2015 Strategic Priorities

Gastrointestinal Steering Committee (GISC)

**Overall goal:** To leverage the resources of the NCTN to improve the outcomes of patients with gastrointestinal cancers. This will be accomplished by studies of new agents and modalities, with emphasis on biomarker-driven research that impacts treatment selection and supports scientific discovery.

**Colon Cancer**

1) Adjuvant trial with incorporation of novel biomarkers (e.g., circulating tumor-DNA) as integrated or integral markers for minimal residual disease and treatment response.
2) Immunotherapy in a priori immunogenic colorectal cancers (MSI-H) and non-immunogenic cancers by exploring immunomodulatory mechanisms.
3) Biomarker-directed treatment approaches in patients with metastatic disease.

**Esophagogastric Cancer**

1) Studies in the locally advanced setting. This includes concepts in the neoadjuvant or high risk adjuvant setting.
2) Immunotherapy and molecularly targeted therapies in gastroesophageal malignancies.

**Hepatobiliary Cancer**

1) Hepatocellular Carcinoma
   a. First line and second line studies of systemic therapy
   b. HCC locally advanced therapy with TACE- combined with therapies such as immune modulators (PD-L1) or others.
2) Biliary Cancer
a. Randomized phase II trial in second line therapy after progression on gemcitabine/cisplatin, targeting FGFr and/or IDH1-2 pathways, MEK inhibition
b. Phase III randomized adjuvant study evaluating combined modality of radiation plus chemotherapy versus systemic therapy in higher risk extra-hepatic biliary cancer.

**Neuroendocrine Tumors**

1) Therapy for advanced NET of tubular GI tract
   a. Randomized phase II or phase III studies of systemic therapy using targeted agents and immunotherapy approaches
   b. Study of regional therapy
2) Therapy for advanced NET of thorax (lung, thymus)
   a. Randomized phase II or phase III studies of systemic therapy using targeted agents, immunotherapy approaches, and cytotoxic agents
3) Therapy for advanced NET of pancreas
   a. Randomized phase II or phase III studies building upon recent advances, and seeking predictive biomarkers

**Pancreas Cancer**

1) Late stage pancreas adenocarcinoma
   a. Evaluation of novel therapies in second/third-line setting
   b. Exploration of immune therapeutic approaches in later stage pancreas adenocarcinoma
2) Borderline resectable (BRPC) and resectable pancreas adenocarcinoma
   a. Studies to explore new treatments and define the optimal type and sequencing of systemic therapy in BRPC
   b. Studies to determine the contribution of radiation therapy to chemotherapy in disease control. If radiation therapy is of value, what is the optimal dose/method of delivery (IMRT vs. SBRT)?
   c. Studies of new neoadjuvant approaches for resectable pancreas adenocarcinoma
Rectal Anal Cancer

1) Investigate the use of total neoadjuvant therapy (TNT), and integration of novel agents and unique approaches in locally advanced rectal cancer.

2) Integrate unique biomarkers (e.g., circulating tumor DNA and use of risk stratification tools) to address patients with a high risk of recurrence for anorectal cancers (T4 and N2/3 disease).

3) Clinical trials of novel approaches utilizing immune modulation for locally advanced and metastatic anal cancer.