

# The Disease Committee Perspective

John A “Drew” Ridge MD, PhD

Fox Chase Cancer Center

Co-Chair Head and Neck Steering Committee

# Clinical Trials Working Group

## Prioritization/Scientific Initiatives (2005)

- Establish an Investigational Drug Steering Committee to collaborate with NCI in early phase drug development
- Establish a network of Steering Committees to address design and prioritization of phase III trials
  - Intergroups
  - Cooperative Groups
  - SPOREs
  - Center Centers
  - “broad oncology community”
- Enhance patient advocate and community oncologist involvement in clinical trial design and prioritization through representation on Steering Committees
- Establish a funding mechanism and prioritization process to ensure that the most important correlative science and quality of life studies can be initiated in a timely manner

# Goals of the Scientific Steering Committees

- Increase the transparency and openness of the trial design and prioritization process
- Enhance patient advocate and community oncologist involvement in design and prioritization
- Convene Clinical Trial Planning Meetings to identify critical questions, unmet needs, and prioritize key strategies.

# Scientific Steering Committees

- Disease-specific
- Investigational Drug
- Symptom Management and Health-Related Quality of Life
- Patient Advocate
- Clinical Imaging

# Disease-Specific Steering Committees

- Brain Malignancies (2010)
- Breast Cancer (~2008)
- Gastrointestinal (2006)
- Genitourinary (2008)
- Gynecologic (2006)
- Head and Neck (2007)
- Leukemia (2009)
- Lymphoma (2009)
- Myeloma (2009)
- Pediatric and Adolescent Solid Tumor (2011)
- Pediatric Leukemia and Lymphoma (2011)
- Thoracic Malignancy (2008)

# Roles of the Disease-Specific Steering Committees

- Increase information exchange at an early stage of trial development
- Increase the efficiency of clinical trial collaboration
- Reduce trial redundancy (phase II and III)
- Develop, evaluate, and prioritize concepts for phase III and large phase II trials
- Conduct Clinical Trials Planning Meetings

# Clinical Trials Planning Meetings

- Identify strategic directions for clinical trials in a specific field
  - Reach consensus on the most important clinical trials to conduct
  - Identify portfolio gaps and emerging scientific opportunities
  - Identify innovative trial design opportunities
- Facilitate innovation and collaboration among the broad oncology community

# Steering Committee Members

- Committee Co-chairs
- Representatives (essentially volunteers)
  - Cooperative Groups
  - SPOREs
  - Community Oncologists
  - Biostatisticians
  - Pathologists
  - Patient Advocates
- NCI staff

# Steering Committee Mission Statement

- The [\*\*]SC functions to harmonize an efficient, cost-effective, science-driven, and transparent process that will identify and promote the "Best Science" in [\*\*] clinical research . . . [by addressing the design and prioritization of phase III trials and large phase II studies].

# Steering Committees at Inception

- Uncertain roles
- Broadly Based
  - Steering Committee
  - Task forces
- Variable numbers of Cooperative Groups involved
  - Competitors or partners?
- How would trials be designed?

# Ongoing Process

- Experience varies by
  - Disease site
  - Year of initiation
- Formal procedures may be frustrating
  - PIs face additional level(s) of review
  - Task Force roles remain undefined
    - » Advisory
    - » Developmental
- Clinical Trials Planning Meetings provide real opportunities

# Lessons Learned

- Steering Committees do not function in identical fashion
  - Vulnerable to misunderstanding
- Cooperative groups demanded autonomy
  - They could not be managed
  - They could be enlisted
- There have been conflicting incentives
  - “Efficiency” vs “broad representation”
  - Academic competition
  - Industry sponsorship

# Roles of the Disease-Specific Steering Committees

- Increase information exchange at an early stage of trial development
- *Increase the efficiency of clinical trial collaboration?*
- *Reduce trial redundancy (phase II and III)?*
- *Develop, evaluate, and prioritize concepts for phase III and large phase II trials*
- Conduct Clinical Trials Planning Meetings

# Disease-Specific Steering Committees

- Are largely meeting their articulated goals
- Are increasingly effective with increasing experience
- Should not be affected adversely by the decline in number of Groups
- Are vulnerable to “one size fits all” prescriptions

# A Surgeon's Perspective

John A “Drew” Ridge MD, PhD

Fox Chase Cancer Center

Co-Chair Head and Neck Steering Committee

# Surgeons in the “New System”

- Individual surgeons occupy leadership positions in several of the Groups
- Surgeons (as a members of a discipline) feel disenfranchised by the new structure
  - Alliance (ACoSOG is no longer independent)
  - NRG (NSABP and GOG have lost independence)
  - Disease-Specific Steering Committees (potential reduction in number of co-chairs)

# Unique Suitability of Trials for the NCTN Program

- Understudied disease or population
- Radiotherapy, *surgery*, or imaging techniques
- *Combination* trials
- Therapy optimization trials (eg *alternative regimens*)
- Unlikely to be undertaken by industry
- Provides important *specimen and data resources* for public use

# Observations

- Opportunities for advancement in the Groups are likely to decline
  - Changes in organizational structure
  - Number of trials performed
- Concerns surrounding this are greater among surgical oncologists
  - Particularly applies to Groups with strong surgical traditions

# Challenges

- Maintain and encourage engagement by junior faculty and community oncologists from all disciplines
- Acknowledge and address declines in morale on the part of surgical oncologists in the clinical trials establishment at all levels