

# **National Cancer Policy Forum Workshop**

## **Improving the Quality of Cancer Clinical Trials**

Welcome and Opening Remarks  
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# Our Goal

Design and execute clinical trials which: (1) provide information that better informs decisions and plans of those responsible for developing a new cancer therapy; (2) move new diagnostic tests and treatments more rapidly towards regulatory approval and incorporation into clinical practice; and (3) reduce the costs of this lengthy process.

# New Clinical Trial Designs

- Trials in patients earlier in drug development
- Prospective use of data to condense trials
- Testing multiple agents simultaneously
- New measures of tumor response
- How to optimally use preclinical information

# Molecular Imaging

- Validate use of imaging tests for selection of treatment
- Validate use of imaging tests for assessment of response
- Standardization of imaging practices to allow comparative analyses
- Moving from preclinical models into the clinic more rapidly
- Efficiencies gained versus costs of imaging procedures

# Screening for Predictive Markers

- Validate use of biomarkers to select therapy
- Validate use of biomarkers to assess response
- Validate use of biomarkers to identify patients with pharmacogenetic contraindications
- Costs of performing biomarker measurement on blood or tissue in real time to inform clinical decisions
- Combinations of markers

# Collaborations Among Academia, Pharma, Biotech and Government

- Reduction of limits on sharing data and tissues
- Standardization of data and records
- Fair sharing of costs of clinical trials, to include payors.

# Regulatory Issues

- Guidance from FDA regarding information required to support clinical use of markers and imaging tests
- Earlier use of combinations, when supported by strong preclinical data
- Enforced post-marketing surveillance with adequate funding, to justify provisional regulatory approval
- Can trials provide additional information that would aid the FDA in its decisions?