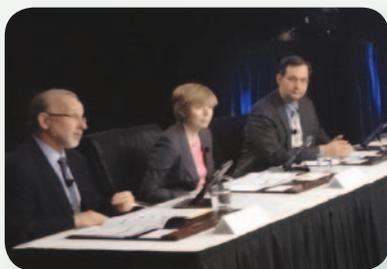


Striving for Consensus: The Application of Existing and Emerging Research Findings to the Practical Management of Gastrointestinal Cancers

Proceedings from a Clinical Investigator Think Tank



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MODERATOR

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CONTENTS

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Striving for Consensus: The Application of Existing and Emerging Research Findings to the Practical Management of Gastrointestinal Cancers

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Because of the prevalent nature of the disease, extensive resources are allocated to colorectal cancer (CRC) research and education. Interestingly, however, although individually less frequently encountered, the collection of non-CRC gastrointestinal (GI) cancers accounts for more cancer-related deaths per annum than do tumors of the colon and rectum combined. Published results from ongoing trials in both of these fields continually lead to the emergence of novel biomarkers and new therapeutic targets and regimens, thereby altering existing management algorithms. In order to offer optimal patient care — including the option of clinical trial participation — the practicing medical oncologist must be well informed of these advances. This CME program uses a roundtable discussion with leading GI clinical investigators to assist practicing clinicians in formulating up-to-date and appropriate clinical management strategies.

LEARNING OBJECTIVES

- Effectively apply the results of practice-changing clinical research to the selection and sequencing of chemobiologic regimens for patients with metastatic CRC.
- Summarize key findings from clinical studies of emerging and newly approved therapeutic regimens for pancreatic cancer, and use this information to guide treatment decision-making.
- Use clinical and molecular biomarkers to optimize the selection of systemic therapy for patients with gastric or gastroesophageal cancer.
- Educate patients with unresectable metastatic neuroendocrine tumors of the GI tract regarding approved and novel treatment approaches and their associated risks and benefits.
- Communicate the benefits and risks of existing and emerging systemic interventions to patients with advanced hepatocellular carcinoma.
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials.

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Video Highlights of the Clinical Investigator Think Tank



Check out highlight clips from this fascinating Think Tank featuring our esteemed clinical investigator panel discussing and debating some of the key clinical management issues across a number of common GI cancers. Visit www.ResearchToPractice.com/GICUTT114/Video for more information.

TRACKS 1-24

- Track 1** Results of the Phase III TRIBE trial of FOLFOXIRI/bevacizumab versus FOLFIRI/bevacizumab as first-line therapy for unresectable metastatic CRC (mCRC)
- Track 2** Results of the Phase III AVEX trial: Improvement in survival with bevacizumab/capecitabine versus capecitabine alone for elderly patients with previously untreated mCRC
- Track 3** **Case discussion:** A 30-year-old patient with abdominal pain is found to have a near obstructing sigmoid mass and is diagnosed with KRAS wild-type, BRAF V600e mutation-positive Stage IIIA CRC with liver metastases
- Track 4** The developing story of RAS and RAF mutations and next-generation sequencing in CRC
- Track 5** Perspectives on first-line therapy for patients with mCRC with and without BRAF mutations
- Track 6** Activity and tolerability of neoadjuvant FOLFOX/ziv-aflibercept in a clinical trial
- Track 7** **Case discussion:** A 70-year-old patient with KRAS wild-type CRC with multiple liver and intra-abdominal lymph node metastases achieves a partial response to CAPOX/bevacizumab
- Track 8** Second-line therapy options for patients with mCRC
- Track 9** Perspectives on the use of ziv-aflibercept versus continuation of bevacizumab after disease progression on FOLFOX/bevacizumab
- Track 10** ML18147 (TML): Results of a Phase III trial evaluating continuation of bevacizumab after first disease progression in patients with mCRC
- Track 11** North American subgroup results from VELOUR: A Phase III trial of ziv-aflibercept with FOLFIRI as second-line therapy for mCRC
- Track 12** **Case discussion:** A 42-year-old patient with KRAS-mutant mCRC whose disease progresses through multiple lines of bevacizumab-based therapies receives regorafenib
- Track 13** Results of a Phase III trial evaluating intravenous calcium/magnesium to prevent oxaliplatin-induced sensory neuropathy
- Track 14** **Case discussion:** A 71-year-old patient with HER2-negative distal gastric adenocarcinoma and peritoneal metastases who experiences disease progression on FOLFOX is enrolled on the REGARD trial
- Track 15** REGARD: Results of a Phase III trial of ramucirumab as second-line therapy for metastatic gastric or gastroesophageal junction (GEJ) cancer
- Track 16** Current status of RAINBOW: A Phase III trial of weekly paclitaxel with or without ramucirumab for metastatic gastric cancer (mGC)
- Track 17** Results of the AVAGAST trial: First-line capecitabine/cisplatin with bevacizumab or placebo for advanced GC
- Track 18** Future directions with and ongoing clinical trials evaluating ramucirumab in GC, hepatocellular carcinoma (HCC) and other solid tumors
- Track 19** **Case discussion:** A 57-year-old patient with a moderately differentiated adenocarcinoma of the GEJ receives neoadjuvant chemoradiation therapy
- Track 20** Results from the CROSS study: Neoadjuvant chemoradiation therapy for esophageal or GEJ cancer
- Track 21** Viewpoints on the use of neoadjuvant anti-HER2-based therapy for HER2-positive GC
- Track 22** Use of a modified 5-FU/trastuzumab regimen for patients with mGC who experience oxaliplatin-related thrombocytopenia with FOLFOX/trastuzumab
- Track 23** Therapeutic options for patients with metastatic HER2-positive gastric and gastroesophageal cancers
- Track 24** TRIO-013/LOGiC: Results of a Phase III trial of lapatinib in combination with capecitabine and oxaliplatin for HER2-positive mGC

TRACKS 25-51

- Track 25** Trials of T-DM1 and pertuzumab in HER2-positive advanced GC
- Track 26** Evaluation of MET pathway biomarkers in a Phase II study of rilotumumab (AMG 102) or placebo with epirubicin, cisplatin and capecitabine for locally advanced or metastatic GC
- Track 27** MetGastric: A Phase III trial of onartuzumab (MetMab) in combination with mFOLFOX6 for patients with metastatic HER2-negative, MET-positive adenocarcinoma of the stomach or GEJ
- Track 28** Differential mechanisms of action of rilotumumab and onartuzumab
- Track 29** Targeting the MET pathway in GC
- Track 30** Results of the PRODIGE 4/ACCORD 11 trial: Effect on quality of life of FOLFIRINOX compared to gemcitabine in patients with metastatic pancreatic cancer
- Track 31** MPACT: Results of a Phase III trial of weekly nanoparticle albumin-bound (*nab*) paclitaxel with gemcitabine versus gemcitabine alone for patients with metastatic adenocarcinoma of the pancreas
- Track 32** **Case discussion:** A 71-year-old patient presents with increasing fatigue, weight loss and ankle swelling and is diagnosed with poorly differentiated adenocarcinoma of the pancreas
- Track 33** Critical evaluation of therapeutic options for patients with advanced pancreatic cancer
- Track 34** Gemcitabine/*nab* paclitaxel versus FOLFIRINOX for patients with advanced pancreatic cancer
- Track 35** Radiofrequency ablation with or without transcatheter arterial chemoembolization in the treatment of HCC
- Track 36** Critical assessment of local treatment modalities in HCC
- Track 37** Evaluation of sorafenib with chemotherapy for advanced HCC
- Track 38** **Case discussion:** A 58-year-old patient diagnosed with hepatitis C 14 years ago presents with chest pain and is found to have multiple liver lesions consistent with HCC
- Track 39** Choosing between liver-directed therapy and systemic therapy for advanced HCC
- Track 40** Dosing of sorafenib and incidence of hand-foot syndrome
- Track 41** Results of a Phase II trial evaluating the MET inhibitor tivantinib as second-line therapy for advanced HCC
- Track 42** METIV-HCC: An ongoing Phase III trial of tivantinib versus placebo as second-line therapy for patients with MET-high inoperable HCC
- Track 43** Investigations of novel anti-angiogenic inhibitors — ramucirumab and regorafenib — for patients with HCC and disease progression on sorafenib
- Track 44** **Case discussion:** A 60-year-old patient with multiple liver metastases is diagnosed with a well-differentiated neuroendocrine tumor (NET)
- Track 45** Response to octreotide → radioembolization in carcinoid NET
- Track 46** Dosing patterns of octreotide for patients with NET
- Track 47** Status of SWOG-S0518: An ongoing Phase III trial of octreotide with interferon alpha versus octreotide with bevacizumab for advanced, poor-prognosis carcinoid NET
- Track 48** **Case discussion:** A 52-year-old patient who previously received treatment for a well-differentiated pancreatic NET presents with new hepatic lesions and opts for treatment with everolimus
- Track 49** Sequencing of first-line therapeutic options for patients with metastatic pancreatic NET
- Track 50** Results of a Phase III trial evaluating failure-free survival for patients with localized GI stromal tumors (GIST) treated with adjuvant imatinib
- Track 51** Duration of adjuvant imatinib for GIST

SELECT PUBLICATIONS

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](#)

Assenat E et al. Sorafenib (S) alone versus S combined with gemcitabine and oxaliplatin in first-line treatment of advanced hepatocellular carcinoma: Final analysis of the randomized phase II GONEXT trial (UNICANCER/FFCD PRODIGE 10 trial). *Proc ASCO* 2013;[Abstract 4028](#).

Bennouna J et al. Continuation of bevacizumab after first progression in metastatic colorectal cancer (ML18147): A randomised phase 3 trial. *Lancet Oncol* 2013;14(1):29-37.

Cheng A-L et al. Regorafenib in patients with hepatocellular carcinoma progressing following sorafenib: An ongoing randomized, double-blind, phase III trial. *Proc ASCO* 2013;[Abstract TPS4163](#).

Cunningham D et al. Bevacizumab plus capecitabine versus capecitabine alone in elderly patients with previously untreated metastatic colorectal cancer (AVEX): An open-label, randomized phase 3 trial. *Lancet Oncol* 2013;14(1):29-37.

Cunningham D et al. MetGastric: A randomized phase III study of onartuzumab (MetMAB) in combination with mFOLFOX6 in patients with metastatic HER2-negative and MET-positive adenocarcinoma of the stomach or gastroesophageal junction. *Proc ASCO* 2013;[Abstract TPS4155](#).

Cunningham D et al. RILOMET-1: An international phase III multicenter, randomized, double-blind, placebo-controlled trial of rilotumumab plus epirubicin, cisplatin, and capecitabine as first-line therapy in patients with advanced MET-positive gastric or gastroesophageal junction adenocarcinoma. *Proc ASCO* 2013;[Abstract TPS4153](#).

Falcone A et al. FOLFOXIRI/bevacizumab (bev) versus FOLFIRI/bev as first-line treatment in unresectable metastatic colorectal cancer patients: Results of the phase III TRIBE trial by GONO group. *Proc ASCO* 2013;[Abstract 3505](#).

Fuchs CS et al. REGARD: A phase III, randomized, double-blind trial of ramucirumab and best supportive care (BSC) versus placebo and BSC in the treatment of metastatic gastric or gastroesophageal junction adenocarcinoma following disease progression on first-line platinum- and/or fluoropyrimidine-containing combination therapy. Gastrointestinal Cancers Symposium 2013;[Abstract LBA5](#).

Hecht JR et al. Lapatinib in combination with capecitabine plus oxaliplatin in HER2-positive advanced or metastatic gastric, esophageal, or gastroesophageal adenocarcinoma: The TRIO-013/LOGiC trial. *Proc ASCO* 2013;[Abstract LBA4001](#).

Loprinzi CL et al. Phase III randomized, placebo-controlled, double-blind study of intravenous calcium/magnesium to prevent oxaliplatin-induced sensory neurotoxicity, N08CB: An alliance for clinical trials in oncology study. *Proc ASCO* 2013;[Abstract 3501](#).

Mitchel EP et al. North American subgroup results from VELOUR: Ziv-aflibercept versus placebo plus FOLFIRI in mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen. Gastrointestinal Cancers Symposium 2013;[Abstract 465](#).

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](#)

REACH: A multicenter, randomized, double-blind, Phase 3 study of ramucirumab (IMC-1121B) drug product and best supportive care (BSC) versus placebo and BSC as second-line treatment in patients with hepatocellular carcinoma after first-line therapy with sorafenib. [NCT01140347](#)

Santoro A et al. Metiv-HCC: A phase III clinical trial evaluating tivantinib (ARQ 197), a MET inhibitor, versus placebo as second-line in patients with MET-high inoperable hepatocellular carcinoma. *Proc ASCO* 2013;[Abstract TPS4159](#).

Santoro A et al. Tivantinib for second-line treatment of advanced hepatocellular carcinoma: A randomised, placebo-controlled phase 2 study. *Lancet Oncol* 2013;14(1):55-63.

Strosberg JR et al. Dosing patterns for octreotide LAR in neuroendocrine tumor (NET) patients: NCCN NET outcomes database. *Proc ASCO* 2013;[Abstract 4142](#).

SWOG-S0518: Phase III prospective randomized comparison of depot octreotide plus interferon alpha versus depot octreotide plus bevacizumab (NSC #704865) in advanced, poor prognosis carcinoid patients. [NCT00569127](#)

Von Hoff DD et al. Results of a randomized phase III trial (MPACT) of weekly nab-paclitaxel plus gemcitabine versus gemcitabine alone for patients with metastatic adenocarcinoma of the pancreas with PET and CA19-9 correlates. *Proc ASCO* 2013;[Abstract 4005](#).

Striving for Consensus: The Application of Existing and Emerging Research Findings to the Practical Management of Gastrointestinal Cancers

QUESTIONS (PLEASE CIRCLE ANSWER):

- The Phase III TRIBE trial evaluating FOLFOXIRI/bevacizumab versus FOLFIRI/bevacizumab as first-line treatment for unresectable mCRC reported an advantage in _____ with the FOLFOXIRI/bevacizumab regimen.
 - Overall response rate
 - Progression-free survival
 - Both a and b
 - None of the above
- The Phase III AVEX trial evaluating bevacizumab/capecitabine versus capecitabine alone for older patients with previously untreated mCRC demonstrated an improvement in _____ with the addition of bevacizumab.
 - Overall response rate
 - Progression-free survival
 - Both a and b
- A Phase III trial evaluating intravenous calcium/magnesium to prevent oxaliplatin-induced sensory neuropathy in patients with CRC reported no benefit in duration of acute sensory neuropathy and no effect on time to cumulative dose-limiting neuropathy with administration of calcium/magnesium.
 - True
 - False
- The Phase III TRIO-013/LOGiC trial of capecitabine/oxaliplatin with or without lapatinib for HER2-positive mGC reported a statistically significant improvement in overall survival with the addition of lapatinib.
 - True
 - False
- The RAINBOW study is evaluating paclitaxel versus paclitaxel and _____ as second-line therapy for patients with mGC.
 - Ziv-aflibercept
 - Bevacizumab
 - Regorafenib
 - Ramucirumab
- The Phase III REGARD trial evaluating ramucirumab with best supportive care versus placebo with best supportive care as second-line therapy for patients with metastatic gastric or GEJ adenocarcinoma demonstrated a statistically significant improvement in progression-free and overall survival with ramucirumab.
 - True
 - False
- Which of the following is an investigational MET pathway inhibitor under evaluation in locally advanced or metastatic GC?
 - Onartuzumab (MetMab)
 - Rilotumumab (AMG 102)
 - Both a and b
 - None of the above
- The Phase III MPACT trial of gemcitabine with or without weekly *nab* paclitaxel for patients with metastatic adenocarcinoma of the pancreas demonstrated a statistically significant improvement in _____ with the addition of *nab* paclitaxel.
 - Progression-free survival
 - Overall survival
 - Both a and b
- METIV-HCC is an ongoing Phase III trial evaluating _____ versus placebo as second-line therapy for patients with MET-high inoperable HCC.
 - Onartuzumab (MetMab)
 - Rilotumumab (AMG 102)
 - Tivantinib (ARQ-197)
- The ongoing Phase III SWOG-S0518 trial is evaluating octreotide with interferon alpha versus octreotide with _____ in advanced, poor-prognosis carcinoid NET.
 - Bevacizumab
 - Trastuzumab
 - Everolimus

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Striving for Consensus: The Application of Existing and Emerging Research Findings to the Practical Management of Gastrointestinal Cancers

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Efficacy and tolerability of ramucirumab for metastatic gastric or GEJ cancer (REGARD trial)	4 3 2 1	4 3 2 1
Improvement in survival on a Phase III trial (AVEX) evaluating bevacizumab/capecitabine versus capecitabine alone for older patients with previously untreated mCRC	4 3 2 1	4 3 2 1
Targeting the MET pathway in GC (rilutumumab, onartuzumab) and HCC (tivantinib)	4 3 2 1	4 3 2 1
SWOG-S0518: An ongoing Phase III trial evaluating octreotide with interferon alpha versus octreotide with bevacizumab in advanced, poor-prognosis carcinoid NET	4 3 2 1	4 3 2 1
Results of a Phase III trial evaluating intravenous calcium/magnesium to prevent oxaliplatin-induced sensory neuropathy in patients with CRC	4 3 2 1	4 3 2 1

Was the activity evidence based, fair, balanced and free from commercial bias?

Yes No

If no, please explain:

Please identify how you will change your practice as a result of completing this activity (select all that apply).

- This activity validated my current practice
- Create/revise protocols, policies and/or procedures
- Change the management and/or treatment of my patients
- Other (please explain):

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

Yes No

If no, please explain:

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Effectively apply the results of practice-changing clinical research to the selection and sequencing of chemobiologic regimens for patients with metastatic CRC. 4 3 2 1 N/M N/A
- Summarize key findings from clinical studies of emerging and newly approved therapeutic regimens for pancreatic cancer, and use this information to guide treatment decision-making. 4 3 2 1 N/M N/A
- Use clinical and molecular biomarkers to optimize the selection of systemic therapy for patients with gastric or gastroesophageal cancer. 4 3 2 1 N/M N/A
- Educate patients with unresectable metastatic neuroendocrine tumors of the GI tract regarding approved and novel treatment approaches and their associated risks and benefits. 4 3 2 1 N/M N/A
- Communicate the benefits and risks of existing and emerging systemic interventions to patients with advanced hepatocellular carcinoma. 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials. 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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Would you recommend this activity to a colleague?

- Yes No

If no, please explain:

As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

- Yes, I am willing to participate in a follow-up survey.
 No, I am not willing to participate in a follow-up survey.

PART 2 — Please tell us about the faculty and moderator for this educational activity

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal					
Faculty					Knowledge of subject matter	Effectiveness as an educator			
Johanna C Bendell, MD	4	3	2	1	4	3	2	1	
Charles S Fuchs, MD, MPH	4	3	2	1	4	3	2	1	
Richard M Goldberg, MD	4	3	2	1	4	3	2	1	
J Randolph Hecht, MD	4	3	2	1	4	3	2	1	
Eileen M O'Reilly, MD	4	3	2	1	4	3	2	1	
Philip A Philip, MD, PhD	4	3	2	1	4	3	2	1	
Moderator					Knowledge of subject matter	Effectiveness as an educator			
Neil Love, MD	4	3	2	1	4	3	2	1	

Please recommend additional faculty for future activities:

Other comments about the faculty and moderator for this activity:

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Gastrointestinal Cancer™

U P D A T E

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