Message From Our NRG Oncology Group Chairs

It is hard to believe but NRG Oncology celebrated its third birthday in March along with the National Clinical Trials Network (NCTN)! We are now preparing our competitive renewal grant application which is expected to be due in January. During the last three years NRG Oncology investigators and staff have worked hard to combine the research objectives, procedures, and policies of our founding legacy groups into a dynamic new organization. There have been difficulties along the way, funding is never as robust as we would like, and NCI approval of our concepts often does not match the pace of our idea development. Yet we have activated 27 trials under the NRG “brand”, and we have another 23 trials from our legacy groups still open and accruing patients. Our membership must be congratulated on our progress.

As we move forward NRG Oncology continues to refine our policies to meet the needs our maturing group. Proposed amendments to the NRG Group Bylaws will be sent to our Voting Members in advance of the July meeting. In addition, the Membership Committee will be reviewing the Membership Criteria so that it reflects the current needs of our members.

Thank you all for your efforts on behalf of NRG Oncology. We are looking forward to seeing many of you at our semiannual meeting in Philadelphia in few weeks.

Philip J. DiSaia, MD

NRG Oncology’s RTOG 0617 Chosen as JCO Top 7 Thoracic Cancer Article for 2016

Impact of Intensity-Modulated Radiation Therapy Technique for Locally Advanced Non-Small Cell Lung Cancer: A Secondary Analysis of the NRG Oncology RTOG 0617 Randomized Clinical Trial

A secondary analysis of NRG Oncology's clinical trial RTOG 0617, published in the Journal of Clinical Oncology (JCO) and established as a Best of JCO 2017 article, was initiated in an effort to compare intensity-modulated radiation therapy (IMRT) and three-dimensional conformal external beam radiation therapy (3D-CRT) outcomes for patients with locally advanced Non-Small Cell Lung Cancer (NSCLC). NRG-RTOG 0617 determined that IMRT was associated with lower rates of severe pneumonitis and cardiac doses, which supports routine use of IMRT for this patient population.

The Journal of Clinical Oncology Article

New Publications Policy

The NRG Oncology Publications Policy was updated and released in March 2017. The new policy and guidelines document can be found on the NRG Oncology website’s Publications page. Follow the link below for more.

Publications Policy & Guidelines
NRG Protocol Support Committee Column

NRG Protocol Support Group Meeting Review
NRG Oncology Houston, TX
February 9-11, 2017

We had a successful meeting in Houston! The PSC Education Committee and Orientation Planning Committee provided excellent seminars that met the education needs of our CRAs/CTNS, both new and experienced, in the field.

Thursday, February 9:
The meeting began with an all-day Orientation Program for new coordinators. Dr. Lawrence Wickerham, NRG Deputy Chair, opened the session with a Welcome and Introduction to NRG Oncology. Subsequent lectures on topics pertinent to the research nurse/coordinator role included: audits, serious adverse event reporting, membership, IRB basics, investigational drug management, Rave, RECIST outcome measurements, quality of life endpoints and measurements, and an update on the PSC Mentorship program. The Orientation Program is held once a year at the Winter NRG Oncology session. We encourage all new coordinators to attend and benefit from the scope of valuable information.

The afternoon session involved rotating breakout sessions. During the breakout sessions, coordinators have an opportunity to engage in discussion, ask questions, and learn information for immediate implementation in their practice. The afternoon sessions included: screening and enrollment, data management, adverse event reporting, and information on different treatment modalities. The sessions were well attended by new CRAs/CTNS and those wishing to catch up and garnish new information. There were 184 people registered.

Friday, February 10:
In the morning the CRA/CTN Committees hosted a Question and Answer Table. This venue allowed one-on-one interaction and the opportunity to ask questions, provide comments, and discuss general information. In the afternoon, the PSC Educational Workshop included substantive lectures on: data delinquency, CTEP investigational drug policies, TRIAD radiation oncology and radiology portal, recruitment survey update, and a CTSU update. Dr. Wally Curran, NRG Oncology Group Chair, opened the Educational Workshop meeting, acknowledged the important role and contribution of the nurses and coordinators, and thanked them for all their efforts. The CTN/CRA Education workshop had 215 people registered. Other PSC business meetings and workshops were held on Thursday evening and Friday.

If you were unable to make these sessions or want to use the presentations as teaching tools, copies of the presentations are posted on the NRG website https://www.nrgoncology.org/About-Us/Meetings/February-2017-Meeting-Resources; login using your CTEP IAM ID.

Remember that continuing educational credits are offered for many of the PSC sessions. We look forward to seeing everyone in Philadelphia on July 13-15, 2017 then in Phoenix January 25-27, 2018.

Protocol Support Committee NRG Oncology Mentorship Working Group

The PSC NRG Mentorship Working Group is one of four working groups under the guidance of the NRG Protocol Support Committee. The purpose of the working group is to provide support to CRNs and CRAs who are new to clinical trials or who have questions about the process and procedures involved in NRG Oncology clinical trials.

The NRG Mentorship Working Group developed a “Welcome To New Members” resource packet designed to facilitate and smooth the introduction to NRG Oncology. This online packet includes information about specific processes to assist in the conduct of NRG Oncology clinical trials. Additionally, the packet includes contact information to individuals who will happily assist you with your questions or help you navigate challenges. The goal of the resource is to clarify NRG Oncology trial operations and procedures, as well as to provide direct contacts for questions.

The resource packet is posted on the NRG website under the <Nurses and CRAs> tab. Select the "Mentorship Program (New to NRG Oncology)” link and then select the “Introductory Materials for NRG Oncology Clinical Trial Coordinators” document.

The NRG Mentorship Working Group is currently developing the Mentor Program. This is an exciting opportunity for members to become involved and we will need Mentors once the program is ready for activation. Stay tuned for more information.

Are you new to NRG Oncology? Are you new to clinical trials? The Mentorship Working Group provides a temporary mentor to help assist you with your questions related to getting started with your clinical trial program. This is not intended to replace the protocol specific questions that should be directed to the PI of the protocol, the Nurse Contact, or the CCD.

For assistance, contact NRG Oncology at 1-800-477-7227 and ask for the contact person for the Pilot Navigator Plan.
Nurses and CRAs on the NRG Oncology Website

Have you explored the NRG Oncology website? Did you know there is a tab for Nurses and CRAs? New information is periodically added, so check it out! You will find the following:

- **Protocol Support Committee (PSC)** - A description of the primary functions of this Committee;
- **Contact information** for the PSC;
- **Mentorship Program** – Introductory Materials for NRG Oncology clinical trial coordinators;
- **PSC Working Groups** – a brief description of the 4 working groups: Education & Training, Mentorship, Protocol Review, and Quality Control;
- **Education & Training** - materials for upcoming meetings are posted prior to each meeting. The February 2017 meeting resources are currently posted here;
- **Past Meeting Resources** – find copies of presentations from past CTN/CRA Educational Workshops, Breakout sessions and Orientation/Introduction to Clinical Trials Workshop.

Explore the Nurses and CRAs page

PSC E-mail Address Box

The PSC established a central e-mail address at NRG Oncology to enhance communication with clinical trial nurses and clinical research associates. This mailbox is a way for you to ask questions and to offer suggestions/comments/feedback to the PSC. The PSC e-mail box will be checked weekly by PSC staff and it is not for urgent matters. Questions regarding protocol guidance and patient care issues should be addressed to the appropriate contacts listed in the individual protocol, not this general PSC mailbox.

The PSC address is nrg-psc@NRGOncology.org

We are currently planning the next PSC education activities for the July 2017 meeting. We are planning to have roundtables for one of the sessions. Multiple tables will be set up to discuss various topics. Attendees will circulate to the tables that are pertinent to their interests. If you have any suggestions for round table topics, please let us know within the next few weeks. We will have both NRG Oncology Headquarters staff and experienced CTNs and CRAs available to provide guidance and answer questions. The meetings are for you and your input is valued.

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**NRG Oncology NCORP Updates**

The new Biomarker, Imaging, & Quality of Life Studies Funding Program (BIQSFP) recently released the 2017 BIQSFP Guidelines. The major changes to the guidelines include:

- Integrated and CEA studies must be submitted within three (3) months of the PI receiving notification by the respective CTEP/DCP PIO, that the concept was approved.
- Anticipated/planned integrated studies should be annotated on the respective CTEP/NCORP Trial Concept Submission Form at the time of parent concept submission.
- QOL biomarker and imaging studies are eligible for BIQSFP funding. QOL/PRO studies other than biomarker and imaging, should be submitted to DCP for Cancer Control credits. The routine collection of QOL/PRO data is covered by DCP Cancer Control credit and is not eligible for BIQSFP funding.
- Exceptions to BIQSFP submission timelines are permitted in rare cases.

The guidelines for Investigator Initiated Federally and Non-Federally Funded Studies has recently implemented a major change to the policy. The time allotted for the development of protocols and concepts for non-NCORP Research Base funded studies will be 90 days and will be consistent with the required time for NCORP Research Based funded trials and studies. This policy will be effective for new concepts starting April 15, 2017.

The 2017 BIQSFP and the Investigator Initiated Federally and Non-Federally Funded Study Guidelines can be found on the NRG Oncology website under NCORP Resources.
NRG Oncology Top Accruing Sites for 2016

The top accruing sites were announced at the NRG Oncology Semiannual Meeting in Houston, Texas February 9-11, 2017. These results were based off of data collected between January 1 - December 31, 2016.

### Top Accruing National Community Research Program (NCORP)

1. Kaiser Permanente NCI Community Oncology Research Program
2. Southeast Clinical Oncology Research Consortium, Inc., NCORP
3. CIRI Oncology Research Alliance NCORP
4. Georgia NCI Community Oncology Research Program
5. Heartland Cancer Research NCORP

### Top Accruing Lead Academic Participating Sites (LAPS)

1. University of Oklahoma Health Sciences Center LAPS
2. CWRU - Case Comprehensive Cancer Center LAPS
3. Washington University - Siteman Cancer Center LAPS
4. Memorial Sloan-Kettering Cancer Center LAPS
5. University of Texas MD Anderson Cancer Center LAPS

### Top Accruing Main Member Sites

1. Seoul National University Hospital
2. Sutter Cancer Research Consortium
3. Thomas Jefferson University Hospital
4. Cadence Cancer Center in Warrenville
5. Froedtert and the Medical College of Wisconsin
6. UF Cancer Center at Orlando Health

### Top 5 Non-US Sites

1. CHUM - Hospital of Notre-Dame
2. University Health Network - Princess Margaret Hospital
3. Asan Medical Center
4. Seoul National University Bundang Hospital
5. Seoul National University Hospital

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Do You Have a Suggestion for Newsletter Content?

Our **NRG Oncology Communications Committee** is always looking for suggestions for information and special achievements to include in our newsletter.

Please send information about special achievements of NRG Oncology members or research teams, suggestions for future articles, and regular features you would like to see in future issues of the **NRG Oncology Newsletter to**: info@nrgoncology.org
NRG Oncology Clinical Trial Highlights

NRG-GU002: Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy With or Without Adjuvant Docetaxel

Background
Despite radical prostatectomy, clearly defined high risk groups of patients with adenocarcinoma of the prostate have been identified that do poorly even with the addition of adjuvant radiation therapy. Of these high-risk patients that receive the standard treatment for this type of cancer, approximately 33 out of 100 are free of cancer at three years. NRG-GU002 seeks to determine the benefit of docetaxel by measuring improvements in freedom from progression (phase II) and subsequently metastasis free survival (phase III) when given in combination with radiation and androgen deprivation in the treatment of high risk prostate cancer post-radical prostatectomy.

NRG-GU002 will be separated two treatment arms. Treatment arm one will receive standard hormone suppression therapy and radiation therapy typically used for these high-risk patients. Treatment arm two will also receive the standard hormone suppression therapy and radiation therapy followed by six doses of docetaxel four to six weeks after radiation therapy.

Primary Objective
To assess the benefit of docetaxel as measured by improvement in freedom from progression (phase II) and subsequently metastasis free survival (phase III) when given in combination with radiation and androgen deprivation in treatment of high risk prostate cancer post-radical prostatectomy

Secondary Objectives
• To assess:
  • overall survival (OS)
  • time to local progression
  • undetectable PSA with a non-castrate testosterone at 2.5 years post-treatment
  • the utility of genomic profiling in making adjuvant therapy decisions post-prostatectomy
  • toxicity of docetaxel in the post-operative setting when combined with radiation and androgen deprivation therapy
  • treatment response by genomically defined subgroups of prostate cancer patients

Schema

| REGISTRATION |
| STRATIFY |
| Gleason Score |
| PSA |
| Decipher Risk Category |

| RANDOMIZE |
| ARM 1 |
| EBT starting 8 weeks after initiation of ADT + ADT: LHRH Agonist/Antagonist + bicalutamide 6 months duration |
| ARM 2 |
| EBT Starting 8 weeks after initiation of ADT + ADT: LHRH Agonist/Antagonist + bicalutamide 6 months duration + Docetaxel starting 4-6 weeks after completion of radiation |

Target Accrual
297 for phase II
612 patients overall

Patient Population
Patients with pathologically proven diagnosis of adenocarcinoma of the prostate as confirmed at the time of prostatectomy. Post prostatectomy Gleason ≥ 7, baseline PSA nadir ≥ 0.2 ng/ml. Surgical FFPE

NRG-GU002 EMR Pilot

NRG Oncology will pilot an Electronic Medical Record (EMR) build template with NRG-GU002. The purpose is to assist sites in configuring their EMR application for this study. By succinctly providing the protocol’s elements that are most relevant to the EMR end user, the template attempts to decrease protocol start up time and use of resources at the site level.

This template’s target audience includes but is not limited to: site pharmacists, investigators, RNs, EMR IT staff and QA personnel. This template does not serve as a substitute for the protocol itself; therefore certain protocol elements not typically contained in an EMR build are excluded.

The goal of the pilot is to evolve and refine the EMR template for broad applicability across the NCTN and the myriad EMR systems. Accordingly, your participation and feedback are invaluable. If you choose to participate in the pilot, NRG Oncology asks that you provide real time input on the template and send any suggested changes to NRG. Additionally NRG will ask you to complete a survey in order to formally evaluate how the EMR template impacted study start up efforts. We appreciate your time and effort on this pilot project.

On the NRG-GU002 protocol page of the NRG Oncology website, you will find the EMR template, a procedure letter that explains the template and includes contact information, and other related materials.
NRG Oncology Clinical Trial Highlights (continued)

NRG-BN002: Phase I Study of Ipilimumab, Nivolumab, and the Combination in Patients with Newly Diagnosed Glioblastoma

**Background**
Patients with newly diagnosed glioblastoma are typically treated with radiation in combination with temozolomide followed by temozolomide alone and approximately only 4 out of 100 are free of tumor growth at five years. Despite advances in surgery, radiation therapy, and chemotherapy, glioblastoma remains an incurable disease. NRG-BN002 will determine the safety of ipilimumab and/or nivolumab in combination with temozolomide in this patient population due to their prior successes with other cancer types.

NRG-BN002 consists of three treatment cohorts. After patients successfully complete the standard concurrent radiation therapy and temozolomide, they will be assigned to one of the following two cohorts: the group receiving ipilimumab (Cohort 1) or the group receiving nivolumab (Cohort 2), in combination with temozolomide. If both cohorts are determined to be safe, Cohort 3 will investigate treating patients with both nivolumab and ipilimumab in combination with temozolomide.

**Primary Objectives**
To determine the maximum tolerated dose of single-agent treatment with ipilimumab, nivolumab and the combination when given with temozolomide during maintenance stage of the treatment for newly diagnosed glioblastoma.

**Secondary Objectives**
- To collect and record the side effect profiles for single-agent treatment with ipilimumab, nivolumab, and the combination when given with temozolomide during the maintenance phase for newly diagnosed glioblastoma.
- To perform pilot studies of immune cells within tumor samples, (e.g. phenotyping tumor infiltrating lymphocytes (TILs) by interrogating tumor tissues from diagnostic tumor blocks).
- To report the number of patients alive at 1 and 2 years after the start of single-agent treatment with ipilimumab, nivolumab, and the combination when given with temozolomide during the maintenance phase for newly diagnosed glioblastoma.

**Target Accrual**
42 patients at maximum

**Patient Population**
Patients with a histopathologically proven diagnosis of glioblastoma or gliosarcoma prior to registration by pathology report. The tumor must be unifocal, confined to the supratentorial compartment and have undergone a gross total or near gross total resection.

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**Schema**

<table>
<thead>
<tr>
<th>COHORT 1</th>
<th>COHORT 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose level 1a - ipilimumab 3 mg/kg q 28 days x 4 cycles; then 3 mg/kg q 3 months x4</td>
<td>Dose level 2a - nivolumab 3 mg/kg q 2 weeks x 4 cycles; then 3 mg/kg q 2 weeks x24</td>
</tr>
<tr>
<td>Dose level 1b - ipilimumab 1 mg/kg q 28 days x 4 cycles; then 1 mg/kg q 3 months x4</td>
<td>Dose level 2b - nivolumab 1 mg/kg q 2 weeks x 4 cycles; then 1 mg/kg q 2 weeks x24</td>
</tr>
</tbody>
</table>

**Based on the results from the dose-limiting toxicity analyses on dose levels 1a and 2a in July 2016, dose levels 1a and 2a were deemed to be safe. Therefore, analyses for Cohorts 1 and 2 were considered to be completed and the study moved on to one of the subsequent cohorts with the combination regimens, Cohort 3.3.**

**COHORT 3.3**

<table>
<thead>
<tr>
<th>Dose level 3.3a</th>
</tr>
</thead>
<tbody>
<tr>
<td>ipilimumab at 1 mg/kg q 4 weeks x 4 and nivolumab at 3 mg/kg q 2 weeks x32</td>
</tr>
<tr>
<td>Dose level 3.3b</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>ipilimumab at 1 mg/kg q 4 weeks x 4 and nivolumab at 1 mg/kg q 2 weeks x32</td>
</tr>
</tbody>
</table>

**Based on the results from the dose-limiting toxicity analysis on dose level 3.3a in January 2017, dose level 3.3a was deemed to be safe. Therefore, analysis for Cohort 3.3 was considered to be completed. According to the study design, the study is currently open to patient accrual on the expansion cohort under dose level 3.3a, in order to provide more safety information on the combination regimens**

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*continued*
NRG Oncology Clinical Trial Highlights (continued)

NRG-HN003: A Phase I and Expansion Cohort Study of Adjuvant Cisplatin, Intensity-Modulated Radiotherapy, and MK-3475 (Pembrolizumab) in High-Risk Head and Neck Squamous Cell Carcinoma (HNSCC)

Background
Head and neck squamous cell carcinoma (HNSCC) is the sixth leading cancer worldwide. The current standards of care for the adjuvant management of locally advanced, HPV-negative HNSCC are determined by pathological risk. Typically, patients with high-risk HNSCC are treated with surgery and subsequently treated with a combination of radiation therapy and cisplatin chemotherapy. The NRG Oncology clinical trial NRG-HN003, a limited institution study, aims to update the current standard of care for high-risk HNSCC to determine if the addition of pembrolizumab to radiation therapy and chemotherapy will ultimately improve outcomes for this patient population. The purpose of NRG-HN003 is to test the timing of the dose of pembrolizumab paired with the radiation and chemotherapy to determine which combination is the safest option for patients.

NRG-HN003 will be separated into three schedule-finding phases (Group 1, 2, or 3). Patients will all receive eight doses of pembrolizumab in addition to the standard treatment of six weeks of radiation therapy and cisplatin chemotherapy. Pembrolizumab may be given to as many as three groups of twelve patients. Each group will receive a full dose of pembrolizumab, but on a different schedule. Group 3 will be assessed first, and the side effects for patients from that group will be evaluated before studying the next treatment schedule group. Once the best schedule of pembrolizumab is determined, 20 patients will receive pembrolizumab according to that schedule.

Primary Objective
To determine the recommended phase II schedule for the combination of MK-3475 (pembrolizumab) and standard, adjuvant cisplatin-radiotherapy in patients with high-risk, HPV-negative head and neck squamous cell carcinoma (HNSCC), based upon dose-limiting toxicity (DLT).

Secondary Objectives
To describe:
- 1-year disease-free survival (DFS), overall survival (OS), locoregional failure (LRF), and rate of distant metastases following treatment with adjuvant cisplatin-radiotherapy and MK-3475 (pembrolizumab);
- the toxicity of the combination of cisplatin radiotherapy and pembrolizumab according to CTCAE v. 4, including immune-related adverse events (AEs);
- the relationship between baseline PD-L1 expression and 1-year DFS;
- baseline immune inflammatory biomarkers in both tumor and tumor-infiltrating lymphocytes (TILs), and correlate them with 1-year DFS;
- baseline and change in expression of peripheral immune-inflammatory biomarkers, including a panel of candidate tumor antigen (TA)-specific memory T cells, and correlate with 1-year DFS.

Target Accrual
32-56 Patients

Patient Population
Patients with stage III-IVb, high-risk squamous cell carcinoma of the oral cavity, oropharynx (HPV-negative), hypopharynx, or larynx who have undergone primary oncologic surgery and demonstrate a high risk pathologic feature (extracapsular nodal extension or positive surgical margin).
NRG Oncology’s NSABP B-51/RTOG 1304

NSABP B-51/RTOG 1304 is a randomized phase III clinical trial evaluating post-mastectomy chestwall and regional nodal XRT and post-lumpectomy regional nodal XRT in patients with positive axillary nodes before neoadjuvant chemotherapy who convert to pathologically negative axillary nodes after neoadjuvant chemotherapy. B-51/1304 opened to accrual in August of 2013 with an accrual goal of 1636 patients. B-51/1304 is looking to answer the question of how to treat those breast cancer patients who are pathologically node positive at initial presentation but convert to pathologically node negative at the time of definitive surgery following neoadjuvant chemotherapy. Will the addition of chest wall and regional nodal external radiation therapy after mastectomy reduce the rate of events for invasive breast cancer recurrence free interval? Will the addition of breast and regional nodal XRT after breast conserving surgery reduce the rate of events for invasive breast cancer recurrence free interval? The trial underwent a substantial amendment in 2016 with changes to the credentialing portion of the trial and also to eligibility. The changes were done in part to reduce the burden for the sites when working with the trial without effecting patient safety.

AIMS

The primary aim of the trial is to evaluate whether the addition of chestwall and regional nodal XRT after mastectomy or breast + regional nodal XRT after breast conserving surgery will significantly reduce the rate of events for invasive breast cancer recurrence-free interval in patients who present with histologically positive axillary nodes but convert to histologically negative axillary nodes following neoadjuvant chemotherapy. Secondary aims of the trial include overall survival, loco-regional recurrence-free interval, distant recurrence-free interval, disease-free survival-ductal carcinoma in situ, and second primary cancer.

RADIATION THERAPY

Mastectomy patients will be randomized to no XRT or to receive comprehensive XRT, which is radiation to the chestwall plus regional nodal areas.

Lumpectomy patients will be randomized to receive standard whole breast XRT (no regional nodal XRT) or to receive comprehensive XRT, which is radiation to the breast plus regional nodal areas.

SYSTEMIC THERAPY

For patients who are going to receive adjuvant chemotherapy, a maximum of 12 weeks of intended chemotherapy may be given but it must be completed before randomization. Patients with ER and/or PgR positive tumors should receive endocrine therapy. Selection of the endocrine therapy will be at the investigator's discretion. The endocrine therapy may be initiated before, during or after completion of XRT at the discretion of the investigator. Anti-HER2 therapy is required for patients whose tumors are HER2 positive. It can be given either with all or with a portion of the neoadjuvant chemotherapy regimen, unless medically contraindicated. Eligible patients must have completed a minimum of 8 weeks of standard neoadjuvant chemotherapy consisting of an anthracycline and/or taxane-based regimen. Patients may have had either a lumpectomy or a mastectomy after completing their neoadjuvant chemotherapy. At the time of definitive surgery, all removed axillary nodes must have been histologically free from cancer (pN0).

CORRELATIVE SCIENCES

Tumor blocks from the primary breast tumor must be submitted for correlative science studies. Specific aims include testing the role of proliferation measures as a prognosticator for patients with residual disease after neoadjuvant chemotherapy and the development of predictors of the degree of reduction in loco-regional recurrence. Submission of a tumor sample from the primary breast tumor is a study requirement for all patients within 90 days following randomization. If applicable, a tumor block from any gross residual disease (> 0.5 cm) at the time of surgery is also required within 90 days following randomization.

ELIGIBILITY

The patient's breast cancer must have been clinically staged as T1-3, N1 at the time of diagnosis and must have had pathologic confirmation of axillary nodal involvement at presentation (before neoadjuvant therapy) based on either a positive FNA (demonstrating malignant cells) or positive core needle biopsy (demonstrating invasive adenocarcinoma).

Patients must have had an ER/PgR/HER2 analysis performed on the primary breast tumor before neoadjuvant therapy. Patients with HER2-positive tumors must have received neoadjuvant anti-HER2 therapy (either with all or with a portion of the neoadjuvant chemotherapy regimen), unless medically contraindicated. Eligible patients must have completed a minimum of 8 weeks of standard neoadjuvant chemotherapy consisting of an anthracycline and/or taxane-based regimen.

There is a Behavioral and Health Outcomes sub-study with the B-51/1304 trial. The BAHO population will include 736 enrolled patients. The BAHO sub-study will look at quality of life issues related to arm function, arm and breast edema, cosmesis, pain, fatigue, and restricted work and social activity. In addition, disruption in everyday function (work, childcare, disability time) will be tracked, along with overall quality of life. Patients will complete questionnaires prior to randomization and at 3, 6, 12, and 24 months from randomization.

Please contact the Clinical Coordinating Dept. with any B-51/1304 clinical questions at (800) 477-7227 or ccdPGH@nrgoncology.org

www.nrgoncology.org
NRG Oncology Featured Publications

From the NRG Genitourinary Cancer Committee

*Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer*

NRG Oncology investigators found that daily bicalutamide during and for 24 months after salvage radiation therapy improved long-term survival for men with persistent or recurrent cancer following radical prostatectomy. The results of NRG Oncology’s RTOG 9601, “Radiation with or without Antiandrogen Therapy in Recurrent Prostate Cancer” will be published in the New England Journal of Medicine on February 2, 2017.

NRG Oncology Full Press Release

NEJM: New England Journal of Medicine Article

From the NRG Breast Cancer Committee


NRG Oncology trial NSABP B-31 found that the FCGR3A-158 polymorphism is predictive of trastuzumab efficacy in patients with early ERBB2/HER2-positive breast cancer. This contrasts with previously reported analyses from similarly designed trials as our results indicate that trastuzumab may be less efficacious in patients who are homozygous for phenylalanine. The results of this study were published in The Journal of the American Medical Association (JAMA) Oncology in March 2017.

JAMA Oncology: The Journal of the American Medical Association Article

*The Effect on Surgical Complications of Bevacizumab Added to Neoadjuvant Chemotherapy for Breast Cancer: NRG Oncology/NSABP Protocol B-40*

NRG Oncology researchers determined that adding bevacizumab to neoadjuvant chemotherapy in the treatment of breast cancer increased surgical complications; however, the most serious complications were not significantly increased. This established that bevacizumab can be used safely perioperatively in the treatment of this patient population. The results of this trial were published in the Annals of Surgical Oncology on November 18, 2016.

Annals of Surgical Oncology Article

Recently Accepted for Journal Publication


Save the date for the next NRG Oncology Semiannual Meeting


Register here today!
In the News

Dr. O’Connell Receives 2016 ACCC Clinical Research Award

Michael O’Connell, MD, vice chairman of the Board of the NSABP Foundation, was the 2016 recipient of the Association of Community Cancer Centers (ACCC) Clinical Research Award. The ACCC Clinical Research Award was given to Dr. O’Connell in recognition of the significant and positive impact of his research on oncology patients, families, and the community. Dr. Jennie Crews, ACCC president, accepted the award on Dr. O’Connell’s behalf on October 20, 2016 at the 33rd National Oncology Conference in St. Louis, MO.

NRG Oncology/NSABP B-42 Poster Receives 1st Prize Best Poster Award at 2017 St. Gallen International Breast Cancer Conference

The St. Gallen Oncology Conferences presented this year’s Best-Poster-Award to Eleftherios P. Mamounas, MD, Hanna Bandos, PhD, Barry C. Lembersky, MD, Charles E. Geyer, Jr., MD, Louis Fehrenbacher, MD, Mark L. Graham, MD, Soonmyung Paik, MD, Sandra M. Swain, MD, D. Lawrence Wickerham, MD, and Norman Wolmark, MD, for the poster, “Effect of extended adjuvant endocrine therapy with letrozole (L) in postmenopausal women with hormone-receptor (+) breast cancer after prior adjuvant therapy with an aromatase inhibitor (AI): NRG Oncology/NSABP B-42.” Dr. Mamounas presented the poster at the St. Gallen International Breast Cancer Conference held March 15-18, 2017 in Vienna, Austria.

NRG Oncology/NSABP B-42 Abstract

Lucas Named Co-PI of NRG Oncology U-24 Biospecimen Grant and Co-Chair of NRG Translational Research Committee

Peter C. Lucas, MD, PhD has been named Co-Principal Investigator for the NRG Oncology U-24 Biospecimen Grant, and Co-Chair of the NRG Translational Research Committee. He replaces Soon Paik, MD, who retired, and joins Richard Jordan, DDS, PhD (corresponding PI) and Nilsa Ramirez, MD, as the current leaders of the NRG Oncology U24 grant that funds the Biospecimen bank operations. Dr. Lucas is a physician scientist in the Department of Pathology at the University of Pittsburgh School of Medicine and a member of the Divisions of Molecular Genomic Pathology and Experimental Pathology. His expertise is in molecular anatomic pathology and breast surgical pathology and he has published extensively in these areas.

Dr. Lucas is the Director, NSABP Foundation Pathology Laboratory. He is a member of the American Society for Investigative Pathology (ASIP), Association for Molecular Pathology (AMP), and the American Society for Clinical Investigation (ASCI).

NRG Oncology/RTOG 0526 Accepted for Presentation at ABS 2017

“A Prospective Phase II Trial of Trans-perineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Cancer after External Beam Radiotherapy” based on the NRG Oncology trial NRG-RTOG 0526 was presented at the American Brachytherapy Society (ABS) 2017 Annual Meeting April 20th through 22nd in Boston, Massachusetts.

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