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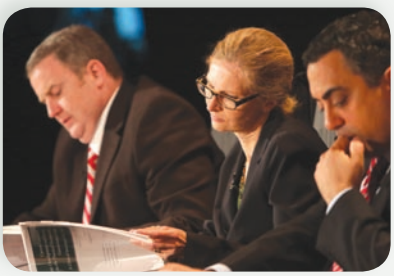
Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Gastrointestinal Cancer

Proceedings from a Clinical Investigator Think Tank



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Richard M Goldberg, MD
Axel Grothey, MD
Matthew Kulke, MD, MMSc
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MODERATOR

Neil Love, MD

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Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Gastrointestinal Cancer

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 per annum cancer-related deaths than do tumors of the colon and rectum combined. Published results from ongoing trials in both 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

- Apply clinical research data to optimize the use of anti-VEGF- and anti-EGFR-based therapy in the treatment of advanced CRC.
- Communicate the benefits and risks of existing and emerging systemic interventions to patients with advanced hepatocellular carcinoma.
- Educate patients with neuroendocrine tumors of the GI tract about novel treatment approaches for unresectable metastatic disease.
- Counsel patients with Stage II colon cancer about their individual risk of recurrence based on clinical, pathologic and genomic biomarkers, and consider adjuvant therapeutic options.
- Communicate the benefits and risks of existing and emerging tyrosine kinase inhibitors for the treatment of high-risk or metastatic gastrointestinal stromal tumors.
- Summarize key findings from clinical studies of emerging 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.
- Counsel appropriately selected patients with GI cancer about participation in ongoing clinical trials.

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TRACKS 1-21

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Track 2 Effects of prior bevacizumab on outcomes from the VELOUR study: A Phase III trial of aflibercept and FOLFIRI for patients with mCRC after failure of an oxaliplatin-based regimen

Track 3 Mechanism of action, response and toxicities of aflibercept, a potent angiogenesis inhibitor fusion protein

Track 4 Targeting angiogenesis — bevacizumab, aflibercept and regorafenib — in the treatment of mCRC

Track 5 ML18147 (TML): Results from a Phase III trial evaluating the addition of bevacizumab to crossover fluoropyrimidine-based chemotherapy for patients with mCRC experiencing disease progression on first-line chemotherapy/bevacizumab

Track 6 Plasma VEGF-A as a putative biomarker for predicting clinical outcome in patients with advanced gastric cancer (GC) treated with bevacizumab

Track 7 Perspectives on improved outcome with the use of bevacizumab beyond first disease progression in the BRiTE registry

Track 8 **Case discussion:** A 60-year-old patient whose Stage II colon cancer was managed without adjuvant therapy 4 years ago presents with K-ras-mutant bilateral liver and lung metastases and the disease progresses on FOLFOX/bevacizumab

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Track 11 Current status of RAISE: A Phase III study of FOLFIRI in combination with ramucirumab or placebo for patients with mCRC progressing during or after first-line therapy with bevacizumab, oxaliplatin and a fluoropyrimidine

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Track 16 Association of K-ras G13D mutation with outcome in patients with mCRC treated with cetuximab

Track 17 Development of next-generation sequencing techniques to detect genomic alterations in CRC and other solid tumors

Track 18 Availability of next-generation sequencing assays to identify potential actionable targets in colon cancer and other solid tumors

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Track 33 Use of nomograms to develop a threshold risk of recurrence at which to administer adjuvant imatinib therapy for GIST

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Track 35 Efficacy and safety of regorafenib in patients with metastatic and/or unresectable GIST after failure of imatinib and sunitinib

Track 36 Ongoing trial strategies in GIST: Evaluation of the second-generation tyrosine kinase inhibitor nilotinib versus imatinib re-treatment after disease progression

Track 37 Perspectives on the potential role of regorafenib in GIST

Track 38 Transarterial chemoembolization (TACE) with or without sorafenib in HCC

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Track 40 Use of sorafenib in advanced Child-Pugh B HCC and management of treatment-related hand-foot syndrome

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Track 42 Appropriate use of TACE and multidisciplinary management of HCC

Track 43 Potential role for mTOR inhibitors in the treatment of HCC

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ADDITIONAL AUDIO AVAILABLE EXCLUSIVELY ONLINE

Please visit **www.ResearchToPractice.com/GICUTT112** for further discussion from the Think Tank. An additional 72 minutes of dialogue is available for download or online listening.

Track 1 **Case discussion:** A 69-year-old man status-post Whipple procedure for a 3.5-cm adenocarcinoma of the pancreas with 2 positive lymph nodes and negative margins

Track 2 Potential use of neoadjuvant FOLFIRINOX for patients with borderline resectable or unresectable pancreatic cancer (PC)

Track 3 Next-generation sequencing and detection of actionable targets in PC by immunohistochemistry, microarray fluorescence in situ hybridization and mutational analysis

Track 4 Classification, differential management and outcomes of biliary tract cancers

Track 5 **Case discussion:** A 75-year-old man with a history of abdominal distress, burping and suspected gallbladder disease is diagnosed with unresectable extrahepatic bile duct cancer and receives cisplatin/gemcitabine

Track 6 Frequent mutation of isocitrate dehydrogenase (IDH)-1 and IDH-2 in cholangiocarcinoma identified through broad-based tumor genotyping

Track 7 Adjuvant therapy in the treatment of biliary tract cancer

Track 8 Practical considerations and challenges — disease subclassifications and inadequate preclinical/animal modeling — in the diagnosis and treatment of pancreatic and biliary tract cancers

Track 9 Perspectives on current therapeutic agents and regimens — gemcitabine, FOLFIRINOX, FOLFIRI and nanoparticle albumin-bound (*nab*) paclitaxel — in PC

Track 10 Critical evaluation of clinical trial designs

Track 11 Clinical management of HER2-positive GC

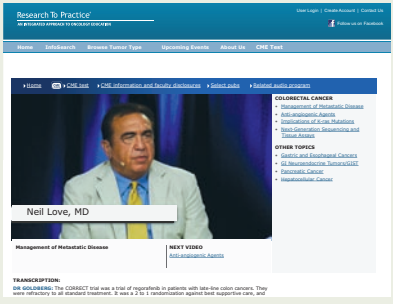
Track 12 Therapeutic options for HER2-negative advanced GC

Track 13 Role of neoadjuvant chemotherapy in GC and potential considerations for the addition of trastuzumab for patients with HER2-positive GC

Track 14 Preoperative chemoradiation therapy for esophageal or gastroesophageal junction cancer

Track 15 **Case discussion:** A 39-year-old man with confirmed HIV infection presents with a 4-cm squamous cell anal carcinoma

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 in the field of gastrointestinal cancer. Visit www.ResearchToPractice.com/GICUTT112/Video for more information.

SELECT PUBLICATIONS

Allegra Joseph C et al. **Effects of prior bevacizumab (B) use on outcomes from the VELOUR study: A phase III study of aflibercept (Afl) and FOLFIRI in patients (pts) with metastatic colorectal cancer (mCRC) after failure of an oxaliplatin regimen.** *Proc ASCO* 2012;**Abstract 3505**.

Arnold D et al. **Bevacizumab (BEV) plus chemotherapy (CT) continued beyond first progression in patients with metastatic colorectal cancer (mCRC) previously treated with BEV plus CT: Results of a randomized phase III intergroup study (TML study).** *Proc ASCO* 2012;**Abstract CRA3503**.

Borger DR et al. **Frequent mutation of isocitrate dehydrogenase (IDH)1 and IDH2 in cholangiocarcinoma identified through broad-based tumor genotyping.** *Oncologist* 2012;17(1):72-9.

Cartwright TH et al. **Effect of the 12-gene colon cancer assay results on treatment recommendations in patients with Stage II colon cancer.** *Proc ASCO* 2012;**Abstract 3626**.

Faron M et al. **Impact on survival of primary tumor resection in patients with colorectal cancer and unresectable metastasis: Pooled analysis of individual patients' data from four randomized trials.** *Proc ASCO* 2012;**Abstract 3507**.

Grothey A et al. **A randomized, double-blind, Phase III study of the irinotecan-based chemotherapy FOLFIRI plus ramucirumab or placebo in patients with metastatic colorectal carcinoma progressive during or following first-line therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (RAISE) (NCT01183780).** *Proc ASCO* 2012;**Abstract TPS3634**.

Horgan AM et al. **Adjuvant therapy in the treatment of biliary tract cancer: A systematic review and meta-analysis.** *J Clin Oncol* 2012;30(16):1934-40.

Kumar A et al. **The impact of HER2 positivity on survival in metastatic gastric and GEJ cancer.** Gastrointestinal Cancers Symposium 2012;**Abstract 17**.

McCahill LE et al. **Primary mFOLFOX6 plus bevacizumab without resection of the primary tumor for patients presenting with surgically unresectable metastatic colon cancer and an intact asymptomatic colon cancer: Definitive analysis of NSABP trial C-10.** *J Clin Oncol* 2012;30(26):3223-8.

Neoptolemos JP et al. **Effect of adjuvant chemotherapy with fluorouracil plus folinic acid or gemcitabine vs observation on survival in patients with resected periampullary adenocarcinoma: The ESPAC-3 periampullary cancer randomized trial.** *JAMA* 2012;308(2):147-56.

O'Connell M et al. **Validation of the 12-gene colon cancer recurrence score (RS) in NSABP C07 as a predictor of recurrence in Stage II and III colon cancer patients treated with 5FU/LV and 5FU/LV+oxaliplatin (FU+Ox).** *Proc ASCO* 2012;**Abstract 3512**.

Ross JS et al. **Use of next-generation sequencing (NGS) to detect a novel ALK fusion and a high frequency of other actionable alterations in colorectal cancer.** *Proc ASCO* 2012;**Abstract 3533**.

Shitara K et al. **Survival of patients with HER2-positive gastric cancer with introduction of trastuzumab.** Gastrointestinal Cancers Symposium 2012;**Abstract 128**.

Tabernero J et al. **Results from VELOUR, a phase 3 study of aflibercept versus placebo in combination with FOLFIRI for the treatment of patients with previously treated metastatic colorectal cancer.** European Multidisciplinary Congress 2011;**Abstract 6LBA**.

Van Cutsem E et al. **Phase III CORRECT trial of regorafenib in metastatic colorectal cancer (mCRC).** *Proc ASCO* 2012;**Abstract 3502**.

Van Hagen P et al. **Preoperative chemoradiotherapy for esophageal or junctional cancer.** *N Engl J Med* 2012;366(22):2074-84.

Von Hoff et al. **Actionable targets in pancreatic cancer detected by immunohistochemistry, microarray fluorescent in situ hybridization (FISH), and mutational analysis.** *Proc ASCO* 2012;**Abstract 4013**.

Wilke H et al. **A randomized, multicenter, double-blind, placebo-controlled Phase III study of paclitaxel with or without ramucirumab in patients with metastatic gastric adenocarcinoma, refractory to or progressive after first-line therapy with platinum and fluoropyrimidine.** *Proc ASCO* 2012;**Abstract TPS4139**.

Zhu AX et al. **A multicenter, randomized, double-blind, Phase III study of ramucirumab and best supportive care versus placebo and BSC as second-line treatment in patients with hepatocellular carcinoma following first-line therapy with sorafenib.** *Proc ASCO* 2012;**Abstract TPS4146**.

POST-TEST

Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Gastrointestinal Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The Phase III CORRECT trial of regorafenib in combination with best supportive care versus placebo in combination with best supportive care for patients with mCRC whose disease progressed on standard therapies reported a statistically significant improvement in median overall survival for patients who received regorafenib.**
   a. True
   b. False

2. **Common side effects associated with aflibercept include _____.**
   a. Asthenia
   b. Diarrhea
   c. Mucositis
   d. Neutropenia
   e. All of the above

3. **The Phase III ML18147 (TML) trial evaluating the addition of bevacizumab to crossover fluoropyrimidine-based chemotherapy for patients with mCRC experiencing disease progression on first-line chemotherapy/bevacizumab reported a statistically significant improvement in median overall survival for patients who received bevacizumab beyond progression.**
   a. True
   b. False

4. **The Phase III RAISE study is evaluating FOLFIRI with _____ or placebo for patients with mCRC progressing during or after first-line therapy with bevacizumab, oxaliplatin and a fluoropyrimidine.**
   a. Aflibercept
   b. Bevacizumab
   c. Ramucirumab

5. **Analyses of data from the CRYSTAL and OPUS trials reported an association between the presence of K-ras G13D mutation and survival benefit among patients with mCRC who had received cetuximab.**
   a. True
   b. False

6. **Recently reported data from the Phase III NSABP-C-07 study validated the Onco*type* DX Colon Cancer Assay Recurrence Score as a predictor of recurrence in patients with Stage II or III colon cancer treated with 5-FU/leucovorin with or without oxaliplatin.**
   a. True
   b. False

7. **The randomized PROMID study, which evaluated octreotide versus placebo as therapy for patients with carcinoid neuroendocrine tumors, reported a significant improvement in time to disease progression for patients who received octreotide.**
   a. True
   b. False

8. **A randomized Phase III trial of regorafenib for patients with metastatic and/or unresectable GIST progressing despite prior treatment with imatinib and sunitinib demonstrated an improvement in _____ for patients who received regorafenib.**
   a. Disease control rate
   b. Progression-free survival
   c. Both a and b
   d. Neither a nor b

9. **The Phase III SSG XVIII trial comparing 12 months to 36 months of adjuvant imatinib therapy for patients with high-risk GIST reported no benefit for patients receiving the longer course of imatinib therapy.**
   a. True
   b. False

10. **The frequency of adverse events for patients with GIST who received imatinib for 3 years on the SSG XVIII trial was significantly higher than the frequency for patients who received imatinib for 1 year only.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Gastrointestinal Cancer

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
Available research data — CORRECT, ML18147 (TML) and VELOUR trials — evaluating continued anti-VEGF therapy for patients with mCRC whose disease has progressed on chemotherapy/bevacizumab	4 3 2 1	4 3 2 1
Data supporting the utility of the Onco*type* DX assay in guiding treatment planning for patients with Stage II or III colon cancer	4 3 2 1	4 3 2 1
Use of next-generation sequencing to detect genomic alterations in CRC	4 3 2 1	4 3 2 1
GIDEON registry: A global investigation on the use of sorafenib in the management of HCC	4 3 2 1	4 3 2 1
Duration of adjuvant imatinib for high-risk GIST	4 3 2 1	4 3 2 1
RADIANT-2: A Phase III trial of octreotide with everolimus for patients with advanced neuroendocrine tumors	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:

- Apply clinical research data to optimize the use of anti-VEGF- and anti-EGFR-based therapy in the treatment of advanced CRC..... 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
- Educate patients with neuroendocrine tumors of the GI tract about novel treatment approaches for unresectable metastatic disease..... 4 3 2 1 N/M N/A
- Counsel patients with Stage II colon cancer about their individual risk of recurrence based on clinical, pathologic and genomic biomarkers, and consider adjuvant therapeutic options..... 4 3 2 1 N/M N/A
- Communicate the benefits and risks of existing and emerging tyrosine kinase inhibitors for the treatment of high-risk or metastatic gastrointestinal stromal tumors..... 4 3 2 1 N/M N/A
- Summarize key findings from clinical studies of emerging 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
- 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

Faculty	Knowledge of subject matter				Effectiveness as an educator			
Tanios Bekaii-Saab, MD	4	3	2	1	4	3	2	1
Emily K Bergsland, 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
Axel Grothey, MD	4	3	2	1	4	3	2	1
Matthew Kulke, MD, MMSc	4	3	2	1	4	3	2	1
Bert H O'Neil, MD	4	3	2	1	4	3	2	1
Alan P Venook, MD	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:

.....

.....

REQUEST FOR CREDIT — Please print clearly

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

Professional Designation:

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

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Gastrointestinal Cancer™

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