Message From Our NRG Oncology Group Chairs

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This “Message From Our NRG Oncology Group Chairs” column is a new addition to the NRG Oncology Newsletter. Each newsletter issue will feature a note from one of our three NRG Oncology Group Chairs. Often, the comments will touch on NRG Oncology initiatives aimed at assisting NRG Oncology investigators in executing the very best research across our large group. Don’t hesitate to suggest topics or ideas for our newsletter and for this column.

It’s hard to believe that NRG Oncology has been operating as one integrated NCI-funded network group for almost a year! The transition from our three legacy groups to NRG Oncology has required literally thousands of person-hours of effort. I remain confident that this work has yielded and will continue to yield tremendous value for cancer patients. We are the NCTN group with the largest and most diverse portfolio of trials and the highest enrollment in the NCTN’s first year of existence. We have the active engagement and participation of all but one of the 30 Lead Academic Participating Sites (LAPS); all of the NCORP sites, including all minority NCORP sites; and all of the major Canadian provincial sites. Despite increasingly demanding timelines and complex regulatory processes, NRG Oncology has activated 8 new trials since its formal inception on March 1, 2014. As of January 1, 2015, NRG Oncology has 108 clinical trials across our seven cancer disease site committees open for patient enrollment.

None of this would have been possible without the active input and participation of all of our members. We know that the transition to the NCTN has been challenging at the institutional and practice level. NRG Oncology leadership remains committed to partnering with all of our members and to assisting with the transition. We welcome any feedback or suggestions at our semiannual meeting in February in San Diego about how we as a group can best accomplish this.

Be sure to put on your calendars our upcoming NRG Oncology meetings in Denver (July 16–19, 2015), Atlanta (January 21–24, 2016), and Philadelphia (June 9–12, 2016). Looking forward to seeing everyone there!

Spotlight: NRG Oncology Gynecologic Cancer Committee

Advancing patient care galvanizes committee members.

The passion and dedication of the research teams supporting cooperative group clinical trials have been the key components in advancing the standard of care for patients with gynecologic cancers, according to Robert Mannel, MD, chair of the NRG Oncology Gynecologic Cancer Committee and director of the Stephenson Cancer Center at the University of Oklahoma in Oklahoma City. “One of the challenges we have in gynecologic cancers is that they represent a relatively rare group of tumors, and any single institution won’t have the patient volume to conduct high-quality, randomized prospective trials. So, being part of the cooperative group structure has enabled people who are passionate about advancing patient care to come together and to work together on new treatment strategies for gynecologic cancer,” says Mannel.

Mannel’s involvement in cooperative group research began when he was a fellow at the University of Irvine under the mentorship of Philip DiSaia, MD, where he was introduced to cooperative group trials and their importance for moving the field of cancer research forward. He then went on to build a cooperative group program at the University of Oklahoma. A GOG member since 1990, Mannel is now a member of NRG Oncology. As Mannel states, “being engaged in an organization that essentially establishes the way we take care of our patients through a very rigorous and scientifically thoughtful process has been very rewarding, and continues to be gratifying as we work on developing better therapies for our patients.” Mannel has served in many capacities in the cooperative group setting, including as site principal investigator, protocol chair of the GOG Protocol Development Committee, and now as chair of the NRG Oncology Gynecologic Cancer Committee. Also providing support for organization and protocol development are committee co-chairs Ronald Alvarez, MD, professor in the Division of Gynecologic Oncology at the University of Alabama at Birmingham; David Gaffney, MD, vice-chair, medical director, and professor of radiation oncology at the University of Utah School of Medicine and Huntsman Cancer Institute in Salt Lake City, Utah; and Ramey Littell, MD, a gynecologic oncologist at Kaiser Permanente in San Francisco, California.
The NRG Oncology Semiannual Meeting, taking place February 5–8 in San Diego, California, will offer attendees many of the familiar activities that continue to draw the research community together, along with several new meeting features. Following are just a few of the meeting highlights in store for the nearly 1300 anticipated attendees. Be sure to view all opportunities at Semiannual Meeting Materials.

2015 GYN Winter Symposium: Thurs., Feb. 5 (8:00 AM–2:30 PM)
The meeting will get underway with the 2015 edition of the symposium that brings together leading gynecologic cancer experts. This year’s symposium (Neoadjuvant Chemotherapy for Ovarian Cancer – Clinical Considerations and Research Opportunities) will discuss the latest neoadjuvant chemotherapy evidence and assessment strategies for advanced ovarian cancer.

Introduction to Clinical Trials: Principles of Clinical Trial Management: Thurs., Feb. 5 (8:00 AM–4:30 PM)
If you are you a nurse or clinical research associate who has been involved in clinical trials for less than a year, register now for this program to obtain in-depth information from experienced clinical trial professionals.

Scientific Session: Fri., Feb. 6 (8:00 AM–10:00 AM)
The session will offer a review of NRG Oncology’s latest research across the vast range of scientific research being conducted by NRG Oncology investigators.

General Session: Sat., Feb. 7 (1:00 PM–2:30 PM)
A new and exciting feature of this session will be the presentation of Outstanding Publications Awards. Investigators from each disease site committee will be recognized for the 2014 publication and abstract presentation deemed by NRG Oncology leadership to have the most scientific impact. Also to be recognized with an Outstanding Site Participation Award are the research sites that exhibited the best overall performance in support of NRG Oncology clinical trials during 2014.

Protocol-Specific Sessions
Attend one of these sessions to learn about recently activated trials as well as to gain new insight into trials that are well underway.

• NRG-BR001 Workshop, Thurs., Feb. 5 (2:00 PM–5:00 PM)
  *Invitation only—if interested in attending, please contact Theresa Powell (215-940-8903; tpowell@acr.org) to register.*
  Join colleagues participating in the NRG-BR001 trial to learn more about carrying out trial logistics and to better understand the expectations, challenges, and solutions associated with treatment planning and image-guided radiotherapy; demonstrations will be included. Also gain insight on plans for transitioning to the NRG-BR002 trial.

• NSABP B-51/RTOG 1304 Educational Session, Fri., Feb. 6 (3:00 PM–4:00 PM)
  *Why should your site accrue patients to the NSABP B-51/RTOG 1304 trial?* Find out by hearing from the protocol leadership, who will discuss trial updates and provide tips for increasing accrual. Learn how you can be part of this exciting trial!

• NRG-CC001 Kick-off Session, Fri., Feb. 6 (10:00 AM–11:00 AM)
  Don’t miss the kick-off meeting for the Cancer Prevention and Control Committee’s NRG CC001 trial expected to activate this spring. The NRG CC001 trial will test rigorously if a novel radiotherapy technique that avoids the hippocampus during whole-brain radiotherapy (WBRT) safeguards against memory decline as compared with standard WBRT.

• GOG 225 Information Session, Fri., Feb. 6 (11:00 AM–12:00 PM)
  Learn about this novel trial that is exploring if a lifestyle intervention can enhance survival and quality of life in ovarian, fallopian tube, and primary peritoneal cancer survivors.

• GOG 225 Workshop, Sat., Feb. 7 (10:00 AM–12:00 PM)
  Take advantage of a great opportunity especially for those who have completed the webinar training—to get hands on experience and gain clarification on any study related topics or issues. Note: Training is mandatory to open the trial.

• NSABP B-52, NSABP B-55, and NRG-BR003 Educational Session, Sat., Feb. 7 (12:00 PM–1:00 PM)
  Hear Charles Geyer, Jr, MD, and Priya Rastogi, MD, discuss the B-55 and B-52 trials, respectively, which currently are open for patient enrollment. Dr. Rastogi will introduce NRG-BR003, an adjuvant therapy trial for women with node-positive or high-risk node-negative, triple-negative invasive breast cancer, which will open to accrual later in 2015.
Currently, a large portion of the trials in NRG Oncology’s gynecologic cancer portfolio are open to enrollment in other countries through the Gynecologic Cancer Intergroup, which facilitates bringing together research groups from around the world. “Part of our goal is to look at new technologies and targeted therapies that can have a real impact on patient care worldwide,” says Mannel, “and having international colleagues participating in those discussions helps us to better understand global needs and how best to address them.” For example, Mannel points to the fact that treatment for cervical cancer, now more prevalent outside the United States, can benefit from international research collaborations such as the Australia New Zealand Gynaecological Oncology Group-led OUTBACK Trial, in which NRG Oncology is participating, which is evaluating a new treatment strategy for locally advanced cervical cancer.

Especially noteworthy Gynecologic Cancer Committee research highlights in 2014 include the publication in the New England Journal of Medicine of the GOG 240 results, which confirmed a survival advantage for the use of bevacizumab in the care management of patients with cervical cancer and led to the FDA's approval of the drug for this indication. Soon to be published are the results from the evaluation of the use of dose-dense paclitaxel therapy and carboplatin with or without bevacizumab for primary ovarian cancer in GOG 262, which Mannel cites as an especially intriguing trial.

Another large trial in ovarian cancer, GOG 252, was completed. Mannel suggests that this trial, which enrolled approximately 1500 patients to investigate the role of intraperitoneal chemotherapy, has a strong potential to define the standard of care for patients with optimally debulked ovarian cancer.
NRG Oncology Research Included in ASCO’s Clinical Cancer Advances 2015

The American Society of Clinical Oncology (ASCO) announced the inclusion of RTOG 9802 long-term results in its Clinical Cancer Advances 2015: ASCO’s Annual Report on Progress Against Cancer released on January 20. The long-term analysis results, presented by Co-principal Investigator Jan C. Buckner, MD, of Mayo Clinic in Rochester, Minnesota, at the 2014 ASCO Annual Meeting, confirmed that procarbazine/CCNU/vincristine (PCV) chemotherapy plus radiotherapy improved both overall survival (OS) and progression-free survival (PFS) in patients with low-grade glioma compared with radiotherapy alone. (See ASCO announcement.)

Co-principal Investigator Edward G. Shaw, MD, of the Wake Forest School of Medicine in Winston Salem, North Carolina, and colleagues published the initial RTOG 9802 results in the Journal of Clinical Oncology in 2012. This earlier analysis, at 5.9 years of median follow-up, showed that patients receiving the combination therapy had a significantly prolonged PFS compared with patients receiving radiotherapy alone; however, the analysis did not show significant improvement in OS from the combination therapy. Whereas, the current long-term analysis, at nearly 12 years of median follow-up, showed that OS was 13.3 years (combination therapy) vs 7.8 years (radiotherapy alone) and that PFS was 10.4 years (combination therapy) vs 4.0 years (radiotherapy alone).

Each year, ASCO conducts an independent review of advances in clinical cancer research that have the greatest potential impact on patients’ lives and publishes the Clinical Cancer Advances report detailing the top advances of the year. Congratulations to all those who supported RTOG 9802 research on the recognition of its important impact.

Bernard Fisher, MD, NSABP Founder, to Appear in Ken Burns’ The Emperor of All Maladies: A Biography of Cancer PBS Series

Bernard Fisher, MD, is one of the many cancer researchers who will chronicle the effort to understand, treat, and ultimately cure cancer in the 6-hour, three-part PBS series to air March 30 to April 1 on most PBS stations. He will appear in the program’s second episode. The Ken Burns’ production is based on Siddhartha Mukherjee’s book, The Emperor of All Maladies: A Biography of Cancer.

Named in its Oncology Luminaries series by ASCO last year for his groundbreaking work in breast cancer research, Dr. Fisher, a surgical oncologist, helped to establish NSABP and became the organization’s chairman in 1967. He served as NSABP chairman for nearly 30 years and currently is a distinguished service professor of surgery at the University of Pittsburgh School of Medicine.

For more about Dr. Fisher’s cancer research contribution, visit ASCO Oncology Luminary.

For more information about the PBS series, visit Explore the Film.

NRG Oncology Science Featured in a Twitter Chat

#RadOnc is a Twitter-based educational initiative coordinated by Zain Husain, MD, of the Smilow Cancer Hospital at Yale-New Haven and Matthew Katz, MD, a member of NRG Oncology’s Social Media Subcommittee and a radiation oncologist at Lowell General Hospital in Massachusetts. The initiative includes a Twitter journal club chat that begins usually on the third Friday of each month, with open comment globally leading up to a live chat hour on the following Sunday at 8:00 PM Central Standard Time.

On January 23, 2015, the #RadOnc Journal Club addressed the recently published RTOG 0129 secondary analysis results, which show that the treatment setting for patients with locally advanced head and neck cancer impacts survival and cancer progression. The article will be available for free access during the discussion period to encourage global participation.

#RadOnc is hosted by Radiation Nation (@Rad_Nation), a Web-based resource designed to improve cancer care through the discussion of clinically important aspects of radiation oncology.
Clinical Trial Highlights

Newly Activated Trial

NRG-BR002: A Phase IIIR/III Trial of Standard of Care Therapy With or Without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer

Activated on December 24, 2014, the NRG-BR002 multiphase clinical trial will test whether ablative therapy (either stereotactic body radiotherapy [SBRT] or surgery) combined with standard systemic therapy (Arm 2) will extend the lives of women diagnosed with oligometastatic breast cancer compared with standard systemic therapy alone (Arm 1).

“Oligometastasis describes an intermediate state of cancer spread between localized disease and widespread metastases. During the last decade, evidence has emerged that patients with controlled primary tumors and limited metastases may survive longer through aggressive treatment of oligometastatic disease prior to or during standard palliative systemic therapy.”

STEVEN CHMURO, MD, PHD
NRG-BR002 Principal Investigator

If the data analysis of the NRG-BR002 randomized phase II component (enrolling 146 women) suggests a significant improvement in the patients’ progression-free survival (PFS), the phase III trial (enrolling 256 more women) will be initiated to determine if patients enrolled in the experimental treatment arm have significantly improved overall survival (OS) at 5 years post-treatment. This will be the first randomized trial to answer whether the addition of ablative therapy can alter the progression of metastatic breast cancer (MBC) treated with standard systemic therapy.

Another important trial objective is to evaluate a promising new technique using the FDA-approved and commercially available CellSearch® assay that detects the presence of circulating tumor cells (CTCs) in patients with MBC. Study investigators predict that patients with few or no CTCs will be ideal candidates for SBRT and will have longer PFS and OS than those with ≥5 CTCs (per 7.5 mL of blood).

Primary Objective

Phase IIIR: To determine whether ablation (through SBRT and/or surgical resection of all known metastases) in oligometastatic breast cancer patients provides a sufficient signal for improved PFS to warrant full accrual to the phase III portion of the trial.

Phase III: To determine whether ablation (through SBRT and/or surgical resection of all known metastases) in oligometastatic breast cancer patients improves OS significantly

Translational Research Primary Objective

To determine whether <5 CTCs (per 7.5 mL of blood) is an independent prognostic (outcome) marker for improved PFS and OS in oligometastatic breast cancer

Target Accrual

402 patients (including the 146 to be accrued in the phase II-R portion)

Patient Population

Patients with locally controlled MBC and ≤2 metastases (at least 1 pathologically confirmed) visualized on CT or PET/CT. Locoregional disease must have undergone treatment at least 3 months prior to study registration per standard of care with no known residual disease.

Schema

- Number of metastases: 1 vs >1
- Hormone receptor status: ER and/or PR positive vs ER and PR negative
- HER2 status: Positive vs Negative
- First-line standard systemic chemotherapy: Yes vs No

Soon-To-Be-Activated Trial

NRG-CC002: Preoperative Assessment and Postoperative Outcomes of Elderly Women With Gynecologic Cancers

The NRG Oncology Cancer Prevention and Control Committee is soon to activate a prospective clinical trial to evaluate if a preoperative geriatric assessment tool can help predict the postoperative outcomes of elderly women, aged 70 years or older, diagnosed with suspected gynecologic cancer.

Retrospective studies have shown that elderly women with gynecologic cancers receive surgical treatment less often than their younger counterparts despite having similar health status—possibly because physicians are concerned about the potential for severe complications. However, it has also been reported that when elderly patients can tolerate surgery, they have rates of initial response to chemotherapy, overall survival, and progression-free survival that are similar to those of younger women with gynecologic cancers.

continued
Clinical Trial Highlights (continued)

Currently, no validated assessments exist to help determine surgical outcomes for major gynecologic oncology operations. Such a tool could be especially valuable in helping to identify elderly patients who are good candidates for primary cytoreductive surgery, who could benefit from surgery being delayed until after neoadjuvant chemotherapy, and who could benefit from mitigating the risks identified by the assessment.

The preoperative assessment tool to be evaluated derives a geriatric assessment (GA)-gynecology (GYN) score from a predictive model using components of an abbreviated geriatric assessment composed largely of self-administered questionnaires. The comprehensive assessment, expected to be completed within approximately 20 minutes, includes an evaluation of the patient’s functional status, comorbidities, psychological status, social functioning, support, and nutritional status.

Target Sample Size: 228 patients

Target Accrual for the Primary Analysis: 100 patients

Note: Study accrual will be closed when either 100 eligible patients undergoing primary cytoreductive surgery or a total of 228 eligible patients are enrolled, whichever comes first.

Patient Population

Patients with suspected ovarian, fallopian tube, primary peritoneal carcinomas or advanced-stage papillary serous uterine carcinoma, irrespective of performance status, who are aged 70 years or older

Primary Objective

To determine whether the preoperative GA-GYN score will be associated with major postoperative complications in elderly patients undergoing open primary cytoreductive surgery

Secondary Objectives

• To explore associations between individual variables of the preoperative geriatric assessment and major postoperative complications in patients undergoing open primary cytoreductive surgery
• To assess the association between the preoperative GA-GYN score and cytoreducibility defined by extent of residual disease in patients undergoing open primary cytoreductive surgery

Exploratory Objectives

A wide range of questions regarding the outcomes of patients who receive neoadjuvant therapy prior to cytoreductive surgery will be explored.

Schema

Clinical Trial Focus

2015 Resolution: NRGize to Accrue Patients With Stage III NSCLC Into a Trial Evaluating Individualized Combined-Modality Therapy

Patients diagnosed with locally advanced non-small cell lung cancer (NSCLC) face an exceptionally grim prognosis, as more than 70% are likely to die from recurrent disease. Research has shown that lung cancer—particularly adenocarcinoma—is remarkably molecularly diverse. This evidence highlights the need for innovative treatment strategies that integrate predictive biomarkers for the use of novel targeted agents.

“If the study meets its primary end points, it will likely change practice patterns. Patients with locoregionally advanced NSCLC would be screened routinely for EGFR-TK mutations and EML4-ALK fusion gene, and individualized therapy would become the standard of care for patients with stage III NSCLC.”

RAMASWAMY GOVINDAN, MD
RTOG 1306 Principal Investigator

continued
Clinical Trial Highlights (continued)

The NRG Oncology trial RTOG 1306 (A Randomized Phase II Study of Individualized Combined Modality Therapy for Stage III Non-small Cell Lung Cancer (NSCLC)) stands as an example of research evaluating targeted agents based on molecular biomarkers. Specifically, study participants with inoperable, locoregionally advanced NSCLC consent to have tumor tissue screened for evidence of either epidermal growth factor receptor (EGFR) tyrosine kinase (TK) mutations or echinoderm microtubule-associated protein-like 4 (EML4) anaplastic lymphoma kinase (ALK) fusion gene at a local Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory. If one (or both) of the biomarkers is present, the participant will be randomized to receive targeted therapy (erlotinib or crizotinib, depending on the laboratory results) plus standard chemoradiotherapy (experimental arm) or chemoradiotherapy alone (standard arm). The trial’s primary objective is to assess whether patients treated with the targeted agent have longer progression-free survival than patients treated with standard therapy alone.

A PowerPoint presentation with more study details is available for investigators’ use in disseminating information about this important trial. See PowerPoint.

More information about the trial is available on the CTSU website and at ClinicalTrials.gov.

Shout Out to Sites
Collecting information and preparing the extensive documentation required for submission of a protocol to an institutional review board (IRB) requires significant collaboration on the part of site research teams. Obtaining expedient IRB approval is critical to beginning study participant enrollment, meeting accrual targets, and obtaining the research data necessary to answer important questions related to improving patient care.

We are pleased to recognize the research sites first to provide notice of IRB approval and first to enroll a study participant onto an NRG Oncology trial.

First Sites to Provide IRB Notifications
NRG-HN002
University of California, San Diego, Moores Cancer Center
Cancer Research for the Ozarks NCORP

First Site to Enroll a Study Participant
NRG-BN001
Central Dupage Hospital Cancer Center

NRG-HN002
Ohio State University Wexner Medical Center

NRG Oncology Highlights From San Antonio

NRG Oncology research was featured prominently at this year’s San Antonio Breast Cancer Symposium, which took place December 9–12, 2014. The nearly 7500 attendees had the opportunity to hear about the exciting strides being made in breast cancer research, including the following four presentations.

NSABP B-31: Intrinsic subtypes, PIK3CA mutation, and the degree of benefit from adjuvant trastuzumab in the NSABP trial B-31

Results of the NSABP B-31 trial, presented during a general session by Soon Paik, MD, of the Yonsei University College of Medicine in Seoul, Korea, and Director/Senior Advisor of the Department of Pathology for the NSABP Foundation, confirmed that considerable molecular heterogeneity exists among HER2-positive breast cancer regarding gene expression and mutation profiling. PIK3CA and PAM50 intrinsic subtypes were not found to be biomarkers for differential response to trastuzumab in the adjuvant setting in NSABP B-31. These data suggest that results from the metastatic and neoadjuvant setting may not always be applicable to the adjuvant setting. Read full abstract.

NSABP B-36: A randomized phase III trial comparing six cycles of 5-fluorouracil, epirubicin, and cyclophosphamide (FEC) to four cycles of Adriamycin and cyclophosphamide (AC) in patients with node-negative breast cancer

Charles Geyer, Jr, MD, FACP, of the Virginia Commonwealth University Massey Cancer Center in Richmond presented results during a general session from the NSABP B-36 trial, which showed that 6 cycles of the FEC-100 regimen did not result in any efficacy advantage over 4 cycles of standard AC in node-negative breast cancer. Additionally, the FEC-100 regimen resulted in greater toxicity. Read full abstract.

NSABP B-40: The effect on overall (OS) and disease-free survival (DFS) by adding bevacizumab and/or antimitabolites to standard neoadjuvant chemotherapy: NSABP Protocol B-40

Results from the NSABP B-40 trial were presented in a poster session by Harry Bear, MD, of the Virginia Commonwealth University Medical Center in Richmond. Adding bevacizumab to standard chemotherapy was shown to improve OS and DFS in women with hormone receptor-positive (HR+) breast cancers. The addition of capecitabine or gemcitabine to neoadjuvant therapy had no significant impact on DFS and OS in patients with operable, HER2-negative breast cancer. Read full abstract.
From the Genitourinary Cancer Committee

Short Course of Hormonal Therapy Prior to Radiotherapy Offers Men With Intermediate-Risk Prostate Cancer Excellent Outcomes

Men with prostate cancer who are at intermediate risk for cancer recurrence after initial treatment are best served with an 8-week course of androgen suppression therapy (AST), followed by radiotherapy (RT) with an additional 8 weeks of AST, according to results of the RTOG 9910 randomized clinical trial published online on December 22, 2014 in the Journal of Clinical Oncology. Read press release.

From the Head and Neck Cancer Committee

Treatment Setting for Patients With Locally Advanced Head and Neck Cancer Impacts Survival and Cancer Progression

Patients with locally advanced head and neck cancer (HNC) treated at medical centers with historically low patient enrollment in HNC clinical trials are more likely to die from their disease compared with those treated at centers with high patient enrollment in HNC clinical trials. Read press release.

From the Brain Tumor Committee

Hippocampus-Sparing Intensity-Modulated Radiotherapy Technique Safeguards Patients’ Memory

Use of an intensity-modulated radiotherapy (IMRT) technique that avoids radiation dose to the hippocampus during whole-brain radiotherapy safeguards patients’ memory, according to results of a clinical trial published online on October 27, 2014 in the Journal of Clinical Oncology. Read press release.

From the Lung Cancer Committee

Standard-Dose Versus High-Dose Conformal Radiotherapy With Concurrent and Consolidation Carboplatin Plus Paclitaxel With or Without Cetuximab for Patients With Stage IIIA or IIIB Non-Small Cell Lung Cancer: a Randomised, Two-by-Two Factorial Phase III Study

Results of the randomized phase III clinical trial RTOG 0617, which enrolled 464 patients with stage III non-small cell lung cancer to evaluate if treatment with high-dose (74 Gy in 37 fractions) compared with low-dose (60 Gy in 30 fractions) radiotherapy or with the addition of cetuximab resulted in improved overall survival, were published online in The Lancet Oncology on January 15, 2015. The investigators concluded that neither high-dose radiation nor the addition of cetuximab improved survival. Read abstract. Listen to a podcast with trial Principal Investigator Jeffrey D. Bradley, MD, a professor of radiation oncology and chief of thoracic service at Washington University School of Medicine in St. Louis, Missouri.

From the Breast Cancer Committee

PIK3CA Genotype and Treatment Decisions in Human Epidermal Growth Factor Receptor 2 (HER2)–Positive Breast Cancer

Results of the analysis evaluating the predictive value of PIK3CA and PAM50 intrinsic tumor subtypes for adjuvant trastuzumab benefit in a subgroup of patients enrolled in the NSABP B-31 clinical trial were published online ahead of print in the Journal of Clinical Oncology on January 5, 2015. The results show that, unlike in the metastatic and neoadjuvant settings, PIK3CA and PAM50 intrinsic subtypes were not predictive markers for adjuvant trastuzumab. Read abstract. Read editorial.

A Prospective Randomized Trial for Good-Risk Ductal Carcinoma In Situ Comparing Radiotherapy With Observation

The RTOG 9804 study sought to identify a “good-risk” subset of patients with ductal carcinoma in situ (DCIS), a breast cancer diagnosis found frequently in mammographically detected cancers, to test the benefit of radiotherapy after breast-conserving surgery compared with observation. The results, published online ahead of print in the Journal of Clinical Oncology on January 20, 2015, confirm that the trial identified successfully a subset of women with good-risk DCIS based on standard pathology features, including nuclear grade, size, and margin width. Although the addition of radiotherapy decreased the local failure rate significantly in the patients accrued to this study, the authors suggest that “the full clinical implications of these results will require further follow-up, given the historic patterns of local failure over 10 to 15 years from diagnosis of good-risk DCIS.” Read abstract.