GI Steering Committee

March 4, 2009

GI Steering Committee

- In full operation for approximately 3 years
- Represents 9 cooperative groups
- Has expanded from 4 to 7 task forces

Esophagogastric

Pancreatic

Hepato-biliary

Colon

Rectal/anal

Neuroendocrine

GI stromal tumors

GI Steering Committee

- Initially had a large number of rejections of reviewed protocols
- A higher percentage of protocols are now being accepted (perhaps after revision)
  - 2006- 1 approved, 4 disapproved
  - 2007- 3 approved
  - 2008- 4 approved, 3 disapproved
  - 2009- 1 disapproved, 1 pending
- Task forces are generally very functional and do most of the protocol development work
- Task forces are generally viewed to be a positive force in protocol development

Clinical Trials Planning Meeting

- Name changed from State of the Science Meeting to reflect the desire to have the meetings focused on trial development
- Second GISC meeting CTPM held in November on hepatocellular carcinoma
- Meeting was more effective than previous meeting (pancreas) because the focus on clinical trials was much tighter

CTPM

- Stronger focus on clinical trials
- Very little basic science input as a result
- Totally new clinical trials will not necessarily materialize
- Directions have been established for future work
- Guidelines for clinical trials development have been formulated
- Reasonably good involvement of non-treating physicians
- Establishing end-points

CTPM

- Have discussed small meetings (10-15 people) to address specific critical issues in protocol development
- Neuroendocrine task force developing CTPM for late this fall
  - Developing a CTPM is time intensive
  - Weekly or bi-weekly conference calls for 5 people for almost a year

Neuroendocrine CTPM

- 1/3 lecture/large group discussion
- 2/3 breakouts and breakout presentations
- Examples of topics
  - Which grades of NET can be included in a single study?
  - Can agreement be reached on parameters for tumor grading?
  - Relevant end-points in this slow-growing tumors
  - Which are the most promising new agents?
  - Trial design for screening new agents
  - Appropriate patient subsets for liver directed therapy
    - Quality definition and end-points for liver directed therapy

GI Steering Committee

- Strengths
  - Has improved the interaction and cooperation between the cooperative groups
  - Has allowed rapid action on critical issues (responding to recent information on k-ras and cetuximab in colorectal cancer)
  - Facilitated cooperative group science to support other groups trials

GI Steering Committee

- Weaknesses
  - Have not been effective in translating ideas from lab to clinical studies
    - Actively working on ways to facilitate the process
  - Difficulty in defining and pushing forward novel ideas
    - Ideas for which you would like to know the answer but don't want to spend the money to get the answer
      - Defining risk/benefit ratios
    - These represent many practical clinical trials
  - Some individuals think we have slowed the process
    - Could be be solved by earlier presentation of ideas to the task force

GI Steering Committee

- Have established a working group to evaluate better incorporation of science into task force operations
  - Translational scientists are on the steering committee, but not necessarily on task forces
- Broaden the task forces with better representation from community physicians and advocates