



## Statistical Center Update

Susan Sutherland  
CALGB Statistical Center

CALGB CRA Committee Meeting, June 2007

---

*For CALGB Participants Only*

## Objectives

- CDUS Reporting
- TeleForm Data Entry

---

*For CALGB Participants Only*

*Slide 2*

## CDUS Reporting Overview

- Primary resource of clinical trial data for the Division of Cancer Treatment and Diagnosis(DCTD) and the Division of Cancer Prevention(DCP).
- Regulatory, scientific, and administrative data monitoring tool
- Applies to Phase I, II, and III studies

---

*For CALGB Participants Only*

*Slide 3*

## NCI-Sponsored Studies Requiring CDUS Reports

- Treatment trials utilizing NCI-supplied investigational agents
- Treatment trials utilizing non-NCI agents (commercial or investigational);
- Non-treatment trials (accrual >100 pts.)

---

*For CALGB Participants Only*

*Slide 4*

## CDUS Reporting Overview

- Submit data per protocol
- Submit correct and complete data
  - Report valid AE grades
  - Specify event when using an Other, specify code
  - Ensure AdEERS reports match AE forms (event, grade, and attribution)
  - Report only one Grade 5 event per patient

---

*For CALGB Participants Only*

*Slide 5*

## Summary

- CDUS used to report clinical trial data to the NCI.

---

*For CALGB Participants Only*

*Slide 6*