NRG Oncology at ASCO 2019

Best of ASCO

Initial reporting of NRG-LU001, randomized phase II trial of concurrent chemoradiotherapy +/- metformin in locally advanced non-small cell lung cancer

**Presenter:** Theodoros Tsakiridis MD, PhD  
**Date/Time:** Saturday, June 1, 2019, 1:39-1:51pm CT  
**Location:** Lakeside, L3, Hall D2

NRG-G1002: A phase II clinical trial platform using total neoadjuvant therapy in locally advanced rectal cancer—First experimental arm initial results

**Presenter:** Thomas George, MD, FACP  
**Date/Time:** Saturday, June 1, 2019, 4:24-4:36pm CT  
**Location:** North Building, L3, Hall B1

Impact of clinical risk category on prognosis and prediction of chemotherapy benefit in early breast cancer by age and the 21-gene recurrence score in TAILORx

**Presenter:** Joseph A. Sparano, MD  
**Date/Time:** Monday, June 3, 2019, 10:45-10:57am CT  
**Location:** Lakeside, L3, Hall D2

Patient-reported outcomes in NRG Oncology/NSABP B-39/ RTOG 0413: A randomized phase III study of conventional whole breast irradiation versus partial breast irradiation in stage 0, I, or II breast cancer

**Presenter:** Patricia Ganz, MD  
**Date/Time:** Monday June 3, 2019, 12:09-12:21pm CT  
**Location:** Lakeside, L3, Hall D2

Updated predictive analysis of the WHO-defined molecular subgroups of low-grade gliomas within the high-risk treatment arms of NRG Oncology/RTOG 9802

**Presenter:** Erica Hlavin Bell, PhD  
**Date/Time:** Monday, June 3, 2019, 2:03-2:15pm CT  
**Location:** South Building, L1, S102

A randomized phase 3 trial of paclitaxel plus carboplatin versus paclitaxel plus ifosfamide in chemotherapy-naive patients with stage I-IV, persistent or recurrent carcinosarcoma of the uterus or ovary: An NRG Oncology trial

**Presenter:** Matthew A. Powell, MD  
**Date/Time:** Monday, June 3, 2019, 1:15-1:27pm CT  
**Location:** South Building, L4, S406

All Presentations

Click here for the full list of NRG Oncology research at ASCO 2019

Awards Lecture

Dr. Wolmark to receive the prestigious Gianni Bonadonna Breast Cancer Award at ASCO’s 2019 Annual Meeting

Norman Wolmark, MD, an NRG Oncology Group Chair and Chairman of the NSABP Foundation, will receive the 2019 Gianni Bonadonna Breast Cancer Award at the annual meeting of the American Society of Clinical Oncology (ASCO), May 31-June 4 in Chicago, IL. As a recipient of this award, Dr. Wolmark will deliver his address, "The Contribution of NSABP Clinical Trials to the Management of Early Breast Cancer: A 60-year Odyssey," on Saturday, June 1, 2019 (4:45-5:30pm CT). The Gianni Bonadonna Breast Cancer Lecture Award recognizes an active clinical researcher with a distinguished record of accomplishments in advancing breast cancer research. For more information about the award and past recipients, click here.
NRG Oncology Study Champions Table

A listing of the current NRG Oncology study champions for other NCTN trials can be found [here on the NRG Oncology website](https://www.nrgoncology.org). Please remember to credit NRG Oncology and to contact the appointed NRG Oncology Champion with any questions or email us at info@nrgoncology.org. The current list of trials with NRG Oncology champions includes:

- **Brain Tumor Trials:** NCCTG N0577 and ECOG-ACRIN EAF151
- **Breast Cancer Trials:** ALLIANCE A011401, ALLIANCE A221505, CCTG MA.39, and SWOG S1416
- **Gastrointestinal Cancer (Colorectal Cancer) Trials:** Alliance A021602, Alliance A021502, SWOG S1613
- **Gastrointestinal Cancer (Non-colorectal Cancer) Trials:** ECOG-ACRIN EA2165 and ECOG-ACRIN EA2174
- **Genitourinary Cancer Trials:** SWOG S1602 and SWOG S1802
- **Gynecologic Cancer Trials:** ECOG-ACRIN EAE16 and COG AGCT531
- **Head and Neck Cancer Trial:** ECOG-ACRIN EA3163
- **Hematology Oncology Trial:** ALLIANCE A061402
- **Lung Cancer Trial:** SWOG S1400
- **NCORP Trials:** ALLIANCE A221208, ALLIANCE A211401 and SWOG 0820

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NRG Oncology Health Disparities Committee

**SAVE THE DATE**

NRG Oncology Health Disparities Committee (HDC) Workshop [Read more](https://www.nrgoncology.org)

Sexual and Gender Minority Related Activities at the National Institutes of Health

*Presented by Karen L. Parker, PhD, MSW*

*Friday, July 19, 2019 from 10-11:30am*
NRG Oncology (NRG) leadership announced the retirement of James Tate Thigpen, MD, from NRG Oncology and The GOG Foundation, Inc. (GOG-F) at the February 2019 Semiannual Meeting in Phoenix, AZ. In his tenure, Dr. Thigpen served as the Gynecologic Oncology Group (GOG) Vice-Chair for Science from 1988 to 2014 and as the Chair for the GOG Partners Initiative from 2010 to 2016. He also chaired the GOG Protocol Committee and later the GOG Protocol Development Committee, and was an active member of many other committees at GOG for over four decades. From 2013 to 2018, Dr. Thigpen was the NRG Oncology Deputy Group Chair for Protocol Prioritization and conduct and was the Chair of the NRG Oncology Concept Prioritization Advisory Committee (CPAC). CPAC dissolved in July 2018 and a new committee was created to oversee NRG trials operationally. Dr. Thigpen Co-Chaired the Protocol Operations Management Committee until his retirement.

Dr. Thigpen was among the first medical oncologists to participate in developing protocols containing chemotherapy and helped launch Master Protocol GOG-0026 under which 116 studies were conducted involving a total of 34 agents, underscoring the dramatic efficiency of this innovative approach. This innovation generated a steady stream of phase II studies with drugs on the rubric of the Medical Oncology Committee. A significant example of these studies was the 1989 launch of cisplatin by the Cancer Therapy Evaluation Program (CTEP), on which Dr. Thigpen reported the drug’s key role in treating ovarian and cervical cancers and germ cell tumors.

Dr. Thigpen created a set of guidelines for protocol conduct, which provided timeframes for study development, content execution, and authorship. These processes have evolved over time, but continue to be a staple for trial conduct and development with combined medical and statistical considerations and authorship guidelines.

“Tate Thigpen has been part of the heart and soul of cooperative group research in a career spanning five decades. His impact can never be fully measured except by understanding the innumerable lives he has touched - patients, families, clinical researchers - all owe a debt of gratitude for how he has helped in the battle against cancer.”

**Robert S. Mannel, MD**
NRG Oncology Group Co-Chair

“Dr. Thigpen was among the first medical oncologists to participate in developing protocols containing chemotherapy and helped launch Master Protocol GOG-0026 under which 116 studies were conducted involving a total of 34 agents, underscoring the dramatic efficiency of this innovative approach. This innovation generated a steady stream of phase II studies with drugs on the rubric of the Medical Oncology Committee. A significant example of these studies was the 1989 launch of cisplatin by the Cancer Therapy Evaluation Program (CTEP), on which Dr. Thigpen reported the drug’s key role in treating ovarian and cervical cancers and germ cell tumors.

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“For over four decades, Dr. Thigpen provided critical leadership in the development of GOG trials that have defined most of the current treatment standards in gynecologic cancer. His depth of knowledge in gynecologic oncology, his passion for advancement in the field, and his mentorship was matched by few. It was a great privilege and honor to work with him.”

**Ronald D. Alvarez, MD**
NRG Oncology Co-Chair of Research Strategy

“"Dr. J. Tate Thigpen, for over four decades, provided scientific leadership for the Gynecologic Oncology Group, and also leadership for the transition into NRG Oncology. Tate mentored dozens of young investigators, many of whom, now constitute the core of current leadership of our clinical trials programs. But for Tate Thigpen, the GOG and NRG would not have experienced the success achieved in moving our field forward through the design and conduct of clinical trials in gynecologic cancer."

**Larry Copeland, MD**
Former NRG Oncology Deputy Group Chair for Research Integrity
Congratulations and Thank You to Dr. Costantino on his Retirement

Joseph P. Costantino, DrPH, will be retiring from his position as Director of the NRG Oncology Statistics and Data Management Center (SDMC) on August 31, 2019. He has been the Director since 2014 and, prior to that, the Director of the NSABP Biostatistical Center since 2004. He began his cancer clinical trial research career as a biostatistician for the NSABP in 1985.

Dr. Costantino is well known and recognized beyond NRG Oncology. He has served on national review and advisory committees for the National Cancer Institute, National Heart, Lung and Blood Institute and the Institute of Medicine as well as the NCI Breast Cancer Steering Committee and the National Clinical Trials Network Leadership Management Committee. He also served many years on the Steering Committee of the Early Breast Cancer Trialists’ Collaborate Group. He is a member of the Society for Clinical Trials, American Society of Clinical Oncology, American Statistical Association, Biometric Society and the American College of Epidemiology.

Dr. Costantino has been an author or co-author of nine book chapters and more than 280 articles or manuscripts in medical or statistical journals. He has had a passion for his profession, a dedication to science and statistics, and his leadership and direction of the SDMC have made a significant difference in the NSABP and NRG Oncology. Dr. Costantino was a key investigator contributing to the development, conduct, and analysis of several clinical trials that have established the efficacy of breast cancer chemoprevention and treatment. These include the BCPT and STAR trials which were the first to demonstrate that drugs could be used to reduce the incidence of breast cancer in healthy women, as well as be used to reduce recurrence of breast cancer in women who have already developed the disease. Another area of substantial contribution has been the development and validation of statistical methods for race-specific breast cancer risk assessment. The resulting breast cancer risk assessment methodology is now commonly used in clinical practice throughout the United States.

Dr. Norman Wolmark noted that the strategic evolution to NRG would not have occurred had it not been for Dr. Costantino’s selfless and exemplary efforts.

To ensure a successful transition, Dr. James Dignam assumed the role of Executive Director of the SDMC and the NRG Group Statistician effective on March 1, 2019 and is pleased to be following Dr. Costantino in this capacity.

“Joe has devoted most of his career to cancer clinical trials, and his effort shows in the many significant advances in which he played a critical role. He has led the NSABP and NRG SDMCs through challenging times and great triumphs. I’m very fortunate to follow him in leading this superb team, and hope we can maintain his level of excellence.”

James J. Dignam, PhD
NRG Oncology Group Statistician
Congratulations and Thank You to Darlene Kiniry on her Retirement

Darlene Kiniry, MS, NRG Oncology’s Head of the Statistical and Data Management Center (SDMC) Information Technology Division and previously with the National Surgical Adjuvant Breast and Bowel Project (NSABP) Biostatistical Center, retired from NRG Oncology in May 2019 after over 33 dedicated years with the organization. Darlene has been a staple of the NRG Oncology organization and we wish her all of the best in her retirement!

Regis Leonard will be the new Head of the Information Technology Division for NRG Oncology’s SDMC. Regis brings more than 41 years of IT experience in support of academic research endeavors to this position with NRG. From 1978 to 2002, he was employed as an IT Systems Integrator for the Mellon Institute at Carnegie Mellon University in Pittsburgh. Regis has been with NRG Oncology SDMC and previously, the NSABP Biostatistical Center, since 2002.

NRG Oncology Member News

JCO's Cancer Stories: The Art of Oncology Podcast – Interview with Dr. Wolmark
Dr. Dan Hayes, a medical oncologist at the University of Michigan Cancer Center, recently interviewed Dr. Norman Wolmark, an NRG Oncology Group Chair and Chair of The NSABP Foundation, as part of the Journal of Clinical Oncology’s Cancer Stories Podcasts: Conversations with Oncology Pioneers, about the history of NSABP. Click here to listen.

Frances (Francy) Fonzi Appointed NCTN Group Banking Committee Member
Frances Fonzi, MPM, Protocol Development and Management Department, NRG Oncology Pittsburgh Operations Office, was recently appointed a member of the NCTN Group Banking Committee (GBC). Francy will fill the committee vacancy created by the retirement of Teresa Bradley in January 2019. Congratulations, Francy!

Dr. Curran selected as ASTRO Gold Medal Award Recipient for 2019
Walter J. Curran, Jr., an NRG Oncology Group Chair and Executive Director of the Winship Cancer Institute at Emory University, was recently selected to receive the American Society for Radiation Oncology (ASTRO) Gold Medal for 2019. The Gold Medal is ASTRO’s highest honor and is awarded to ASTRO members who have made outstanding contributions in radiation oncology, including the areas of research, clinical care, teaching, and service. Congratulations and thank you for your hard work and dedication, Dr. Curran! Read more on ASTRO’s website.

Dr. Knoll to Serve on the ASCO Cancer Communications Committee
Miriam (Mimi) Knoll, MD, the Medical Director of the Department of Radiation Oncology at Mountainside Medical Center and a member of the NRG Oncology Communications Committee and Patient Engagement Working Group, was recently selected to serve as a member on the American Society of Clinical Oncology (ASCO) Cancer Communications Committee starting at the society’s Annual Meeting in June 2019. Congratulations, Dr. Knoll!

Dr. Dignam Selected to be a Fellow of the Society for Clinical Trials
James (Jim) Dignam, PhD, NRG Oncology Group Statistician at the Statistics and Data Management Center (SDMC) and Professor of Biostatistics at the University of Chicago, was recently inducted as a fellow of the Society for Clinical Trials (SCT). This honor extends to SCT members who have made significant contributions to the advancement of clinical trials as well as to the Society. Congratulations, Dr. Dignam!
NRG Oncology Trial Highlight: NRG-BR004

A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer

Recently Activated

About this trial:
The phase III trial NRG-BR004 is being conducted to determine if adding atezolizumab to a standard regimen of the dual HER2-targeted monoclonal antibodies trastuzumab and pertuzumab along with the chemotherapy drug paclitaxel, will improve progression-free survival for patients with newly documented HER2-positive metastatic breast cancer. Patients will be randomly assigned to one of two possible treatment arms. Patients on arm 1 will receive paclitaxel with trastuzumab and pertuzumab and a placebo and patients on arm 2 will receive paclitaxel with trastuzumab and pertuzumab and the study drug atezolizumab. Secondary endpoints that will be observed include overall survival, overall objective response, duration of objective response, cumulative incidence of brain metastases, and frequency of adverse events including cardiac events and late immune-related toxicities.

More trial information can be found on ClinicalTrials.gov
Protocol documents can be found on CTSU.org

“The CLEOPATRA trial, which evaluated the addition of pertuzumab to trastuzumab and a taxane in patients with recently documented metastatic HER2 positive breast cancer, demonstrated a clinically meaningful improvement of 6.1 months in median PFS and an even more compelling improvement of 15.7 months in median OS. These long-term results strongly suggest that an important component of the activity of the dual antibodies is immune mediated, and NRG-BR004 is building on those impressive results by evaluating the incorporation of the PD-L1 inhibitor, atezolizumab into a standard first-line regimen. We are pleased to make this exciting trial available to investigators throughout the NCTN.” - Dr. Geyer

NRG Oncology Trial Highlight: SWOG/NRG-S1806

Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer

Recently Activated

About this trial:
SWOG/NRG S1806 is a phase III trial studying a combination of chemotherapy and radiotherapy with or without immunotherapy (atezolizumab, monoclonal antibody against PD-L1) in patients with muscle invasive bladder cancer. This trial will be assessing bladder intact event-free survival (BI-EFS) at the time from the date of randomization to the first documentation of a BI-EFS event up to five years from treatment. Secondary endpoints include overall survival, modified BI-EFS, biopsy response, complete response duration, progression-free survival, metastasis-free survival, cancer-specific survival, and quality of life.

More trial information can be found on ClinicalTrials.gov
Protocol documents can be found on CTSU.org

“This will be the largest bladder-sparing trimodality therapy trial to-date for MIBC. It offers the potential to make chemoradiotherapy even better with the addition of immunotherapy, and thus could be practice changing.” - Dr. Efstathiou
NRG Oncology Trial Highlight: NRG-GI006

Phase III Randomized Trial of Proton Beam Therapy (PBT) Versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer

Recently Activated

About this trial:
The NRG-GI006 clinical trial will compare proton beam radiotherapy to intensity modulated photon radiotherapy in patients with stage I-IVA esophageal cancer. The trial will be primarily assessing the overall survival rates and incidence of grade 3 or greater cardiopulmonary adverse events associated with each treatment. Secondary outcome measures include pathologic response rate, grade 4 lymphopenia during chemoradiotherapy, lymphocyte counts, locoregional failures, distant metastatic-free survival, progression-free survival, quality-adjusted life years, and cost-benefit economic analysis of treatment between the proton and photon radiotherapy treatment arms.

More trial information can be found on ClinicalTrials.gov
Protocol documents can be found on CTSU.org

“It is well known that compared to photon radiotherapy, proton beam radiotherapy can significantly reduce the RT dose to the heart and lungs, but whether this is clinically impactful to affect patient outcomes is not known. NRG-GI006 is the definitive trial to determine that the dosimetric benefit of proton beam radiotherapy can translate to clinical benefit in esophageal cancer patients.” - Dr. Lin

NRG Oncology Trial Highlight: NRG-GY014

A Phase II Study of Tazemetostat (EPZ-6438) (IND # 138671) in Recurrent or Persistent Endometrioid or Clear Cell Carcinoma of the Ovary, and Recurrent or Persistent Endometrioid Endometrial Adenocarcinoma

Recently Activated

About this trial:
NRG-GY014 is designed to examine the overall response rate of the drug tazemetostat (EZH2 inhibitor) in patients with recurrent clear-cell and endometrioid ovarian, fallopian tube or primary peritoneal cancer, as well as recurrent endometrioid endometrial cancer. Secondarily, the trial will be examining toxicity, progression-free survival, and overall survival of the patients receiving tazemetostat. Lastly, researchers will be evaluating BAF250a expression in the trial participant samples to examine the correlation of ARID1A mutation status and clinical response to the study drug, and the correlation between ARID1A mutation and BAF250a expression in an attempt to identify potential mutations that are predictive in patients with preserved BAF250a expression. Participants on this study will receive tazemetostat twice daily on days 1-28 (one cycle of treatment) and the courses will repeat every 28 days if there are no signs of disease progression or unacceptable toxicity. Patients will be followed every 3 months for 2 years and then every 6 months for 3 years.

More trial information can be found on ClinicalTrials.gov
Protocol documents can be found on CTSU.org

“This study is an exciting opportunity to examine the potential clinical efficacy of a novel epigenetic agent, tazemetostat, in the treatment of recurrent ovarian, fallopian tube, primary peritoneal and uterine cancer.” - Dr. Eskander
NRG Oncology Trial Highlight: NRG-HN004

Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer with a Contraindication to Cisplatin

Amended and Reactivated

About this trial:
The NRG-HN004 trial was recently amended and reopened for accrual for the phase II portion. This study will be comparing two different types of immunotherapy treatments: durvalumab and cetuximab. Patients on treatment arm 1 will receive cetuximab intravenously concurrent with intensity-modulated radiotherapy and patients on treatment arm 2 will receive durvalumab intravenously concurrent with intensity-modulated radiotherapy. The primary aim of NRG-HN004 in phase II is to determine progression-free survival between treatment arms. In phase III of the study, the primary aim will be to determine overall survival between treatment arms.

More trial information can be found on ClinicalTrials.gov
Protocol documents can be found on CTSU.org

NRG Oncology at NACCDO-PAMN in Oklahoma

The NRG Oncology Communications team and Executive Director Kati Stoermer attended the National Association of Cancer Center Development Officers (NACCDO) and Public Affairs and Marketing Networking (PAMN) Conference hosted by the University of Oklahoma Stephenson Cancer Center. The conference provided our Communications and Development teams to gather information on best practices for communicating with members, sites, and patients as well as development strategies to improve operations. Moving forward, NRG Oncology is looking forward to implementing some of what was learned.

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NRG Oncology Trial Highlight: NRG-LU003


Recently Activated

About this trial:
NRG-LU003 is a National Cancer Institute and NRG Oncology phase II trial studying clinical benefit of second or third generation ALK inhibitors in patients with late-stage, ALK-positive non-small cell lung cancer (NSCLC), who develop progression after a second-generation ALK inhibitor. Treatment will be based on genetic alterations identified upon tumor biopsy.

The ALK inhibitors included in this study are lorlatinib, ceritinib, alectinib, brigatinib, ensartinib, and crizotinib. NRG-LU003 will also be comparing the chemotherapy drugs pemetrexed with cisplatin or carboplatin in this patient population. The primary aim of the trial is to determine the response rate for each ALK inhibitor therapy for patients who have the relevant mutation (G1202/c1156y/I1171/l1196/V1180/F1174/compound mutation) and compare the response rate to patients who receive the same ALK inhibitor therapy with no mutations. For the no ALK-resistance mutation patients, the primary aim is to compare the response rate to those patients who are randomly assigned to concurrently receive chemotherapy drugs to those patients who receive another ALK inhibitor therapy.

More trial information can be found on ClinicalTrials.gov
Protocol documents can be found on CTSU.org

“NRG-LU003 is the first large scale clinical trial in which patients who progress on a second generation ALK inhibitor will be treated based on the genetic alterations in their tumor biopsy”. Another aim is to compare tissue biopsy to the liquid biopsy for concordance and possibly replacing tissue biopsy based on the data.” - Dr. Malik

Join us for the NRG-LU003 kick-off meeting at the NRG Oncology Semiannual Meeting on July 20, 2019, 10:30-11:30am CT to learn more about this trial.

Send us your feedback

Our NRG Oncology Communications Committee is always looking for suggestions and feedback on our materials. If you have comments or would like to submit ideas or articles for future newsletters, email us at:

nrg-broadcasts@nrgoncology.org
Diversity in Clinical Trials

“In 2019, 1,762,450 new cancer cases and 606,880 cancer deaths are projected to occur in the United States.”¹ Despite advanced treatment options and rigorous standards, research to find new treatments and to evolve current standards must continue in order to save lives. Clinical trial participation is paramount to fighting cancer and to finding cures. “The objective of cancer research is to generate new knowledge that can be used to improve survival and quality of life for patients with cancer. Clinical trials are the key step in advancing potential new cancer treatments from the research setting to the cancer care clinic, and patient participation in trials is crucial to this success.”¹² Clinical trial enrollment is estimated to account for only 2 to 3% of all cancer patients.⁵ For years the National Institute of Health (NIH) and American Cancer Society (ACS) have worked to increase awareness of racial and ethnic disparities in clinical trial participation and to increase clinical trial enrollment of these populations.⁹,¹⁰,¹¹ Nonetheless, enrollment of minority groups remains low and potentially “limits the generalizability of research findings”.⁵

“Many racial and ethnic groups in the United States and around the world are affected disproportionately by certain types of cancers.”¹⁰,¹³ Also, “race and ethnicity have been linked to differences in genetic predispositions to disease”⁴. With the introduction of targeted therapies, it is increasingly important that all racial and ethnic groups are included in clinical trial enrollment, otherwise, minority groups miss out on the opportunity to be included in the identification of treatment safety and efficacy.²

Continued on next page
Diversity in Clinical Trials (continued)

In order to increase enrollment of this population, we must address the barriers to clinical trial participation. According to Salman et al, the major barriers to clinical trial participation are physician-related, patient-related and system-related. Examples of physician-related barriers are awareness, attitude, and personal bias. Patient-related barriers may involve perception, fear, and mistrust. System- barriers include the trial design, inclusion/exclusion criteria of the trials, access, and financial burdens. The myriad and complex factors that impose barriers to clinical trial participation require in-depth evaluation to begin to correct the problem.

The following are some of the proposed solutions:

- **Increase Awareness**
  - Internal awareness: At the institution-level, educate physicians and research staff on: available open trials; the importance of racial and ethnic minority group inclusion in clinical trial enrollment; and how to address barriers to enrollment. Formal training and classes could facilitate ongoing education.
  - External awareness: Create research flyers, pamphlets, posters, etc and distribute them to community centers and at local events to enhance community awareness. A research presence at community events which includes time to discuss the possibility of clinical trial participation with leaders and general members of the community will enhance community knowledge and understanding. Consequently, people are comfortable enough to ask questions and seek trial participation when confronted with a cancer diagnosis.

- **Development of Trials:** Consider racial and ethnic group inclusion during clinical trial development; design trials according to the needs and priorities of the community members to ensure interest in the trial; carefully consider inclusion/exclusion criteria for relevance to the study disease and treatment and remove clinically irrelevant criteria that disproportionately impacts racial and ethnic minority groups. Create and distribute to participating sites culturally sensitive recruitment that includes rationale for inclusion of racial and ethnic groups should.

- **Informed Consent Form (ICF) Process:** To improve participant comprehension, write the ICF in easy to understand language. Minority groups may be suspicious of the consent form and, by signing, they will lose their rights. The person performing the consent process should have ample time to discuss, review, answer questions, and allay misconceptions. “It is essential to emphasize that the intention of the informed consent is to protect the participants rather than to ask them to give up their legal rights or to take risks or something unpredictable and suspicious.” Consider additional financial and time costs (e.g. travel, parking, meals) and provide assistance, if possible. To avoid trial explanation delay and to allow time for a prospective participant to fully consider the trial, consents (and translators) should be available in different languages for non-English speaking populations.

- **Bias:** Physicians, nurses, research staff, and patients can all have biases. Staff members may perceive a patient as not having interest, or the financial or emotional support to participate in a trial. Patients may believe they are not valued; they are being used as a guinea pig; or they may distrust the physician and the institution. It is important for physicians to develop a solid, trust-based relationship with the patient. Physicians and research staff should fully explain the trial to the patient and family without bias or preconceived ideas. “Investigators must be culturally sensitive and aware of the impact of appropriate communication and patient trust. Above all they must believe in the importance of clinical research and be committed to enrollment and possess the ability to encourage diverse groups of patients to also believe and participate in clinical trials.” They should be willing and open to discuss all scenarios and allay fears. “Effective and appropriate communication between health care providers and the potential participants may increase the patients’ willingness and ability to adhere to the trial’s requirements.”

Continued on next page
Diversity in Clinical Trials (continued)

- **Nurses**: The oncology research nurse plays a huge role in the successful enrollment and participation of any research patient, but especially those of an ethnic or minority group. The nurse is often the first line in patient questions, concerns, and understanding. It is important for the nurse to be knowledgeable about the trial, treatment and disease but also about the fears, misconceptions, and potential barriers that a minority group member may face. Institutions should provide appropriate culturally sensitive educational opportunities for the research nurse. Nurses belonging to ethnic and minority groups should be included in research teams to help diminish the barriers discussed above and improve the trust and communication of potential research participants. 10

Although it has been historically difficult to enroll diverse populations to clinical trials, as we move forward in this century with growing awareness and sensitivity to the issue, it is hoped that the participation disparities will be resolved. It is important for science, understanding, and advancement of knowledge that people of all races, ethnic and socioeconomic backgrounds will be equally represented in clinical trial research.

[Click here for the printable version of this article and the references section](#)

**Who Do You Contact with NRG Oncology Protocol Specific Questions?**

If you have a question about an NRG Oncology protocol, first check the protocol. If you do not find the answer in the protocol, the first few pages of the protocol list the study team, their study-specific roles, and contact information. Occasionally protocol-specific questions are submitted to the PSC mailbox and, usually, we direct you to the protocol-specific contact. Your questions are important and require a timely response, so please use the protocol-provided contact information.

Also, refer to the following two documents on the NRG Oncology website under **Resources and Data Management Resources**:

- **Protocol Contacts and Guidance** for contacts and information pertaining to NRG Oncology clinical trials.

- **Data Management Contact List** for the data management contacts for all NRG studies including the legacy studies. These data managers are NRG Oncology staff who work directly with the specified protocols and data. They can help you with your specific questions.

**Who Do You Contact for Questions about NRG Membership, Roster, Reimbursement, Website and IT and General Nurse/CRA Questions?**

On the NRG Oncology website under **Resources**, the **Contact Us tab** includes the main contact information for NRG Oncology as well as contacts for membership, roster, reimbursement, website and IT, publications, and general Nurse/CRA questions. You will also find the PSC mailbox, which can be used to submit suggestions for educational topics or comments you would like to share with the PSC.