The Cancer Moonshot Initiative

The White House organized a series of 270 events throughout the country to gain support for the Cancer Moonshot Initiative, with the goal of speeding up cancer research and ultimately finding the cure for cancer. Currently, cancer is the second leading cause of death in the United States. The American Cancer Society expects that 1.68 million Americans will be diagnosed with some form of cancer and approximately 600,000 people will die from cancer this year.

At the Cancer Moonshot Summit in Washington, D.C. on June 29, 2016, Vice President Joe Biden announced that monitoring of researchers with federal funding who have not published in a timely manner and those who have not provided the raw, published data for public sharing may have their funding cut. NRG Oncology Deputy Group Chair for Publications, Dr. Deborah Bruner who attended the Summit Meeting, commented that, “NRG Oncology’s Publications Committee has always held the responsibility to ensure timely publications, especially of primary endpoints, and welcomes Biden’s plan.” The as yet unanswered question is: How will the National Cancer Institute (NCI) define “timely”?

Typically, “timely” was defined as within a year from a study’s completion, however, with Biden’s focus on big data and data sharing, the Cancer Moonshot Initiative could accelerate that time frame. Additionally, the ability to have clinical trials data freely available for those who wish to reproduce results may have implications for publications review and the response to those trying to replicate our findings in the future. NRG Oncology welcomes the concept of reproducibility and will need to monitor how this will impact our processes. Making the cooperative group data freely accessible is currently being pursued and will need further review by our Ancillary Studies Committee.

As the Cancer Moonshot Initiative moves forward, we anticipate providing further updates in our newsletter and through other communications materials.

More Information on the Cancer Moonshot Initiative:

NBC News article on Vice President Biden’s comments regarding the Cancer Moonshot Initiative.

NCI’s report on the Blue Ribbon Panel and their 10 recommendation topics.
NRG Oncology at ASTRO

NRG Oncology research will be well represented at the upcoming American Society for Radiation Oncology (ASTRO) Annual Meeting taking place September 25-28 in Boston, Massachusetts. Seven disease sites will be represented through either plenary session presentations, oral presentations, or poster sessions. The following six trials are a few examples of the research being presented this year:

**Plenary Session Presentations**
*Monday, September 26, 2016 - 2:15 - 3:45 PM - Grand Ballroom*

  Presenter: Bradley R. Prestidge, MD - DePaul Medical Center, Bon Secours Cancer Institute

- **NRG-RTOG 1203**: A Phase III Randomized Trial Comparing Patient Reported Toxicity and Quality of Life During Pelvic Intensity Modulated Radiation Therapy (IMRT) as Compared to Conventional Radiation Therapy  
  Presenter: Ann H. Klopp, MD - MD Anderson Cancer Center

- **NRG-RTOG 0415**: NRG Oncology/RTOG 0415, Phase III Noninferiority Study Comparing 2 Fractionation Schedules in Patients with Low-Risk Prostate Cancer: Prostate Specific Quality of Life Results  
  Presenter: Deborah W. Bruner, PhD - Emory University, Winship Cancer Institute

**Oral Presentations**
- **NRG-RTOG 0129 and 0522**: Intensity-Modulated Radiotherapy versus Three-Dimensional Conformal Radiotherapy in Head and Neck Squamous Cell Carcinoma: A Pooled Analysis of NRG Oncology/RTOG 0129 and 0522  
  Presenter: Min Yao, MD - Case Western Reserve University School of Medicine  
  *Wednesday, September 28, 2016 - 7:45 - 9:00 AM - Room 160 A/B/C*

- **NRG-RTOG 0813**: Efficacy and Toxicity Analysis of NRG Oncology/RTOG 0813 Trial of Stereotactic Body Radiotherapy (SBRT) for centrally located non-small cell lung cancer (NSCLC)  
  Presenter: Andrea Bezjak, MD - Princess Margaret Cancer Centre  
  *Sunday, September 25, 2016 - 1:15 - 2:45 PM - Room 156 A/B/C*

- **NRG-RTOG 9802 and 9813**: A Mutation and Prognostic Biomarker Study in Grade II and III Gliomas Utilizing a Combined Cohort of NRG Oncology/RTOG 9802 and 9813  
  Presenter: Erica H. Bell, PhD - Ohio State University  
  *Tuesday, September 27, 2016 - 2:45 - 4:15 PM - Room 160 A/B/C*

**Click Here for the Full Schedule of NRG Oncology Abstracts at ASTRO**

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**The Communications Committee Needs Your Feedback**

Do you read the NRG Oncology Newsletter, receive our email broadcasts, or follow us on Twitter? If so, we could use your feedback!

The NRG Oncology Communications Committee wants to hear your opinions and ideas. We are looking for feedback regarding the frequency and the content you are receiving from us through our newsletter, website, Twitter page, and more. We encourage any creative ideas that could help you be even more invested in the material we send out.

Please take our survey and let us know what types of topics you would like to see included in our communications at NRG Oncology!
Featured Clinical Trial Results

GYNECOLOGIC ONCOLOGY GROUP PROTOCOL 240 – THREE YEARS AFTER

By Krishnansu S. Tewari, MD
Professor-in-Residence & Director of Research and Continuing Medical Education
Division of Gynecologic Oncology
University of California, Irvine
Principal Investigator & Study Chair of GOG 240

Background (and Preamble):
Although cytologic screening programs with or without high risk human papillomavirus (HPV) DNA testing have dramatically reduced the incidence and mortality rates due to cervical cancer in developed countries, in the United States there are still over 12,000 new cases and 4,000 deaths attributable to this disease every year. Globally, cervical cancer is the third most common cause of cancer-related mortality in women with over 500,000 new cases and 250,000 deaths annually. Upon successful implementation, cervical cancer vaccination programs are expected to reduce the disease burden further.

Microinvasive and small tumor diameter cases (eg., International Federation of Gynecology and Obstetrics (FIGO) stages IA1-IB1 <2 cm) may be treated successfully with conization or radical trachelectomy plus lymphadenectomy in order to preserve the uterus for future childbearing if desired. Most early stage lesions (eg., FIGO IB1), however, are curable with radical hysterectomy, bilateral lymphadenectomy plus/minus tailed adjuvant therapy. Locally advanced cancers (FIGO stages IB2-IVA) are treated with cisplatin-based chemoradiation plus high-dose rate brachytherapy, but the recurrence rate approaches 50% which is unacceptable. To address this, adjuvant chemotherapy in this setting is being studied in the OUTBACK trial. Patients with isolated, central pelvic recurrences with no evidence of metastases may be salvaged through extirpative procedures. However, following the widespread adoption of chemoradiation protocols in which chemotherapy has been integrated for its use as a radiosensitizer and ability to eradicate subclinical micrometastases, most women who relapse following chemoradiation plus brachytherapy fail locally and at distant sites, precluding their candidacy for pelvic exenteration. Historically, the clinical course for women with unresectable persistent and recurrent disease, as well as those who present initially with metastatic cervical cancer (i.e., FIGO stage IVB), has been devastating, with systemic, platinum-based combination chemotherapy being typically palliative and associated with short-lived responses (or lack of response altogether due to acquired drug resistance from platinum exposure in the frontline setting with radiotherapy). In point of fact, GOG protocol 204 led by Monk et al was closed for futility at interim analysis when it was determined that none of the investigational platinum combinations (ie., topotecan, gemcitabine, vinorelbine) were expected to outperform the control, cisplatin-paclitaxel. Women with recurrent disease suffer from necrotic tumor in the irradiated field with concomitant tumor-related pain, neuropathy, renal failure and malnutrition, each of which individually or in combination may be associated with rapid deterioration of quality of life (QoL). Median survival is counted in months, with most of these relatively young women dying within seven to 12 months, leaving small children behind.

Clearly, the treatment of recurrent/metastatic cervical cancer has represented a high, unmet clinical need, and despite 8 phase 3 randomized clinical trials in this population conducted by the GOG, very little progress (if any) was made over three decades. Recognizing that the palliative platinum-paclitaxel chemotherapy doublet was demonstrating less activity among women who had received prior platinum with radiotherapy, the mandate sent to the GOG in 2006 by the National Cancer Institute’s (NCI) Cancer Therapy Evaluation Program (CTEP) was to explore the efficacy and tolerability of a non-platinum chemotherapy doublet in the 9th phase 3 randomized trial. Based on laboratory data by Bahadori et al suggesting synergy between topotecan and microtubule-modulating agents such as paclitaxel,2 and a phase II trial by Tiersten et al demonstrating the tolerability and reasonable activity of topotecan plus paclitaxel in preirradiated recurrent cervical cancer patients,3 the topotecan-paclitaxel chemotherapy doublet was selected as the investigational arm for what would ultimately become GOG protocol 240. However, many members of the GOG’s Cervical and Vulvar Medicine (CVM) Committee (chaired in 2006 by David H. Moore) remained concerned that “platinum resistance” in this disease was just a surrogate for “chemotherapy resistance”. A new approach to bring innovative interventions to patients with cervical cancer was needed.

Click Here to Read the Full Article of NRG Oncology’s GOG 240 Protocol - Three Years After
NRG-GU001: Randomized Phase II Trial of Postoperative Adjuvant IMRT Following Cystectomy for pT3/pT4 Urothelial Bladder Cancer

**Background**
Currently enrolling, NRG-GU001 aims to determine if postoperative IMRT will reduce pelvic tumor recurrence (occurring either in isolation or together with distant metastases) with acceptable toxicity in patients with pT3/pT4 transitional cell bladder cancer following cystectomy.

Despite improved surgery and systemic therapy, the problem of significant pelvic failure in pT3/4 patients following cystectomy remains. This pelvic failure can occur alone (15-20%) or as is more often the case, in conjunction with distant metastases. As such, it constitutes an absolute ceiling on the curability of bladder cancer by surgery and chemotherapy, and also can be a source of significant patient morbidity. The patients expected to benefit from a reduction in pelvic recurrence are the 15% of patients in whom that recurrence is the sole site of failure as well as those patients in whom symptomatic pelvic failure is prevented.

Given that patients with locally advanced cancer have a high rate of systemic metastases, it is important to determine the impact of pelvic radiotherapy not only on pelvic relapse but also on overall disease-free survival (DFS). NRG-GU001 will look for a 10% increase in DFS, which will warrant proceeding to a confirmatory phase III trial. This will only proceed to a phase III trial if the initial primary pelvic failure and secondary DFS endpoints are met with acceptable toxicity.

**Primary Objective**
To evaluate the ability of post-cystectomy adjuvant radiotherapy to safely reduce pelvic tumor recurrence, defined as pelvic recurrence-free survival.

**Secondary Objectives**
- To evaluate increase in disease-free survival
- To evaluate toxicity of adjuvant pelvic radiotherapy

**Target Accrual**
185 patients

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**Patient Population**
Patients with pT3/pT4 pN0-2 urothelial (either pure urothelial or primary urothelial mixed with other subtypes) bladder cancer following radical cystectomy (ileal conduits or neobladders permitted). Study design also accommodates either neoadjuvant or adjuvant chemotherapy use.

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**Schema**

**PATIENT POPULATION**
Patients with pT3/pT4 pN0-2 urothelial (either pure urothelial or primary urothelial mixed with other subtypes) bladder cancer following radical cystectomy.

**STRATIFICATION**
- Neoadjuvant preoperative or postoperative adjuvant chemotherapy vs. No Chemotherapy
- Pelvic relapse risk category: Intermediate vs. High

**REGISTRATION**
Within 105 days of radical cystectomy

**TIMING OF REGISTRATION**
- Patients who will not receive postoperative adjuvant chemotherapy: Within 14 days of registration
- Patients who will receive postoperative adjuvant chemotherapy: Within 28 days of completion of the chemotherapy

**Arm 1: Standard Arm**
- No Radiotherapy

**Arm 2: Experimental Arm**
- Postoperative adjuvant IMRT radiotherapy 50.4 Gy in 28 fractions

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This trial addresses an important clinical problem and provides the opportunity for urooncologic teams to discuss the need to optimize pelvic control for these patients. A recent amendment permits neobladder inclusion and has liberalized the timelines for registration and randomization. Just as elections are won one vote at a time, so too the success of this trial is expected to depend on individual sites entering one or two patients per year. The investigator team wants to very much emphasize that the effort of each and every clinician in enrolling those one or two patients per annum is much appreciated.

LIBNI EAPEN, MD, FRCPC
NRG-GU001 Principal Investigator

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continued
NRG-RT0G 1112: A Randomized Phase III Study of Sorafenib Versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma

Background
Hepatocellular carcinoma (HCC) is the fifth most common solid organ cancer and the third most common cause of cancer death globally, responsible for an estimated 600,000 deaths annually (Jemal 2010). Although HCC is less common in North America, the incidence has increased from 1.4 to 2.4 per 100,000 over the past two decades, and it is expected to continue to rise.

Cirrhosis, due to alcohol, viral hepatitis, autoimmune hepatitis, hemochromatosis, and non-alcoholic steatohepatitis (NASH) increase the risk of HCC developing. Patients with Hepatitis C cirrhosis have a 5-20% 5-year cumulative incidence of HCC, and even in the absence of cirrhosis, hepatitis B infection is associated with a 15% risk of HCC. Many patients with cirrhosis have impaired liver function that impacts HCC prognosis and limits treatment options. Most patients are not surgical candidates. Including operable patients, the overall 5-year survival of HCC patients is less than 10%, emphasizing the need for improved therapies.

The experimental arm of NRG-RT0G 1112 consists of Stereotactic Body Radiation Therapy (SBRT) followed by sorafenib. The dose of sorafenib during the first 28 days following SBRT is half standard dose to reduce the potential increase in toxicity due to radiation sensitization that may occur during the time period following SBRT. NRG-RT0G 1112’s treatment of SBRT followed by sorafenib aims to improve overall survival in HCC patients by improving hepatic and vascular control of HCC, compared to sorafenib alone.

Primary Objective
To determine if SBRT improves overall survival in HCC patients treated with Sorafenib.

Secondary Objectives
• To measure vascular thrombosis response post Sorafenib versus SBRT followed by Sorafenib
• To measure differences in health-related quality of life (QOL) and quality-adjusted survival in HCC patients treated with Sorafenib compared to SBRT followed by Sorafenib
• To collect biospecimens for future correlative studies to investigate differences in potential biomarkers in patients treated with Sorafenib versus SBRT followed by Sorafenib

Target Accrual
368 Patients

Patient Population
Patients with a diagnosis of HCC (initial, recurrent, progressive and/or refractory to other therapies) diagnosed pathologically (histologically or cytologically) or with imaging demonstrating at least one solid liver lesion or vascular tumor thrombosis (involving portal vein, IVC and/or hepatic vein) >1 cm with arterial enhancement and delayed washout on multiphasic computerized tomography (CT) or magnetic resonance imaging (MRI) in the setting of cirrhosis or chronic hepatitis B or C without cirrhosis.

Patients who are not suitable for (or refractory to) resection, RFA or TACE, with intact liver function (Child Pugh A) may be eligible. Patients may have up to 5 discrete HCCs (in addition to the vascular HCC), none more than 15 cm in maximum diameter, and up to 3 cm of extrahepatic HCC is permitted.

Schema

REGISTRATION

STRATIFY
Vascular involvement (IVC, right or left main branch or main portal vein vs. other vascular involvement vs. none)

Hepatitis B or B and C vs. C vs. Other

North American site vs. Non-North American site

HCC volume/liver volume (<10% vs. 10-40 vs. >40%)

RANDOMIZE

Arm 1
Daily Sorafenib

Arm 2
SBRT alone (27.5 Gy - 50 Gy in 5 fractions)

Followed by Sorafenib alone daily

“NRG-RT0G 1112 is the first phase III study of radiation therapy in the treatment of hepatocellular carcinoma. It is a priority study, endorsed by the NIH hepatobiliary task group, with the potential to change practice if radiation therapy is shown to improve survival and/or quality of life of patients with advanced hepatocellular carcinoma, who are generally treated with the present standard of care, Sorafenib alone. At present, 3 - 4 patients are being accrued per month, and one quarter of the planned patients have been accrued. With your help, we can increase the accrual rate and complete this study sooner. I strongly encourage you to open RT0G 1112 and participate in this exciting study that is striving to define the role of radiation therapy in this setting.”

LAURA DAWSON, MD
NRG-RT0G1112 Principal Investigator
NRG Oncology Featured Publications

This newsletter feature highlights recent articles published by NRG Oncology-affiliated investigators that represent the breadth and depth of NRG Oncology’s research endeavors.

From the Gastrointestinal Cancer Committee

Quality of Life and Symptoms in Long-term Survivors of Colorectal Cancer: Results from NSABP Protocol LTS-01

The NRG Oncology, National Surgical Adjuvant Breast and Bowel Project (NSABP) LTS-01 trial explored health-related quality of life (HRQL), clinical symptoms, and health behaviors in long-term colorectal cancer survivors (defined as ≥5 years) to discover the long-term effects of colon and rectal cancer treatments. The study determined that long-term survivors of colorectal cancer experienced higher HRQL (e.g. physical health, mental health) compared to the general population, and that other disease-related symptoms did not detract from overall quality of life. The results of this study were recently published in the August issue of Journal of Cancer Survivorship.

NSABP LTS-01 collected patient-reported outcomes in long-term survivors of colorectal cancer via telephone survey using instruments to measure HRQL including physical health, mental health, and clinical symptoms. Long-term colorectal cancer survivors that were treated in previous NSABP trials were recruited from 60 sites and 708 patients completed the LTS-01 interview.

The participants experienced a significantly higher HRQL compared with age group-matched non-cancer controls as measured by the SF-12 Physical Component Scale (PCS), the SF-12 Mental Component Scale (MCS), and the SF-36 Vitality Scale. Multivariable modeling indicated that better overall physical and mental health (SF-12 PCS and MCS), positive body image as measured by the European Organization for Research and Treatment of Cancer Colorectal Module (EORTC-CR38 scale), and less fatigue (as measured by the Fatigue Symptom Inventory) were strongly associated with overall quality of life as measured by the global health rating. The ability to perform instrumental activities of daily living, experience of cancer (as measured by Impact of Cancer), gastrointestinal complaints (as measured by EORTC-CR38 scale), and pain (as measured by Brief Pain Inventory) were not important predictors.

Within the setting of a clinical trial, long-term survivors of colorectal cancer have higher HRQL than the general population. Treatment regimens do not appear to be associated with any significant late effects on quality of life. “This work is important since the number of colorectal cancer survivors is increasing. Further research is needed to determine if an intervention to address fatigue, for example, could lead to improvements in overall quality of life,” said Marcia M. Russell, MD a co-author of the manuscript.

Dr. Gore Appointed NRG Oncology Publications Committee Co-Chair

We are pleased to announce that Dr. Elizabeth Gore has been appointed as a Co-Chair for the NRG Oncology Publications Committee. Dr. Gore is a radiation oncologist at the Froedtert Hospital and the Medical College of Wisconsin, specializing in thoracic oncology. Gore is a long-term RTOG Legacy member and an active NRG Oncology participant. She currently is a member of the NRG Oncology Membership Committee and Co-Chair of the New Investigators Committee. Through the Medical College of Wisconsin and NRG Oncology, Dr. Gore has participated in and developed numerous clinical trials that have advanced the care of cancer patients, both nationally and internationally.

Podcast About Predatory Publishers

NRG Oncology Publications Committee has had questions about predatory publishers soliciting authors via email to publish in their journals. We encourage you to listen to this helpful podcast from Roger Watson, Editor of Journal of Advanced Nursing and Nursing Open, a reputable open access journal. Watson's podcast is a short and succinct description of predatory publishers AND the new scam of predatory conferences. He also describes resources for checking if a journal is reputable.

Here is the podcast:
Predatory Publishers and Journal Hijackers
NRG Oncology Semiannual Meeting Recap

General Session
NRG Oncology Group Chair Phillip J. DiSaia, MD greeted attendees at the General Session for the July 2016 NRG Oncology Meeting in Dallas, Texas. The General Session provided attendees with an update on NRG Oncology activities since the last meeting, including the recognition of the top accruing institutions for the first half of 2016, member updates, a question and answer segment on the NCI National Clinical Trials Program (NCTN) Recompetition, an update from the NCI NCTN Core Correlative Sciences Committee (CCSC), and the acknowledgment of the Joan K. Mauer Memorial Quality Assurance Award.

D. Lawrence Wickerham, MD announced the top accruing sites for the first half of 2016 and provided a membership update for NRG Oncology. Between the dates of January 1, 2016 through June 30, 2016, the top accruing site for National Community Research Program (NCORP) was Kaiser Permanente NCI Community Oncology Research Program; for Lead Academic Participating Sites (LAPS), the top accruing site was the University of Oklahoma Health Sciences Center LAPS; and Seoul National University Hospital achieved the top accruing site for both main member and international sites.

Click here to view the list of top accruing sites for the first half of 2016.

Joan K. Mauer Memorial Quality Assurance Award
During the meeting, Frederick B. Stehman, MD was presented with the Joan K. Mauer Memorial Quality Assurance Award for his valuable contributions to the quality assurance program in support of NCI-sponsored clinical trials and his dedication through active participation in quality assurance functions.

NRG Scientific Session
NRG Oncology’s Scientific Session began with Andrea Denicoff, MS, RN, Head of NCTN Clinical Trial Operations, describing the new NCTN Study Champions process and the roles of co-Principal investigators and CTSU in supporting study champions and cross-network accrual.

Eddy Yang, MD, PhD, Translational Chair of EAY131-B discussed the interim analysis results of the NCI’s Molecular Analysis for Therapy Choice (NCI-Match) Trial. The trial opened in August 2015 with 10 treatment arms and the study plans to add at least 14 more arms in the coming months. The NCI-MATCH interim analysis concluded that a trial of therapy based on genetic characteristics of the tumor is feasible in the NCTN and NCORP. A high proportion of less common malignancies found in this early analysis open options for advances in these cancers. Additionally, performing this analysis early in the trial permits enhancements to the study structure and allows realistic planning for additional drugs or targets. Moving forward, Yang explained there will be a greater focus on communication to encourage physicians to register only the most appropriate patients and further exploration on partnerships that may increase enrollment to arms with rare mutations.

Joanne L. Blum, MD provided an interim joint analysis of the ABC (anthracyclines in early breast cancer) phase III trials (USOR 06-090, NSABP B-46/I/USOR 07132, NSABP B-49 [NRG Oncology]) comparing docetaxel plus cyclophosphamide (TC) to anthracycline/taxane-based chemotherapy regimens (TaxAC) in women with high-risk, HER2 negative breast cancer. The analysis determined that invasive disease-free survival (IDFS) was improved with TaxAC when compared to TC. Four year overall survival (OS) was high in both groups. Additional follow-up and correlative studies will be conducted to identify biomarkers of anthracycline benefit, which will be crucial for fully determining the utility of anthracyclines across the heterogeneous patient population of this study.

Lead Author of NRG-RTOG 9601, William Shipley, MD discussed the results of this phase III trial for patients following radical prostatectomy (RP) with pT2-3, pN0 prostate cancer (PC) and elevated PSA levels: anti-androgen therapy (AAT) with bicalutamide during and after salvage radiation therapy (RT) compared to placebo plus salvage RT. With a median follow up of 13 years, the addition of 24 months of peripheral androgen blockage (AAD) during and after salvage RT significantly improved overall survival, reduced metastatic PC, and reduced death from PC. The overall survival and time to metastatic PC subgroup analysis, also indicates that AAT added to salvage RT is most likely to benefit patients with tumors with a Gleason score of 7 or 8-10, entry PSA values of 0.7 to 4.0, or tumors having positive surgical margins.

Barbara Norquist, MD provided data for the NRG-GOG218 study on mutations in homologous recombination genes and response to treatment. The results concluded that women with ovarian cancer with mutations affecting homologous recombination had significantly longer progression free survival (PFS) and overall survival (OS) than those with no mutations, mutations affecting homologous recombination were found with all histologic subtypes of ovarian cancer, and mutation status did not significantly modify the effect of bevacizumab on PFS. Voichita Bar-Ad, MD presented the results for the correlation between the severity of cetuximab-induced skin rash and clinical outcome for head and neck cancer patients. Bar-Ad’s conclusions included that grade 2-4 cetuximab rash was associated with better survival possibility due to reduction of distant metastasis and that grade 2-4 in-field radiation dermatitis was associated with a higher rate of late grade 2-4 skin fibrosis.
In the News

Bruner Inducted in Honor Society of Nursing, Sigma Theta Tau International, 2016 Nurse Researcher Hall of Fame
Deborah Watkins Bruner, RN, PhD, FAAN, a co-Principal Investigator of the NRG Oncology NCORP, recently was one of 19 nurse researchers inducted into the Honor Society of Nursing, Sigma Theta Tau International (STTI) International Nurse Researcher Hall of Fame at STTI’s 27th International Nursing Research Congress in Cape Town, South Africa. The International Nurse Researcher Hall of Fame recognizes nurse researchers who have achieved significant and sustained national or international recognition and whose research has improved the profession and the people it serves. The honorees’ research projects will be shared through STTI’s Virginia Henderson Global Nursing e-Repository, enabling nurses everywhere to benefit from their discoveries and insights. Among her many achievements, Bruner is an internationally renowned researcher, scholar, and mentor; ranked among the top 5% of all NIH researchers in the world according to the Blue Ridge Institute; published over 145 peer-reviewed journal articles, 5 books, and 11 book chapters, leading to numerous honors and awards; and, is the first and only nurse to lead a National Cancer Institute (NCI) sponsored clinical trials cooperative group, the Radiation Therapy Oncology Group (RTOG) Community Clinical Oncology Program (CCOP) Research Base. Bruner’s research contributions have impacted changes in clinical practice guidelines and her work has been incorporated into course curriculum, training, and guideline manuals for radiation oncology nurses in hospitals in the U.S. and through ONS programs and publications. Additionally, her work has led to her appointment to multiple high level U.S. national committees and positions that set national policy.

Scroggins Receives 2016 AACR Distinguished Public Service Award on Behalf of All Advocates
Mary (Dicey) Jackson Scroggins, Chair of the NRG Oncology Patient Advocate Committee, received the 2016 American Association for Cancer Research (AACR) Distinguished Public Service Award, which she accepted on behalf of advocates everywhere. In her acceptance speech, Scroggins stated, “In accepting this award on behalf of survivors, patients, and advocacy communities everywhere, I thank them all for the opportunity and privilege of serving them and, more importantly, for the opportunity of serving with them”. She continued to commend advocates for their unselfish dedication of actively choosing to leave no person behind without standard of care, equal access, and champions.

Scroggins—an ovarian cancer survivor—has been an active member of the advocate community for 19 years. She cofounded In My Sister’s Care, an organization focused on eliminating health disparities and improving gynecologic cancer awareness and care for medically underserved women; is a founding partner in Pinkie Hugs, LLC, a writing and film production firm specializing in social justice-focused documentaries; works with numerous national and international organizations dedicated to enhancing progress in women’s cancers and to ensuring health equity; and has served in many other ways in the cancer advocacy community. Scroggins largely attributes her achievements in the advocacy community to the work, dedication and lives of many others, stating, “I stand with you, yet in awe of you, and I stand in your debt”.

Click Here to Watch Mary Jackson Scroggins’ Full Acceptance Speech

Giaddui to Receive Resident Poster Viewing Recognition Award at ASTRO
NRG Oncology physics resident Tawfik Giaddui was selected by the American Society for Radiation Oncology’s (ASTRO) Annual Meeting Scientific Program Committee as the second place Resident Poster Viewing Recognition Award winner for the abstract titled, “Improving Treatment Planning Quality, Consistency, and Efficiency Using Rapid and Auto Planning: A Feasibility Study Based on the NRG-HN002 Clinical Trial”. Giaddui will be recognized for the award at ASTRO’s Annual Meeting taking place on September 25-28 in Boston, Massachusetts.
Eriko was born on July 3, 1962 in a small village of Hiroshima prefecture. She grew up a cheerful and clever young lady alongside a little brother Toru. Sensing a desire to serve, Eriko went to nursing school at the Kawasaki Medical School, Kurashiki-City, and then went on to midwifery school at Okayama University. She started work as a midwife/nurse at the Kawasaki Medical School Hospital in 1985. Eriko was loved by all of her patients and colleagues, demonstrating keen compassion and clinical excellence, and quickly assumed the role of Chief Nurse of the Obstetrics and Gynecology outpatient clinics at the Kawasaki Medical School Hospital.

In 1995, Eriko decided to learn more about the breadth and scope of nursing in the United States and was accepted by the University of South Carolina School of Nursing in Columbia. After one year of language training, she once again excelled in her studies and graduated Summa Cum Laude in 1999.

Eriko then applied to the top eight graduate schools for nursing ranked by USA Today and was accepted by all of them! Eriko decided to go to the University of California, San Francisco because she wanted to better understand Clinical Research Management, which was a very new concept in nursing in Japan. Not unexpectedly, she graduated from UCSF as a straight “A” student in 2001. This was the start of her career in clinical trials research and where her celebrated skill set really proliferated.

After coming back to Japan, Eriko worked as an Assistant Professor at the Kawasaki University of Medical and Welfare, and began the tireless work of preparing and organizing the infrastructure to develop a new research affiliate entity, GOG Japan. Once GOG Japan was accepted as a full member of GOG, Eriko moved to Kitasato University in Tokyo to establish the Data Center of the renovated JGOG in 2003. The first trial she administered was JGOG3016, the celebrated phase III trial that showed dose-dense paclitaxel was significantly better than 3-weekly paclitaxel in combination with carboplatin in primary ovarian cancer; a trial that has had a global impact in the management of women with this disease. Another important JGOG trial for her was JGOG3017, which tested a new chemotherapeutic regimen against the conventional paclitaxel/carboplatin regimen specifically in clear cell carcinoma of the ovary. She not only coordinated this trial in Japan, but also internationally through the GCIG network – another groundbreaking first among investigator-initiated trials in Japan. This trial was recently published in the Journal of Clinical Oncology, where she served as one of its authors.

Eriko next tackled the complex regulatory and operational barriers to bring GOG-0218 to Japan. GOG-0218 trial was the first investigator-initiated registration trial to be conducted under the new Japanese clinical trials system. It was the first international trial for the Japanese government where the investigational product (bevacizumab) was imported from the NCI (USA) by Japanese investigators. It was due to her integration, and endless optimism that this trial became a reality and a success in Japan. Based on the results of this trial, particularly reflected in the quality of data from Japanese patients, the Japanese government approved bevacizumab for 1st line treatment for ovarian cancer. This was also the first regulatory approval for a cancer therapeutic based on an investigator-initiated trial in the history of the Japanese FDA.

Another recent challenge and success was iPocc trial. She coordinated and navigated this trial with expert precision using another new Japanese clinical trial system called “Advanced Medical Care System.” However, there are many more examples reflecting her footprint including, GOG-0213, the Symptom Benefit study, the ALIENOR Trial, and the PAOLA trial, just to name a few. The PAOLA trial is another investigator-initiated trial for olaparib in ovarian cancer in collaboration with French group, GINECO, and her new position of GOTIC/KAST. She was working hard to prepare NRG B-51 Trial and NRG-GY004 to open in Japan.

As JGOG joined the GCIG, Eriko became a member of its Harmonization Working Group. Through her diligence and achievements in these commitments, Eriko became well known and was further loved by all who knew her because of her engaging and charming personality. She always put others first, even though she had been fighting breast cancer since 2006; a burden she fought valiantly, yet quietly.

Because of her leadership and personal integration into quality management, evaluation of GOG Japan has always been AAA. As everyone can imagine from her perfect quality control record, Eriko never cut corners. This was also true of her attention to her friends and guests, especially from abroad, whom she welcomed warmly. Eriko never showed her agony to others and passed away quietly. She was 54 year old - two days after the iPocc trial completed accrual – a trial in which she took great pride. Eriko Aotani will be profoundly missed by our entire research community, but she left a legacy of profound excellence in clinical trial management and personal kindness, which will survive in the time to come.
Protocol Support Committee

NRG Oncology Mentorship Working Group Update

“Welcome to New Members” Resource Packet

The “Welcome to New Members” resource packet details specific NRG Oncology processes and includes contact information to direct questions and to obtain assistance. The resource packet is posted on the NRG website under the Nurses and CRAs tab. Follow the link to Mentorship Program (New to NRG Oncology) and click on the “Introductory Materials for NRG Oncology Clinical Trial Coordinators” link.

Mentor Program

Are you new to NRG Oncology? Are you new to clinical trials? The Mentorship Working Group will connect you with a temporary Mentor who will answer questions and assist you with your transition into 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 Clinical Coordinating Department (CCD) - Pittsburgh.

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

Additionally, the NRG Mentorship Working Group is currently developing a formal Mentor Program. This is an exciting opportunity for member involvement and we will be looking for Mentors once the program is ready for activation. Stay tuned for more information!

National Coverage Analysis (NCA)

Determining billable services is often one of the core tasks of PIs and coordinators prior to local study implementation. In the current medical billing climate, this is becoming an increasingly prominent issue for clinical trial coordinators. For several years, NCTN sites have asked for a tool to assist with clinical trial billing compliance. In response, CTSU launched the pilot phase of the National Coverage Analyses (NCA) program in April 2016. The pilot developed NCAs for select NCTN and NCORP trials.

To facilitate billing compliance, the NCA process evaluates study requirements and details procedures that are: considered routine care and billable; covered by trial funding; not billable, not funded, and may be the financial obligation of the patient. In addition, the NCA includes applicable NCD codes and the rationale for coverage determinations. The development and the review of the NCA document includes the CTSU, the Lead Protocol continued
Protocol Support Committee (continued)

Organization (LPO), study investigators and billing consultants.

As of August 16, 2016, NCAs are available for the following NRG protocols: NRG-HN001, NSABP-B55, NRG-CC001, NRG-CC003 and NRG-BR-003. NCA drafts submitted for LPO review or pending study activation include: NRG-LU001, NRG-HN002, and NRG-GY006. NCAs in-progress include: GOG-0286B, NRG-GI001 and NRG-GI002. For the pilot phase, CTSU selected recently activated NRG studies. Going forward, trials in development will be submitted for NCA evaluation at time of first CTEP submission. Currently active studies not part of the pilot have been prioritized for NCA development.

NCAs are posted on the CTSU website under the Funding Information tab of the protocol-specific page. The document is called the Coverage Analysis Worksheet. At this time, the CTSU website does not include a comprehensive list of studies with Coverage Analysis Worksheets; you need to look under each individual study. However, the CTSU Summer 2016 newsletter includes a table that lists completed and in-progress NCA documents.

Important Things to Consider: The NCA is a guidance document. The CTSU follows National Coverage Determinations as defined by Medicare and the National Comprehensive Cancer Network (NCCN) guidelines as the basis of the coverage analysis. Institutions that use this tool should also consider their local institutional requirements and local/State coverage determinations, as there can be local variations.

This project is still in the Pilot Phase. The CTSU requests feedback for further improvements of the NCA template and process. Sites may provide feedback by using the “Feedback” button in the upper right corner of the CTSU website or by sending comments to the CTSU Help Desk.

Quality of Life / Patient Reported Outcomes Data Compliance

Quality of Life (QOL) / Patient Reported Outcomes (PRO) is a secondary objective in many clinical trials and, therefore, it is extremely important that these assessments be completed at the time points designated in the protocol. In an effort to maintain good QOL/PRO data compliance, please keep the following points in mind:

- Many studies require that QOL/PRO assessments continue at designated time points, even if patients have discontinued protocol therapy. Refer to each protocol to determine if QOL/PRO assessments are to be continued following disease progression and/or discontinuation of protocol therapy.
- Many QOL and PRO instruments have been translated in several different languages.
- Review the forms to ensure completeness prior to submission.
- Request a supply of QOL/PRO Scantron forms when a trial is activated so they are available when you enroll your first patient; NRG Scantron Order Forms for some studies are now available on the CTSU website.
- The timing of QOL/PRO assessments for many studies are based on time from enrollment rather than based on treatment cycle. A PRO Date Calculator is available for some studies on the CTSU website, allowing you to calculate at the time the patient is enrolled the due-dates for all QOL/PRO assessments throughout the course of the study.
- If you encounter difficulties in maintaining QOL/PRO data collection or are uncertain of the assessment schedule, contact a member of the PCOR Committee or the QOL/PRO Study Chair for a specific protocol.

Please make every effort to ensure that all QOL/PRO assessments are completed on time per protocol guidelines. This data is a very important component of oncology clinical trials. Your extra time and effort to maintain QOL compliance is vitally important for final data analysis and the potential for improving the future care of patients.