

Steering Committee Update
CTAC
March 10, 2010

Today's Presentation

- **Steering Committee (SC) Update**
 - SC Activities & System: Dr. Jaffe
 - Disease-specific SC Scientific Accomplishments:
Dr. Mooney
- **Discuss strategies for future presentations to CTAC regarding the SC process**
- **SC Evaluation to be discussed by Dr. Prindiville following these presentations**

Steering Committee System

- **Components of the System**
 - Current SC
 - SCs in development
 - System transparency
- **Process Metrics**
- **Scientific Accomplishments**

Current Steering Committees

- **Investigational Drug Steering Committee (IDSC):** Provides strategic input into the clinical development plans for new agents for early phase clinical trials
- **Symptom Management and Quality of Life Steering Committee (SxQOL):** Evaluates and prioritizes symptom management intervention clinical trial concepts to be conducted through the CCOP mechanism
- **Patient Advocate Steering Committee (PASC):** Develops and shares best practices for patient advocate interactions in SCs
- **Disease-specific Scientific Steering Committees (SSC's):** Prioritize phase 3 and large phase 2 concepts conducted by the Cooperative Groups

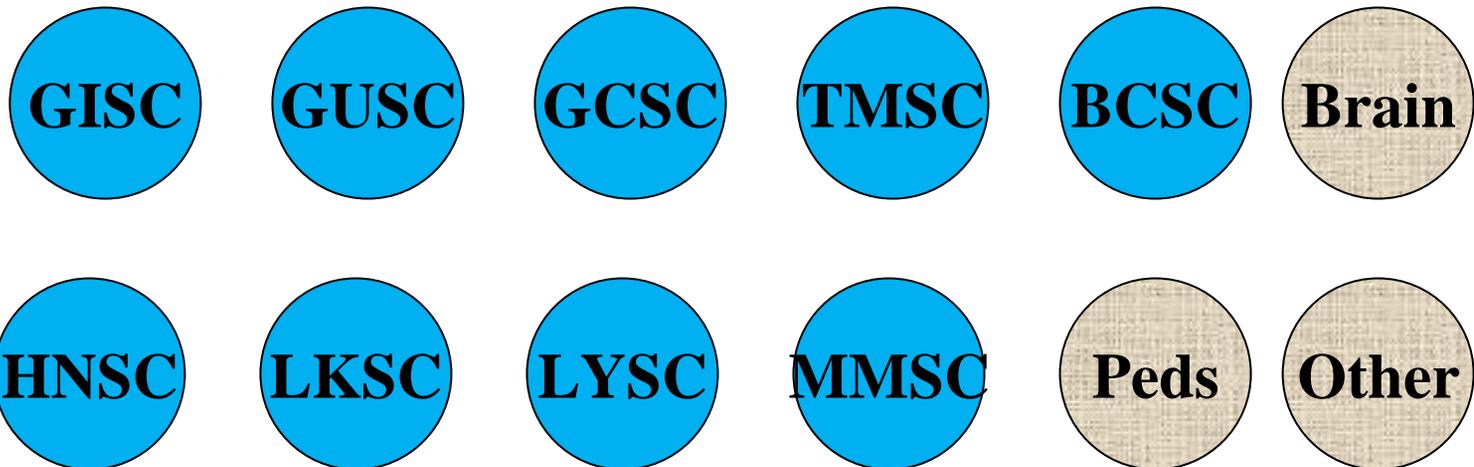
SC's Currently in Development for 2010

- **Clinical Imaging Steering Committee (CISC):**
 - Review concepts with primary imaging endpoints
 - Provide a forum to provide strategic input to in imaging activities in clinical trials
- **Brain**
- **Pediatric**

Scientific Steering Committee System

Clinical Imaging Steering Committee (CISC)

Investigational Drug Steering Committee (IDSC)



Symptom Management and QOL SC (SxQOL)

Patient Advocate Steering Committee (PASC)

System Transparency

- SC membership & meetings:
 - Major components of oncology community represented; Coop Groups, SPOREs, translational scientists, community oncologists, biostatisticians, advocates, NCI staff, and liaisons from non-disease specific SCs
 - Monthly conference calls
 - Face-to-face meetings
- SC Chairs conference calls: Chair, Dr. Joel Tepper
- Newsletters
 - IDSC
 - CCCT
- Written materials
 - Approved concept list
 - Clinical Trials Planning Meeting Executive Summaries or Manuscripts

Steering Committee System

- Components of the System
- **Process Metrics**
 - Number of evaluated concepts
 - Concept approval rate
 - Timelines
 - Accrual
- Scientific Accomplishments

Scientific Steering Committees

- Prioritize phase 3 and large phase 2 trials conducted by the Cooperative Groups
- Discuss unforeseen implementation and accrual issues
- Clinical Trial Planning Meetings:
 - Identify critical questions & unmet needs in a specific cancer
 - Prioritize and develop key strategic priorities for future clinical trials including
 - Foster innovation & collaboration among clinician/scientists

Process Metrics: 2006 – February 2010

SC	Year Established	No. Concepts Evaluated	Approved	No. Trials Open	PIO to 1 st SC Evaluation** (mean, days)
GISC	2006	24	11 (45%)	5	24
GCSC	2006	28	22 (79%)	11	23
HNSC	2007	4	2 (50%)	0	21.5
SxQOL	2007	23	12 (52%)	3	39
GUSC	2008	8	4 (50%)	1	55
BCSC	2008	10	3 (30%)	0	55
TMSC	2008	2	1 (50%)	0	14
TOTAL		98	55 (56%)	20	

** PIO to 1st SC Evaluation: Concepts approved in 2008 - 2009

Steering Committee System

- Components of the System
- Process Metrics
- **Scientific Accomplishments**
 - Clinical Trial Planning meeting summaries
 - Recently approved concepts
 - Other accomplishments

Clinical Trials Planning Meeting

- Identify critical questions & unmet needs in a specific cancer
- Foster innovation & collaboration among clinician/scientists
- Prioritize and develop key strategic priorities for future clinical trials including:
 - Develop a consensus on the most important clinical trials to conduct
 - Near-term (6-12 months)
 - Long-term (18-36 months) initiatives

Organ Site Specific Meetings: Goals

- Accelerate clinical and translational research
- Foster collaborations across funding mechanisms
- Meeting objectives and outcomes aligned with the scientific priorities of the specific organ site
- Managed collaboratively by CCCT and the Translational Research Program (TRP)
- Plan to initiate program in 2010

SC Information: What is most useful?

- System Overviews: Process metrics
- Individual SC presentations as done in the past
 - SC Chairs present accomplishments and recommendations from CTPMs? (IDSC, SxQOL, GISC, HNSC, GUSC have presented)
 - CTEP/DCP Program Officers present approved concepts
- Presentation by extramural representative addressing
 - Scientific successes
 - Barriers
- Written Information