

## **58<sup>th</sup> Meeting of the NCI Director's Consumer Liaison Group, September 21-23, 2011**

### **Optimizing Clinical Trials**

The following is a list of ideas about changes, improvements, and activities that the cancer research community must undertake related to cancer clinical trials in order to capitalize on recent cancer research discoveries. This list was generated by DCLG members during a wrap-up session of the September 2011 meeting. To frame the discussion the following questions were posed to members: What needs to change within the current clinical trial system in order to take advantage of new molecular science? What can the advocacy community do to create a broader understanding about the need for change within the clinical trials system, and how can it support these changes?

#### **Infrastructure**

- Implement a common IT infrastructure for the cancer clinical trials network
- Find ways to match/connect electronic health records with cancer clinical research
- Create standards for tumor profiling and characterization technologies
- Standardize tools for tissue collection and patient care across institutions conducting clinical trials
  - Pool resources across the NCI networks
  - Incentivize the use of tools and compliance with standards (provide a blueprint with corresponding budget for implementation)

#### **Patient Access and Selection**

- Increase patient access to clinical trials
- Increase community oncologists' access to the clinical trials system
- Better identify which patients should be enrolled in which clinical trials; as a routine part of the clinical trials process, screen patients for the relevant mutation/target as part of eligibility criteria; larger sample sizes needed than for typical treatment trials
  - Need reimbursement for this screening. What is the true cost of a molecularly driven trial? Need to broaden what is reimbursed as part of a trial
  - Concern of patient fatigue if only 20% are eligible
- Improved understanding of the importance of biomarkers in determining who will benefit from a particular treatment
  - Community needs increased access to testing sites
- Lessen the impact of comorbidities on patient eligibility
  - Ensure comorbidities are necessary, rather than standard exclusions
- Research and develop more reliable diagnostics with clinical utility
  - Patient reimbursement for diagnostic tests
  - Standard operating procedures for the use of diagnostics in community labs

## Science

- Understand the scientific challenges and limitations to drug discovery, particularly drug combinations
  - Consider what the non-drug opportunities might be
- Better integrate phase 0 trials into the clinical trial process; expand utilization of this pre-clinical activity
- More closely scrutinize a phase 2 trial before proceeding with a phase 3 trial
  - Look for big patient benefit, not marginal results, before moving to phase 3 (i.e. have a healthy skepticism of the clinical trial data)
- Improve prioritization of phase 3 trials across all cancer types
- Integrate CBPR principles into the creation, development, and conduct of clinical trials

## Communication and Education

- Understand trial design options and ask questions. Support researchers in considering all the options and utilizing the most appropriate trial design for each particular study
  - Promote a better understanding of adaptive trial design and its appropriate use (not a fit for all studies)
- Educate patients about the importance of the clinical trial process and their participation
  - Be able to address skepticism
  - Understand new clinical trials (biomarker based) and how to explain them to newly diagnosed patients
  - Alternatively, savvy patients: Why go on a trial if science is moving faster than clinical trial system?
- Educate IRBs about the patients' perspective on reasonable/relative risk related to tissue collection, testing, and other procedures that have the capacity to inform treatment decisions
  - Address when IRBs are protecting the institution vs. protecting the patient
  - Work with a national organization