

Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

Proceedings from a Clinical Investigator Think Tank



FACULTY

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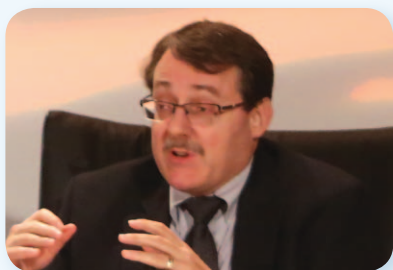


MODERATOR

Neil Love, MD

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Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Many controversies and clinical questions currently surround the management of localized breast and colorectal cancers. Central among these is the use and effectiveness of available biomarkers in guiding decision-making regarding adjuvant treatment. This CME program brings together leading clinical investigators in the fields of breast and colon cancer to provide perspectives on the development, assessment and clinical utility of select genomic assays and biomarkers that are available to assist clinicians managing these highly prevalent diseases. By reviewing available clinical trial data and relevant case scenarios, this initiative will help learners to ascertain the effectiveness of diagnostic, prognostic and predictive biomarkers as they relate to the adjuvant treatment of breast and/or colorectal cancer.

LEARNING OBJECTIVES

- Recognize the evolving application of biomarkers and multigene assays in the management of breast and colon cancer, and effectively use these tools to refine or individualize treatment plans for selected patients.
- Determine the utility of the *Oncotype DX*® Recurrence Score® assay in counseling patients with ER-positive early breast cancer about their risk of recurrence and the potential benefits of adjuvant chemotherapy.
- Counsel patients with Stage II and Stage III colon cancer about their individual risk of recurrence based on clinical, pathologic and genomic biomarkers, and consider adjuvant therapeutic options based on an evaluation of this information.
- Assess the utility of the *Oncotype DX* DCIS Score® assay in counseling patients with DCIS about their risk of recurrence and the potential benefits of radiation therapy.
- Evaluate the evidence-based benefits of adjuvant chemotherapy for patients with Stage II colon cancer and the risks and benefits of oxaliplatin-containing chemotherapy in lower-risk Stage III disease.
- Counsel appropriately selected patients about participation in ongoing clinical trials.

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Video Highlights of the Clinical Investigator Think Tank

The screenshot shows the Research To Practice website interface. At the top, there's a navigation bar with links like Home, Info/Research, Research Forum Topics, Upcoming Events, About Us, and CME Tools. Below this, a video player is embedded, showing a panel discussion with Norman Wolmark, MD. To the right of the video player, there's a list of topics: Role of biomarkers in clinical decision-making, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing, Clinical decision-making and genomic testing. Below the video player, there's a transcript section titled "TRANSCRIPT:" with a small text block.

Visit www.ResearchToPractice.com/BiomarkersTT115/Video to access a number of short video segments and corresponding transcripts from the Think Tank featuring the faculty discussing and debating some of the key clinical management and research issues in the field.

TRACKS 1-22

- Track 1 Case discussion:** An otherwise healthy 92-year-old man with moderately differentiated adenocarcinoma of the descending colon with 7 of 32 positive nodes
- Track 2** Utility of the *Oncotype DX*® 12-gene colon cancer assay in assessing the value of oxaliplatin-containing adjuvant chemotherapy in patients with Stage III colon cancer
- Track 3** Risks and benefits of adjuvant chemotherapy for very elderly patients with colon cancer
- Track 4 Case discussion:** A 45-year-old premenopausal woman with a T1b ER/PR-positive, HER2-negative infiltrating ductal carcinoma (IDC), 1 of 4 positive nodes and an *Oncotype DX* 21-gene Recurrence Score® (RS) of 12
- Track 5** RxPONDER: A Phase III trial of adjuvant endocrine therapy with or without chemotherapy for patients with node-positive, ER-positive, HER2-negative breast cancer (BC) and an RS of 25 or lower
- Track 6** Incorporating the patient perspective on chemotherapy into adjuvant treatment decisions
- Track 7** Prognostic and predictive utilities of the 21-gene RS and Adjuvant! Online for women with ER-positive, node-negative BC: Results from the NSABP-B-14 and NSABP-B-20 trials
- Track 8** Perspectives on the value and limitations of the Adjuvant! Online program in breast and colon cancer
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- Track 10** Effect of genomic assays on clinical decision-making
- Track 11** Counseling patients about the concept of reducing the risk of recurrence and related numeracy
- Track 12** Role of the *Oncotype DX* 21-gene RS in clinical decision-making for patients with BC and limited nodal involvement
- Track 13** Use of the *Oncotype DX* 21-gene RS in ER/PR-positive, node-positive BC
- Track 14** Clinical utility of the *Oncotype DX* 21-gene RS in decision-making about adjuvant chemotherapy in BC
- Track 15** Validation of the 12-gene RS as a predictor of recurrence in patients with Stage II and Stage III colon cancer treated with 5-FU/leucovorin with or without oxaliplatin on the Phase III NSABP-C-07 trial
- Track 16** Evaluating the absolute benefits of chemotherapy in patients with colon cancer based on the *Oncotype DX* 12-gene RS
- Track 17** Peripheral neuropathy with adjuvant oxaliplatin
- Track 18** CALGB-80702: An ongoing Phase III trial of 6 versus 12 cycles of adjuvant FOLFOX with celecoxib or placebo for patients with resected Stage III colon cancer
- Track 19** Use of the *Oncotype DX* 12-gene RS for adjuvant decisions in colon cancer
- Track 20** Controversy regarding the benefits of adjuvant chemotherapy in Stage II colon cancer
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TRACKS 1-19

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- Track 2** Reliance on standard clinicopathologic markers versus genomic assays for prognosis in breast and colon cancer
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- Track 4** Biological determinants of tumor recurrence in Stage II colon cancer
- Track 5** Viewpoint on the clinical utility of the *Oncotype DX* 21- and 12-gene RS for breast and colon cancer, respectively
- Track 6** Status of ECOG-E5202: A Phase III study of FOLFOX with or without bevacizumab for patients with Stage II colon cancer at high risk of recurrence to prospectively determine the prognostic value of molecular markers
- Track 7** Direct comparison of risk classification among the MammaPrint®, Mammostrat® and *Oncotype DX* assays in early-stage BC
- Track 8** Prognostic discrimination using a 70-gene signature among patients with ER-positive BC and an intermediate 21-gene RS
- Track 9** Limitations of the 21-gene RS compared to traditional clinicopathologic markers
- Track 10** Advantages of the 21-gene RS compared to the MammaPrint assay
- Track 11** **Case discussion:** A 37-year-old woman with a 2.1-cm, ER-positive, HER2-negative, node-negative BC and a 21-gene RS of 19
- Track 12** Counseling patients with BC and an intermediate RS
- Track 13** **Case discussion:** A 51-year-old woman with Stage II, microsatellite instability (MSI) high, BRAF V600E mutation-positive adenocarcinoma of the colon who does not receive adjuvant therapy and experiences relapse 1 year later
- Track 14** Prognostic role of deficient DNA mismatch repair and BRAF mutations in colon cancer
- Track 15** Perspectives on the reliability of MSI testing
- Track 16** Independent validation of the prognostic ColoPrint® genomic signature for patients with Stage II colon cancer
- Track 17** **Case discussion:** A 72-year-old woman with a 1.2-cm focus of ductal carcinoma in situ (DCIS) and an *Oncotype DX* DCIS Score® of 20 who forgoes radiation therapy
- Track 18** Prediction of local recurrence risk for patients with DCIS
- Track 19** Viewpoints on the current utility of the *Oncotype DX* DCIS Score in decision-making about radiation therapy

BONUS AUDIO AVAILABLE EXCLUSIVELY ONLINE

Please visit www.ResearchToPractice.com/BiomarkersTT115 for additional discussion.

- Track 1** Intrinsic subtypes of BC
- Track 2** Predictive value of the *Oncotype DX* 21-gene assay compared to other genomic assays in BC
- Track 3** The gene expression-based signature BC index (BCI) identifies patients with ER-positive BC at risk for early and late distant recurrences
- Track 4** Use of BCI to assess the appropriateness of chemotherapy at diagnosis and the need for extended adjuvant endocrine therapy beyond 5 years
- Track 5** **Case discussion:** An 84-year-old man undergoes limited resection of an obstructing mass of the transverse colon that is biopsy confirmed to be a moderately well-differentiated T3N1 adenocarcinoma of the colon

- Track 6** Considerations for ordering a 12-gene colon cancer assay for elderly patients with a high risk of colon cancer recurrence
- Track 7** Timing of adjuvant chemotherapy after surgery for colon and breast cancer
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- Track 9** Community oncologist utilization of the 12-gene colon cancer assay
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- Track 11** Cost effectiveness of the 21-gene RS in the context of multifactorial decision-making to guide chemotherapy for early-stage BC
- Track 12** **Case discussion:** A 48-year-old premenopausal woman with a 2.1-cm, ER/PR-positive, HER2-negative IDC who recently completed 5 years of adjuvant tamoxifen
- Track 13** Continuing adjuvant tamoxifen to 10 years versus stopping at 5 years for ER-positive early BC
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- Track 22** Prognostic impact of the 21-gene RS in patients presenting with Stage IV BC
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- Track 24** Debating the results of the Phase III CALOR trial: Adjuvant chemotherapy for radically resected locoregional relapse of BC
- Track 25** **Case discussion:** A 64-year-old woman who develops a 6-cm local recurrence after 10 years of adjuvant endocrine therapy
- Track 26** Results of CALGB/SWOG-80405: A Phase III trial of FOLFIRI or FOLFOX with bevacizumab or cetuximab for patients with KRAS wild-type untreated metastatic adenocarcinoma of the colon or rectum
- Track 27** Interpreting the results of CALGB/SWOG-80405 and FIRE-3 (FOLFIRI with cetuximab versus FOLFIRI with bevacizumab as first-line therapy for metastatic colorectal cancer)
- Track 28** Evaluation of the RAS wild-type patient population from the CALGB/SWOG-80405 and FIRE-3 trials
- Track 29** Ongoing correlative retrospective analyses of the CALGB/SWOG-80405 study
- Track 30** Importance of correlative studies in furthering cancer research

Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. The Phase III RxPONDER study randomly assigns patients with ER-positive, HER2-negative BC, 1 to 3 positive nodes and an *Oncotype* DX 21-gene RS of 25 or _____ to adjuvant endocrine therapy with or without chemotherapy.
 - a. Lower
 - b. Higher
2. The *Oncotype* DX 12-gene RS predicts recurrence risk in which of the following?
 - a. Stage II colon cancer
 - b. Stage III colon cancer
 - c. Both a and b
 - d. Neither a nor b
3. Which of the following statements is true about the direct comparison of risk classification among the MammaPrint, *Oncotype* DX and Mammostrat assays for patients with early-stage BC?
 - a. The 3 assays classify a large proportion of patients differently, resulting in significant discordance rates for all risk categories
 - b. Considerable homogeneity and concordance are seen across risk categories for all 3 assays
 - c. The 3 assays provide equivalent information and uniformly guide treatment decision-making
 - d. Both b and c
4. The *Oncotype* DX assay for patients with DCIS who have undergone local excision, with or without tamoxifen, predicts the risk of local recurrence.
 - a. True
 - b. False
5. Patients with colon cancer and an *Oncotype* DX 12-gene low-risk RS derive less absolute benefit from adjuvant oxaliplatin than do patients with a higher-risk RS.
 - a. True
 - b. False
6. The *Oncotype* DX 21-gene RS _____ for patients with early-stage, node-negative, ER-positive invasive BC.
 - a. Predicts chemotherapy benefit
 - b. Predicts likelihood of distant breast cancer recurrence
 - c. Both a and b
 - d. Neither a nor b
7. In comparison to currently available multigene BC assays, which of the following is a limitation of the Adjuvant! Online program for patients with BC?
 - a. Lack of reliability in prognostic predictions
 - b. Prediction that all patients will benefit from adjuvant therapy to some extent
 - c. No limitations; both are equally useful
8. Which of the following statements is true about currently available multigene assays for early BC?
 - a. They are interchangeable for classifying patients into prognostic risk groups
 - b. Each is largely driven by estrogen receptor expression and proliferation
 - c. Each predicts benefit from adjuvant chemotherapy

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon 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
Validation of the <i>Oncotype</i> DX 12-gene RS as a predictor of recurrence in patients with Stage II and Stage III colon cancer treated with 5-FU/leucovorin with or without oxaliplatin on the Phase III NSABP-C-07 trial	4 3 2 1	4 3 2 1
Utility of the 12-gene RS to guide decision-making regarding the addition of oxaliplatin to adjuvant 5-FU	4 3 2 1	4 3 2 1
Prospective validation study of the <i>Oncotype</i> DX DCIS Score in predicting the risk of local recurrence after resection alone for DCIS	4 3 2 1	4 3 2 1
Prognostic and predictive utility of available breast cancer genomic assays	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice
☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with breast and colon cancer do you see per year? Breast Colon.....

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:

- Recognize the evolving application of biomarkers and multigene assays in the management of breast and colon cancer, and effectively use these tools to refine or individualize treatment plans for selected patients 4 3 2 1 N/M N/A
- Determine the utility of the *Oncotype* DX Recurrence Score assay in counseling patients with ER-positive early breast cancer about their risk of recurrence and the potential benefits of adjuvant chemotherapy 4 3 2 1 N/M N/A
- Counsel patients with Stage II and Stage III colon cancer about their individual risk of recurrence based on clinical, pathologic and genomic biomarkers, and consider adjuvant therapeutic options based on an evaluation of this information 4 3 2 1 N/M N/A
- Assess the utility of the *Oncotype* DX DCIS Score assay in counseling patients with DCIS about their risk of recurrence and the potential benefits of radiation therapy 4 3 2 1 N/M N/A
- Evaluate the evidence-based benefits of adjuvant chemotherapy for patients with Stage II colon cancer and the risks and benefits of oxaliplatin-containing chemotherapy in lower-risk Stage III disease 4 3 2 1 N/M N/A
- Counsel appropriately selected patients 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:

Additional comments about this activity:

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- ☐ 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
Steven R Alberts, MD, MPH	4	3	2	1	4 3 2 1
Harold J Burstein, MD, PhD	4	3	2	1	4 3 2 1
Joseph A Sparano, MD	4	3	2	1	4 3 2 1
Alan P Venook, MD	4	3	2	1	4 3 2 1
Norman Wolmark, 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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I certify my actual time spent to complete this educational activity to be _____ hour(s).

Signature: Date:

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