

**National Cancer Policy Forum
Workshop on
Multi-Center Phase III Clinical Trials and NCI Cooperation Groups
Washington, DC ♦ Day 2 - July 2, 2008**

**Industry Session 3:
Data Collection Standards
to Establish Safety and Efficacy**

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Session 3: The Landscape

- a. **Informed consent**
- b. **Case report forms**
- c. **Independent review (adjudication) committees**
- d. **Monitoring methods**
- e. **Extent of databases**
- f. **Publicity of data: trials existence and results**

Session 3: Questions

1. **What data are needed to show safety and efficacy of cancer therapeutics?**
2. **What changes could be made to improve upon current requirements?**
3.
 - a) **Is it possible to create a set of standards with sufficient breadth and interpretability to provide broad applicability to cancer?**
 - b) **How would these standards address the variability in clinical trials such as prevention trials, treatment trials, or trials aimed at specific cancers with unique characteristics?**