

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

## **CME Information**

### **TARGET AUDIENCE**

This educational activity has been designed to meet the educational needs of medical oncologists, hematology-oncology fellows, nurse practitioners and other healthcare providers involved in the treatment of breast and colon cancer.

### **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.

### **ACCREDITATION STATEMENT**

Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

### **CREDIT DESIGNATION STATEMENT**

Research To Practice designates this enduring material for a maximum of 2 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

### **HOW TO USE THIS CME ACTIVITY**

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 75% or better and fill out the Educational Assessment and Credit Form located at [ResearchToPractice.com/BiomarkersTT115/Video/CME](https://ResearchToPractice.com/BiomarkersTT115/Video/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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Professor of Oncology  
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**Data and Safety Monitoring Board:** BioSphere Medical, Pfizer Inc.

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**Advisory Committee:** Amgen Inc, Celldex Therapeutics, Curis Inc, Eisai Inc, Johnson & Johnson Pharmaceuticals, MetaStat Inc, Pfizer Inc; **Consulting Agreement:** Genentech BioOncology; **Contracted Research:** ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company; **Paid Research:** Merck, Takeda Oncology.

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**Advisory Committee:** Bayer HealthCare Pharmaceuticals; **Consulting Agreements:** Bayer HealthCare Pharmaceuticals, Sanofi; **Contracted Research:** Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, Genentech BioOncology, GlaxoSmithKline, Lilly, Onyx Pharmaceuticals, an Amgen subsidiary.

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**Advisory Committee:** Genentech BioOncology; Other Remunerated Activities: Sanofi.

**MODERATOR** — Dr Love is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME activities from the following commercial interests: AbbVie Inc, Amgen Inc, Astellas Scientific and Medical Affairs Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Biodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc, Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, Daiichi Sankyo Inc, Dendreon Corporation, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, ImmunoGen Inc, Incyte Corporation, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Lilly, Medivation Inc, Merck, Myriad Genetic Laboratories Inc, NanoString Technologies, Novartis Pharmaceuticals Corporation, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pharmacyclics Inc, Prometheus Laboratories Inc, Regeneron Pharmaceuticals, Sanofi, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Teva Oncology, Tokai Pharmaceuticals Inc and VisionGate Inc.

**RESEARCH TO PRACTICE STAFF AND EXTERNAL**

**REVIEWERS** — The scientific staff and reviewers for Research To Practice have no real or apparent conflicts of interest to disclose.

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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:** July 2015

**Expiration date:** July 2016

## Select Publications

- Ahn SG et al. **Prognostic discrimination using a 70-gene signature among patients with estrogen receptor-positive breast cancer and an intermediate 21-gene Recurrence Score.** *Int J Mol Sci* 2013;14(12):23685-99.
- Albain KS et al. **Prognostic and predictive value of the 21-gene Recurrence Score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: A retrospective analysis of a randomised trial.** *Lancet Oncol* 2010;11:55-65.
- Alberts SR et al. **Prospective evaluation of a 12-gene assay on patient treatment decisions and physician confidence in mismatch repair-proficient stage IIa colon cancer patients.** *Proc ASCO* 2014;Abstract 396.
- Alvarado M et al. **Clinical utility of the 12-gene DCIS score assay: Impact on treatment recommendations.** *Proc ASCO* 2014;Abstract 11050.
- Brufsky AM. **Predictive and prognostic value of the 21-gene Recurrence Score in hormone receptor-positive, node-positive breast cancer.** *Am J Clin Oncol* 2014;37(4):404-10.
- Carlson JJ, Roth JA. **The impact of the Oncotype DX breast cancer assay in clinical practice: A systematic review and meta-analysis.** *Breast Cancer Res Treat* 2013;141(1):13-22.
- Cartwright T et al. **Effect of the 12-gene colon cancer assay results on adjuvant treatment recommendations in patients with stage II colon cancer.** *Curr Med Res Opin* 2014;30(2):321-8.
- Dowsett M et al. **Prediction of risk of distant recurrence using the 21-gene Recurrence Score in node-negative and node-positive postmenopausal patients with breast cancer treated with anastrozole or tamoxifen: A TransATAC study.** *J Clin Oncol* 2010;28:1829-34.
- Fehrenbacher L et al. **NSABP B-47: A randomized phase III trial of adjuvant therapy comparing chemotherapy alone to chemotherapy plus trastuzumab in women with node-positive or high-risk node-negative HER2-low invasive breast cancer.** *Proc ASCO* 2013;Abstract TPS1139.
- Goldstein LJ et al. **Prognostic utility of the 21-gene assay in hormone receptor-positive operable breast cancer compared with classical clinicopathologic features.** *J Clin Oncol* 2008;26:4063-71.
- Gray RG et al. **Validation study of a quantitative multigene reverse transcriptase-polymerase chain reaction assay for assessment of recurrence risk in patients with stage II colon cancer.** *J Clin Oncol* 2011;29(35):4611-9.
- Kerr DJ, Shi Y. **Biological markers: Tailoring treatment and trials to prognosis.** *Nat Rev Clin Oncol* 2013;10(8):429-30.
- Lagios MD, Silverstein MJ. **Risk of recurrence of ductal carcinoma in situ by Oncotype DX technology: Some concerns.** *Cancer* 2014;120(7):1085.
- Lin CC et al. **The prognostic role of microsatellite instability, codon-specific KRAS, and BRAF mutations in colon cancer.** *J Surg Oncol* 2014;110(4):451-7.
- Maak M et al. **Independent validation of a prognostic genomic signature (ColoPrint) for patients with Stage II colon cancer.** *Ann Surg* 2013;257(6):1053-8.
- Mamounas EP et al. **Prognostic impact of the 21-gene Recurrence Score (RS) on disease-free and overall survival of node-positive, ER-positive breast cancer patients (pts) treated with adjuvant chemotherapy: Results from NSABP B-28.** *J Clin Oncol* 2012;30(Suppl 27);Abstract 1.
- Sinicrope FA et al. **Prognostic impact of deficient DNA mismatch repair in patients with stage III colon cancer from a randomized trial of FOLFOX-based adjuvant chemotherapy.** *J Clin Oncol* 2013;31(29):3664-72.
- Solin LJ et al. **A multigene expression assay to predict local recurrence risk for ductal carcinoma in situ of the breast.** *J Natl Cancer Inst* 2013;105(10):701-10.
- Srivastava G et al. **Prospective multicenter study of the impact of Oncotype DX colon cancer assay results on treatment recommendations in stage II colon cancer patients.** *Oncologist* 2014;19(5):492-7.
- Tang G et al. **Comparison of the prognostic and predictive utilities of the 21-gene Recurrence Score assay and Adjuvant! for women with node-negative, ER-positive breast cancer: Results from NSABP B-14 and NSABP B-20.** *Breast Cancer Res Treat* 2011;127(1):133-42.
- Venook AP et al. **Biologic determinants of tumor recurrence in stage II colon cancer: Validation study of the 12-gene Recurrence Score in cancer and leukemia group B (CALGB) 9581.** *J Clin Oncol* 2013;31(14):1775-81.
- Yothers G et al. **Validation of the 12-gene colon cancer Recurrence Score in NSABP C-07 as a predictor of recurrence in patients with stage II and III colon cancer treated with fluorouracil and leucovorin (FU/LV) and FU/LV plus oxaliplatin.** *J Clin Oncol* 2013;31(36):4512-9.