TARGET AUDIENCE
This activity is intended for medical oncologists, hematology- oncology fellows and other allied healthcare professionals involved in the treatment of colorectal, gastric and pancreatic cancer.

OVERVIEW OF ACTIVITY
Cancer of the colon and rectum is the fourth most frequently diagnosed cancer and the second most common cause of death among all neoplasms in the United States, accounting for approximately 8% of all cancer deaths. Although individually less frequently encountered, the collection of noncolorectal gastrointestinal (GI) cancers account for more per annum cancer-related deaths than those attributed to tumors of the colon and rectum combined. Two noncolorectal GI tumors in particular — gastric and pancreatic cancer — have witnessed several recent advances that have drastically altered current treatment considerations and approaches. As such, educational opportunities relevant to the clinical management of colorectal, gastric and pancreatic cancers are essential for medical oncologists responsible for delivering comprehensive care.

These video proceedings from a CME symposium held during the 2015 ASCO Annual Meeting feature discussions with leading researchers with an expertise in colorectal, gastric and pancreatic cancer regarding actual patient cases and related clinical research findings. By providing information on the latest research developments and their potential application to routine practice, this activity is designed to not only improve clinicians’ knowledge of recent data related to the rapidly evolving GI cancer treatment landscape but also to provide them with practical perspectives to help them become better and more effective caregivers.

LEARNING OBJECTIVES
- Individualize local and systemic treatment for patients with metastatic CRC that is isolated to the liver.
- Implement a clinical plan for the management of advanced HER2-positive gastric cancer, incorporating existing and emerging targeted treatments.
- Appreciate available clinical research data documenting the efficacy of ramucirumab in advanced gastric or gastro- esophageal junction cancer, and discern how this agent can be optimally integrated into clinical practice for patients with HER2-negative and HER2-positive disease.
- Appraise the rationale for and clinical data with investigational anti-PD-1 and/or anti-PD-L1 antibodies in patients with gastric cancer.
- Consider age, performance status and other clinical factors in the selection of systemic therapy for patients with metastatic pancreatic adenocarcinoma (PAD).
- Appreciate available safety and efficacy data with nanoparticle albumin-bound (nab) paclitaxel in combination with gemcitabine, and develop effective strategies to appropriately integrate this regimen into the management of metastatic PAD.
- Describe the proposed mechanism of action and available research data with ruxolitinib in pancreatic cancer, and use this information to counsel appropriate patients regarding ongoing trials evaluating this novel approach.
- Recall new data with other investigational agents demonstrating promising activity in colorectal, gastric and pancreatic cancers.

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This CME activity consists of a video component. To receive credit, the participant should watch the video, complete the Post-test with a score of 70% or better and fill out the Educational Assessment and Credit Form located at ResearchToPractice.com/GITumorPanel15/CME.

CONTENT VALIDATION AND DISCLOSURES
Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-the-art education. We assess potential conflicts of interest with faculty, planners and managers of CME activities. Real or apparent conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process:

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Hardware/Software Requirements:
A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later
Adobe Flash Player 10.2 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: September 2015
Expiration date: September 2016
Select Publications

Peter C Enzinger, MD


Schwartzberg LS et al. PEAK: A randomized, multicenter phase II study of panitumumab plus modified fluorouracil, leucovorin, and oxaliplatin (mFOLFOX6) or bevacizumab plus mFOLFOX6 in patients with previously untreated, unresectable, wild-type KRAS exon 2 metastatic colorectal cancer. *J Clin Oncol* 2014;32(21):2240-7.


Axel Grothey, MD
A randomized, open-label phase III Intergroup study: Effect of adding bevacizumab to cross over fluoropyrimidine based chemotherapy (CTx) in patients with metastatic colorectal cancer and disease progression under first-line standard CTx/bevacizumab combination. NCT00700102


Tabernero J et al. RAISE: A randomized, double-blind, multicenter phase III study of irinotecan, folic acid, and 5-fluorouracil (FOLFIRI) plus ramucirumab (RAM) or placebo (PBO) in patients (pts) with metastatic colorectal carcinoma (CRC) progressive during or following first-line combination therapy with bevacizumab (bev), oxaliplatin (ox), and a fluoropyrimidine (fp). Gastrointestinal Cancers Symposium 2015;Abstract 512.


J Randolph Hecht, MD
A phase 1b/2 study of MEDI4736 in combination with tremelimumab, MEDI4736 monotherapy, and tremelimumab monotherapy in subjects with metastatic or recurrent gastric or gastroesophageal junction adenocarcinoma. NCT02340975

A phase Ib clinical study of BBI608 in combination with standard chemotherapies in adult patients with advanced gastrointestinal cancer. NCT02024607


KEYNOTE-059: A phase II clinical trial of pembrolizumab as monotherapy and in combination with cisplatin+5-fluorouracil in subjects with recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma. NCT02335411

KEYNOTE-061: A phase III, randomized, open-label clinical trial of pembrolizumab (MK-3475) versus paclitaxel in subjects with advanced gastric or gastroesophageal junction adenocarcinoma who progressed after first-line therapy with platinum and fluoropyrimidine. NCT02370498
Select Publications

Muro K et al. Relationship between PD-L1 expression and clinical outcomes in patients (Pts) with advanced gastric cancer treated with the anti-PD-1 monoclonal antibody pembrolizumab (Pembro; MK-3475) in KEYNOTE-012. Gastrointestinal Cancers Symposium 2015;Abstract 03.

Phase I study of soluble LAG-3 (IMP321) and gemcitabine in patients with advanced pancreas cancer. NCT00732082


Eileen M O'Reilly, MD

A phase 1b study of the safety and tolerability of ruxolitinib in combination with gemcitabine with or without nab-paclitaxel in subjects with advanced solid tumors. NCT01822756

A phase 2, randomized, double-blind study of gemcitabine and nab-paclitaxel combined with momelotinib in subjects with previously untreated metastatic pancreatic ductal adenocarcinoma preceded by a dose-finding, lead-in phase. NCT02101021

A randomized multicenter phase Ib/II study to assess the safety and the immunological effect of chemoradiation therapy (CRT) in combination with pembrolizumab (MK-3475) compared to CRT alone in patients with resectable or borderline resectable pancreatic cancer. NCT02305186

A randomized pilot/pharmacodynamic/genomic study of neoadjuvant paricalcitol to target the microenvironment in resectable pancreatic cancer. NCT02030860

An exploratory phase 2 study of neoadjuvant chemotherapy followed by stereotactic body radiation therapy (SBRT) with algenpantucel-L (HyperAcute®-pancreas) immunotherapy in subjects with borderline resectable pancreatic cancer. NCT02405585


Hurwitz H et al. A randomized double-blind phase 2 study of ruxolitinib (RUX) or placebo (PBO) with capecitabine (CAPE) as second-line therapy in patients (pts) with metastatic pancreatic cancer (mPC). Proc ASCO 2014;Abstract 4000.

JANUS 1: Randomized, double-blind, phase 3 study of the Janus kinase (JAK) 1/2 inhibitor, ruxolitinib, or placebo in combination with capecitabine in subjects with advanced or metastatic adenocarcinoma of the pancreas who have failed or are intolerant to first-line chemotherapy. NCT02117479

JANUS 2: A randomized, double-blind, phase 3 study of the JAK 1/2 inhibitor, ruxolitinib or placebo in combination with capecitabine in subjects with advanced or metastatic adenocarcinoma of the pancreas who have failed or are intolerant to first-line chemotherapy. NCT02119663


Neoadjuvant FOLFIRINOX and chemoradiation followed by definitive surgery and postoperative gemcitabine for patients with borderline resectable pancreatic adenocarcinoma: An Intergroup single-arm pilot study. NCT01821612
NEOPAC: Adjuvant gemcitabine versus NEOadjuvant gemcitabine/oxaliplatin plus adjuvant gemcitabine in resectable PAncratic Cancer: A randomized multicenter phase III study. NCT01521702

Phase 1/2 safety and feasibility of gemcitabine and nab-paclitaxel in combination with LDE-225 as neoadjuvant therapy in patients with borderline resectable pancreatic adenocarcinoma. NCT01431794

Phase II study of preoperative FOLFIRINOX versus gemcitabine/nab-paclitaxel in patients with resectable pancreatic cancer. NCT02243007


Philip A Philip, MD, PhD


GATSBY: A randomized, multicenter, adaptive phase II/III study to evaluate the efficacy and safety of trastuzumab emtansine (T-DM1) versus taxane (docetaxel or paclitaxel) in patients with previously treated locally advanced or metastatic HER2-positive gastric cancer, including adenocarcinoma of the gastroesophageal junction. NCT01641939

HELOISE study: A study of Herceptin (trastuzumab) in combination with cisplatin/capecitabine chemotherapy in patients with HER2-positive metastatic gastric or gastro-esophageal junction cancer. NCT01450696

JACOB: A double-blind, placebo-controlled, randomized, multicenter phase III study evaluating the efficacy and safety of pertuzumab in combination with trastuzumab and chemotherapy in patients with HER2-positive metastatic gastroesophageal junction or gastric cancer. NCT01774786


RAINBOW: A randomized, multicenter, double-blind, placebo-controlled phase 3 study of weekly paclitaxel with or without ramucirumab (IMC-1121B) drug product in patients with metastatic gastric adenocarcinoma, refractory to or progressive after first-line therapy with platinum and fluoropyrimidine. NCT01170663

RAINFALL: A randomized, double-blind, placebo-controlled phase 3 study of capecitabine and cisplatin with or without ramucirumab as first-line therapy in patients with metastatic gastric or gastroesophageal junction adenocarcinoma. NCT02314117

Eric Van Cutsem, MD, PhD


RECOUSE: A randomized, multicenter, adaptive phase II/III study to evaluate the efficacy and safety of trastuzumab emtansine (T-DM1) versus taxane (docetaxel or paclitaxel) in patients with previously treated locally advanced or metastatic HER2-positive gastric cancer, including adenocarcinoma of the gastroesophageal junction. NCT01607957

