring Target Tumor Burden

- Measure in at least one dimension with a minimum size of:
 - 10 mm by CT scan (regardless of scanner type) and MRI
 - 10 mm caliper measurement by clinical exam (when superficial)
 - 20 mm by chest X-ray
- Include all target lesions:
 - Up to a maximum of *five* lesions
 - Maximum of two lesions per organ
 - Representative of all involved organs

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Assessment of Lymph Nodes

- Target nodes measured in the *short* axis
- Definitions:
 - Target lesion: short axis ≥ 15 mm
 - Non-target lesion: short axis 10mm to < 15 mm
 - Normal size: short axis < 10 mm
- *Short axes* of target nodes added to the sum of diameters

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Summary of Target Lesions

- Non lymph node lesions ≥ 10 mm by CT or MRI
- Lymph nodes with short axis ≥ 15 mm by CT or MRI
- Lytic bone lesions that meet definition of target lesion
- Cystic lesions that can be re-measured and meet definition of target lesion

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Complete Response

- Disappearance of all lesions
- All pathological lymph nodes (target or non-target) must have reduction in short axis to <10 mm
- *The sum may not be "0" if there are target lymph nodes*
- Normalization of tumor marker level

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Progressive Disease

- Target Lesions:
 - 20% increase in the sum of diameters taking as reference the smallest sum of diameters recorded since the treatment started (nadir)
 - AND
 - Minimum 5 mm increase over the nadir
 - Any new lesion

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Comprehensive online training for
RECIST 1.1 is available on the
CALGB web site training tab

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Summary

- Check studies for updates involving:
 - CTCAE v. 4
 - OPEN
 - RECIST 1.1
- RECIST 1.1 contains many changes to the process for assessing response.
- Complete the RECIST 1.1 training located on the CALGB web site.

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