



Community Clinical Oncology Program:

Response to IOM Report

Lori Minasian, MD

Acting Director, Division of Cancer Prevention
Chief, Community Oncology and Prevention
Trials Research Group





Community Clinical Oncology Program

- **Three Components (three RFAs)**
 - **CCOP**
 - Community Consortium to Accrue
 - **Minority Based CCOP**
 - Minority Catchment Area CCOP to Accrue
 - **CCOP Research Base**
 - Cooperative Group
 - Cancer Center
 - Funded to Design/Develop, Conduct Clinical Trials in Cancer Prevention and Control
 - Primary mechanism to fund Groups to conduct trials other than treatment



CCOP Research Bases Research Focus

- **Scope of Research Grown over Time**
- **Cancer Prevention Trials**
 - Phase III trials interventions to reduce risk of developing cancer
- **Cancer Control Trials**
 - Include methods for early detection of cancer, interventions to improve quality of life, treat symptoms or toxicities, and improve continuing and palliative care
 - QOL on Treatment Trials
 - Ancillary Studies to Treatment Trials
- **Harmonization**
 - Data Elements Different



IOM Goal #1

- **Improve the Speed & Efficiency of Design, Launch, Conduct of Clinical Trials**
- **Eight Cooperative Groups Funded as CCOP Research Bases**
 - **6 Will Need to Re-Compete this summer**
- **CCOP Research Base to describe Transitions**
 - **RBs will describe their efforts for overall transition**
 - **RBs expected to develop research plan for cancer prevention/control in the new structure**



IOM Goal #1

- **Streamline & Harmonize**
 - **Cancer Control Trials on CTSU**
 - Use of RSS, Investigator Registration, etc
 - Audit Guidelines Apply to RBs
 - Adverse Event Collection
 - Trials on CTSU & in CTEP Enterprise
 - **Consistent Ongoing Efforts to Coordinate Process for Trials Between CCOP & CTEP**
 - **Unique Needs for Cancer Control Trials**



Partnerships:

- **Interventions often not drugs**
- **Encourage Collaborative Funding**
 - **Investigator initiated grant (NIH, ACS, etc)**
 - Grant funds intervention + other
 - Study conducted through Groups as CC study
 - ECOG Survivorship Study
 - CALGB 2 nutritional interventions
 - EDRN funded grant for clinical validation of biomarker assay
 - Allows other investigators to partner with Groups
 - **Seeking Grant Funding Lengthens Trial Development Timelines**



IOM Goal #2

- **Incorporate Innovative Science & Trial Design**
- **Cancer Control Endpoints NOT same as Treatment**
 - Encourage Novel Trial Designs
 - Question should Dictate the Trial Design
 - Assessments for Response Differ in CPC
 - Consensus on Trial Design Can Take Longer
- **Encourage Translational Studies on CPC trials**



IOM Goal #2

- **Incorporate Innovative Science & Trial Design**
- **Bio-repository with Prevention Trials**
 - Mostly Blood (WBC, serum)
 - Tissue for Cancer Endpts
 - Not Included in Tumor Banks...except GOG
- **Bio-repository for Selected Cancer Control Studies (?)**



IOM Goal #3

- **Improve Prioritization, Selection, Support**
- **Disease Steering Committees**
- **Symptom Management SC**
 - **DCP Always Included Outside Expertise**
- **Prevention**
 - **Pre 2000: Special Study Section with Expertise Specific to Study Design**
 - **No Standing SC; Ad Hoc with Study Specific Expertise**



IOM Goal #3

- **Improve Diversity**
- **Prospective Minority Recruitment Plans**
 - Diversity of Institutions (focus on minority pop)
 - Modification Eligibility Criteria
- **CCOP Strategic Plan**
 - Identify Relevant Research Questions in Underserved Populations for study by Research Bases
 - Develop trans-disciplinary working group
 - ASCO/NCI Health Disparities Research Collaborative Project

ASCO/NCI Cancer Disparities Research Collaborative Project

- ASCO Health Disparities Advisory Board and Research Committee
- Goal: Increase collaboration among academic , community and public institutions to jointly define and test solutions to eliminate cancer disparities
 - Phase I: Generate Consensus Statement with Recommendations (e.g., priority research questions, methodologies for interoperable data collection; tactics to incorporate ancestry genes and germline DNA)
 - Phase II: Selection of Specific Research Projects using collective data bases



IOM Goal #4

- **Incentivize Participation of Patients/Physicians**
 - **Revising Funding Model for Sites and Investigators**
 - **Exploring Ways to Incorporate Multiple Principal Investigators in CCOP grant structure**
 - **Seeing Changes to Health Care Delivery Reflected in CCOP Structure**
 - **Initiated Teleconference Calls to Share Information Across CCOP Network**



Patients Participating on Trials

- **Klabunde, JNCI 2011**
- **Editorial: Accrual: Let's Look at the Physicians**
 - **58% Americans Greatly Value Clinical Research**
 - **> 70% would consider participating**
 - **6% Had Physician Recommend Participation**
- **Mayo Clinic Survey of Patients Seen**
 - **78% Expected The Physicians to Inform Patients about Clinical Trials**
- **Many Physicians Already Listed as NCI Investigators do not Accrue**