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ABSTRACTS

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The Future of Cooperative Clinical Research in Gastrointestinal Oncology

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The structure of the cancer clinical trials cooperative groups in the United States have undergone, and will continue to undergo, major changes. This is partially related to the changes in the science, and the increasing knowledge that allows for improved trial designs. However, it is also related to a change in the environment at the NCI resulting from reports that have been issued over the past 5-7 years. The two most prominent are the reports issued by the Institute of Medicine entitled "*A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*", and the report from the Clinical Trials Working Group (CTWG) of the NCI.

These reports suggested major changes in the structure of the cooperative groups, the interaction of the groups with the NCI, and the development of disease specific Steering Committees to prioritize and approve large Phase II and Phase III concepts arising from the cooperative groups. This has resulted in the development of plans for consolidation of the 10 existing US cooperative groups into four groups, with some of those consolidations already planned. This intent is for the cooperative groups to function more as a network, than as multiple individual entities with full credit being given for enhancing the cooperation between the groups.

In GI cancer, the GI Steering Committee (GISC) was one of the first two NCI sponsored steering committees that were established. This group is composed of the GI cancer leadership from each of the cooperative groups, as well as having representation from the translational research community (PO1, RO1 and SPORE investigators), community physicians, patient advocates, biostatistics, and from other Steering Committees (Quality of Life, Investigational Drug). The GISC, in order to function efficiently, has established seven disease related task forces to work on protocol development, interaction between groups, and proposing initial prioritization recommendations for the GISC. Those Task Forces include: esophago-gastric, pancreas, liver, GIST, GI neuroendocrine, colon, and anal-rectum. Each task force has representation from each adult cooperative group, with the intent of fostering collaboration between the cooperative groups, avoiding duplication of effort, and helping to refine protocols prior to formal submission to the NCI.

As part of the attempt to have the cooperative groups work in an organized collaborative effort, rather than multiple individual efforts, the Task Forces have taken other responsibilities. The first is that there have been five GI related Clinical Trials Planning Meetings. These have generally been 1 ½ day meetings devoted to a specific topic, the most recent meeting being a collaboration between the colon task force and the ano-rectal task force, with both joint and independent sessions. The purpose of these meetings has been to develop a specific framework in which the clinical trials effort for the next 3 years could proceed.

In addition, the Task Forces have worked to produce guidelines and broad recommendations for future research. These have included attempts to standardize criteria for entry onto clinical trials, uniform definition of certain disease states, decisions not to lump certain categories of patients into single trials, etc.

All of this work is being done within the framework of a rapidly changing knowledge of the basic science behind many cancers. There is now a much stronger emphasis on developing correlative science studies that will be able to provide both predictive markers for response to specific therapies, as well as prognostic markers to allow us to define both low and high-risk patient subsets. There has been an increased emphasis on performing randomized Phase II studies, to obtain a clear signal as to likely efficacy of a therapeutic intervention. As we move forward it is likely that most cancers will be heavily subdivided, and it will be essential that we learn which of our therapies are most appropriate for specific biological and anatomical categories of each disease. Collaborations between the various clinical specialties will be essential, as will be enhanced collaboration between the clinician and the basic and translational scientists.