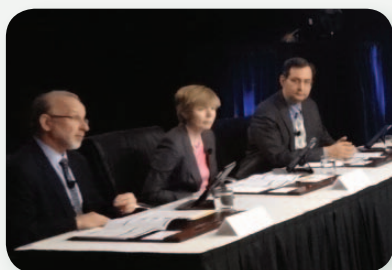


# Striving for Consensus: The Application of Existing and Emerging Research Findings to the Practical Management of Gastrointestinal Cancers

## *Proceedings from a Clinical Investigator Think Tank*



### FACULTY

Johanna C Bendell, MD  
 Charles S Fuchs, MD, MPH  
 Richard M Goldberg, MD  
 J Randolph Hecht, MD  
 Eileen M O'Reilly, MD  
 Philip A Philip, MD, PhD



### MODERATOR

Neil Love, MD

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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

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### 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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## FACULTY



**Johanna C Bendell, MD**  
Director, GI Oncology Research  
Associate Director, Drug Development Unit  
Sarah Cannon Research Institute  
Nashville, Tennessee



**J Randolph Hecht, MD**  
Professor of Clinical Medicine  
Carol and Saul Rosenzweig Chair in Cancer  
Therapies Development  
Director, UCLA GI Oncology Program  
Santa Monica, California



**Charles S Fuchs, MD, MPH**  
Director, Center for Gastrointestinal Cancer  
Dana-Farber/Harvard Cancer Center  
Professor of Medicine  
Harvard Medical School  
Boston, Massachusetts



**Eileen M O'Reilly, MD**  
Associate Attending  
GI Medical Oncology Service  
Memorial Sloan-Kettering Cancer Center  
Associate Professor of Medicine  
Weill Medical College of Cornell University  
New York, New York



**Richard M Goldberg, MD**  
Professor of Medicine  
Physician-in-Chief  
OSUCCC—James Cancer Hospital and  
Richard J Solove Research Institute  
Klotz Family Chair in Cancer Research  
The Ohio State University  
Columbus, Ohio



**Philip A Philip, MD, PhD**  
Professor of Oncology and Medicine  
Director of GI and Neuroendocrine Tumors  
Vice President of Medical Affairs  
Karmanos Cancer Institute  
Wayne State University  
Detroit, Michigan

## MODERATOR



**Neil Love, MD**  
Research To Practice  
Miami, Florida

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## Video Highlights of the Clinical Investigator Think Tank

The screenshot shows a video player interface. At the top, there is a navigation bar with the Research To Practice logo and a search bar. Below the navigation bar, there is a video player showing a woman, Johanna C. Bendell, MD, speaking. The video title is "Management of Metastatic Colorectal Cancer". To the right of the video player, there is a list of video titles, including "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer", "Management of Metastatic Colorectal Cancer". Below the video player, there is a "TRANSCRIPTION" section with the text: "DR BENDELL: The T303 trial was a randomized Phase III study that was looking at FOLFIRI plus her versus FOLFIRI plus her. And this is building on a trial that was performed years ago of FOLFIRI versus..."

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](http://www.ResearchToPractice.com/GICUTT114/Video) for more information.

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## 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):**

1. 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.
  - a. Overall response rate
  - b. Progression-free survival
  - c. Both a and b
  - d. None of the above
2. 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.
  - a. Overall response rate
  - b. Progression-free survival
  - c. Both a and b
3. 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.
  - a. True
  - b. False
4. 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.
  - a. True
  - b. False
5. The RAINBOW study is evaluating paclitaxel versus paclitaxel and \_\_\_\_\_ as second-line therapy for patients with mGC.
  - a. Ziv-aflibercept
  - b. Bevacizumab
  - c. Regorafenib
  - d. Ramucirumab
6. 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.
  - a. True
  - b. False
7. Which of the following is an investigational MET pathway inhibitor under evaluation in locally advanced or metastatic GC?
  - a. Onartuzumab (MetMab)
  - b. Rilotumumab (AMG 102)
  - c. Both a and b
  - d. None of the above
8. 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.
  - a. Progression-free survival
  - b. Overall survival
  - c. Both a and b
9. METIV-HCC is an ongoing Phase III trial evaluating \_\_\_\_\_ versus placebo as second-line therapy for patients with MET-high inoperable HCC.
  - a. Onartuzumab (MetMab)
  - b. Rilotumumab (AMG 102)
  - c. Tivantinib (ARQ-197)
10. The ongoing Phase III SWOG-S0518 trial is evaluating octreotide with interferon alpha versus octreotide with \_\_\_\_\_ in advanced, poor-prognosis carcinoid NET.
  - a. Bevacizumab
  - b. Trastuzumab
  - c. 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 (rilotumumab, 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)**

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

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				
<b>Faculty</b>					<b>Knowledge of subject matter</b>	<b>Effectiveness as an educator</b>		
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
<b>Moderator</b>					<b>Knowledge of subject matter</b>	<b>Effectiveness as an educator</b>		
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:

**REQUEST FOR CREDIT — Please print clearly**

Name: ..... Specialty: .....

Professional Designation:

- MD     DO     PharmD     NP     RN     PA     Other .....

Street Address: ..... Box/Suite: .....

City, State, Zip: .....

Telephone: ..... Fax: .....

Email: .....

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# Gastrointestinal Cancer™

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## U P D A T E

Neil Love, MD  
Research To Practice  
One Biscayne Tower  
2 South Biscayne Boulevard, Suite 3600  
Miami, FL 33131

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