

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