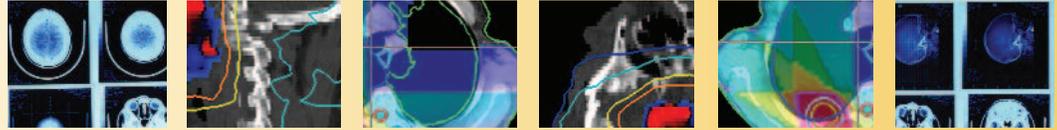


FALL 2011



Note from the Group Chairman

Let me add my congratulations to the many authors and architects of the RTOG research results presented in 31 ASTRO 2011 abstracts and in the 28 peer-reviewed manuscripts already published in 2011. These numbers are just a partial demonstration of the robust level of scientific inquiry operating within the group. Special kudos go to Drs. Jeffrey Bradley and Jeff Michalski for their ASTRO Plenary Presentations of RTOG research on Monday October 3rd, representing half of the entire ASTRO Plenary Session this year.



Walter J. Curran, Jr. MD

Giving a brief update on the re-alignment of the national cancer cooperative groups can be challenging. We continue our significant and very positive discussions with both NSABP (The National Surgical Adjuvant Breast and Bowel Project) and GOG (Gynecologic Oncology Group) in our efforts to create an effective structure within which the members of all three groups can most effectively function. We are looking to RTOG members to advise us on how to position this new organization for success in our unique community and university oncology ecosystems. Expect lots of discussion of this topic at our next RTOG Semiannual Meeting at the Westin Peachtree Plaza in Atlanta from January 19 to 22, 2012.

RTOG Had Prominent Presence at 2011 ASTRO Annual Meeting

Congratulations to the co-authors and other research participants on the 31 RTOG abstracts presented at the 53rd American Society for Radiation Oncology (ASTRO) Annual Meeting held in Miami Beach, FL from October 2-6, 2011.

This year's RTOG presentations at ASTRO highlighted the group's research efforts on behalf of patients with brain tumors, head and neck cancer, lung cancer, breast cancer, gastrointestinal cancer, and genitourinary cancer. RTOG studies were featured in two of the four ASTRO plenary sessions. RTOG Lung Cancer Committee Chair Jeffrey Bradley, MD (Washington University, St. Louis), presented the preliminary results of a large phase III lung cancer trial (RTOG 0617), and Jeff Michalski, MD, RTOG Vice Chairman for Advanced Technology, presented a toxicity analysis of the high-dose arm of a large phase III prostate cancer trial (RTOG 0126), funded in part by ASTRO's Radiation Oncology Institute. The ASTRO meeting also highlighted how RTOG serves as an educational resource for the next generation of radiation oncology investigators. Vinai Gondi, MD (University of Wisconsin, Madison), a former RTOG Fellowship Program participant, won ASTRO's Resident Clinical/Basic Science Research Award for a project he began as an RTOG fellow and he presented project results at scientific and special residents' sessions.

RTOG MEETING REGISTRATION INFORMATION NOW ONLINE

www.rtog.org/AboutUs/RTOGMeetings.aspx

In This Issue

- Page 2** Medidata Rave Implementation Underway
- Page 3** The RTOG Website has a New Look
- Pages 4-5** People in the News
- Page 6** RTOG Welcome and Congratulations
- Page 7** RTOG's New Website Offers Workshop Videos
- Page 8** RTOG Publication Highlights

Visit www.RTOG.org for the latest group news

Medidata Rave Implementation Underway

The Long-Awaited Clinical Data Management System Will Offer Many New Efficiencies

The timely collection of accurate data is at the heart of clinical trials research. Currently, site research personnel participating in National Cancer Institute (NCI)-sponsored trials need to be proficient in using multiple clinical data management systems (CDMS). Fortunately, relief from managing the complexities of multiple systems is in sight. Expected for rollout in 2012, Medidata Rave, a state-of-the-art CDMS, will become available across all research sites participating in NCI-sponsored clinical trials. After coordinating extensive review of available systems, NCI is facilitating the Cooperative Groups' move to Medidata Rave through user licenses and implementation financial support.

Sandy McDonald, BSN, RN, RTOG Director of Data Management, who is leading the Medidata Rave implementation for RTOG, is very excited about the new functionality it will offer sites. "The CDMS will have a single sign-on for all NCI clinical trials and, once a site user logs on, all studies in which the site is participating will be available. Having the same interface and functionality for all NCI Cooperative Group trials will make the end user's life much easier," explains McDonald.

Ed Kellar, a consultant guiding the CDMS implementation for both RTOG and the American College of Radiology Imaging Network (ACRIN), emphasizes that Medidata Rave is a very intuitive system, which helps with end-user training and

"A significant benefit is reduced training time required with a single CDMS, and Medidata Rave offers a comprehensive, self-paced training online."

adoption. Kellar comments, "A significant benefit is reduced training time required with a single CDMS, and Medidata Rave offers a comprehensive, self-paced training online." The first time an end user logs into the system, an invitation will be sent to complete the one-time required online training.

McDonald also is enthusiastic about the new system's potential for saving data entry time and minimizing errors. "The vast majority of data entry issues will be handled at the point of entry. The data entry fields will have "edit checks" to help prevent data entry errors. For example, if a value is entered that is out of acceptable range, an error message will pop up," she elaborates. Once a completed case report form is saved, the end user will receive immediate confirmation of the successful data submission or notification of missing or inconsistent data.



All queries will be resolved electronically, either immediately, or at a later time through a trial-specific task list that shows data issues that need to be reviewed, data forms that are past due, along with study notification alerts and messages.

NCI project coordinator for Medidata Rave implementation, Mike Montello, PharmD, MBA, associate branch chief of the NCI's Clinical Investigations Branch, predicts a significant impact from the new system. "It touches every aspect of clinical trials research to include the science, patient safety, and regulatory issues," says Montello. Emphasizing the significant savings of time and effort the system presents for site users, he adds, "Reducing research personnel's administrative burden and increasing the focus on patient care is one of the most significant benefits of Medidata Rave implementation."

"Reducing research personnel's administrative burden and increasing the focus on patient care is one of the most significant benefits of Medidata Rave implementation."

While Montello is confident that Medidata Rave will have a huge positive effect for sites participating in NCI's clinical research, he acknowledges NCI's awareness of the need for a thoughtful deployment to ensure a positive experience for site users from the start.

The RTOG Website Has a New Look

www.RTOG.org

Have you browsed the RTOG’s newly redesigned website yet? If not, please take the opportunity to peruse the expanded information as well as the more intuitive navigation features that help website visitors more easily obtain the information they need. In addition, we hope all will appreciate the fresh look of the graphics and enjoy seeing colleagues from RTOG member sites featured on the home page (see sidebar).

Following is a description of the new features:

Protocol Table: Sort protocols by disease site, phase, or status. Click on the protocol number to view a Protocol Summary Page.

Protocol Summary Pages: Each protocol has its own summary page that includes

- A summary of the primary objective and patient population
- The target accrual and the number accrued
- The sites with IRB approval
- Protocol forms
- Broadcast announcement archive
- Case credits and reimbursement information
- Information for Canadian sites
- Regulatory Information
- Current version date of the protocol

Publications Table: Sort publications by disease category, disease site, publication type, or research focus. Still under construction, the table currently lists publications from 2009 to 2011, with prior publications to be posted in the near future.

RTOG is interested to learn what you like about the new site and additional suggestions you might have for improving it. Please send your comments to Karan Boparai at kboparai@acr.org.

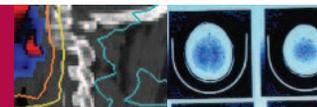


CALLING FOR PHOTOS AND IMAGES!

Photos and graphic images of RTOG member institutions featured on the website’s home page will be updated every several months. In addition to communicating an institution’s affiliation with RTOG, the photos and images also serve as a link to the institution’s own website. RTOG member institutions interested in being featured may submit photos to Karan Boparai at kboparai@acr.org.

RADIATION THERAPY ONCOLOGY GROUP

newsletter



Please send information on awards, honors, change of position, etc. to Heather Morris at hmorris@acr.org.

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Group Chair | Walter J. Curran, Jr., MD, Emory University

Deputy Group Chair | Mitchell Machtay, MD, Case Western Reserve University

Group Statistician | James J. Dignam, PhD, University of Chicago

Director of Clinical Trials Administration | Sharon Hartson Stine

Editor | Heather Morris

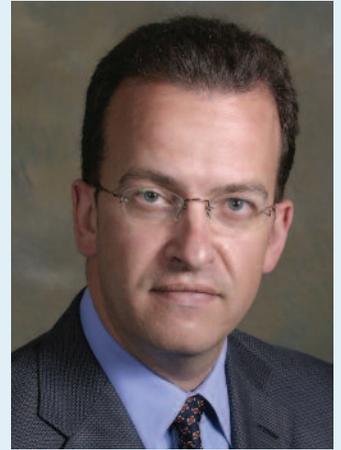
RTOG is administered by the American College of Radiology (ACR) and is located in the ACR Clinical Research Center.



People in the News

Richard C.K. Jordan, DDS, PhD, Directs RTOG Biospecimen Resource

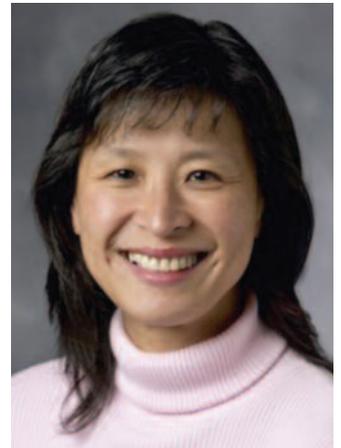
RTOG announced that Richard Jordan, DDS, PhD, FRCPath will direct the RTOG Biospecimen Resource housed at the University of California, San Francisco (UCSF). Jordan is a professor of oral pathology, pathology and radiation oncology at UCSF and is Director of the Oral Pathology Diagnostic Laboratory and the UCSF Oral Cancer Tissue Bank. Jordan assumes the directorship with the departure of Fredric Waldman, MD, who was instrumental in bringing the program to UCSF in 2008. “Being part of Dr. Waldman’s team to design the program’s framework was a great experience, and my involvement in its continued growth has been professionally rewarding,” says Jordan who has served as co-deputy director of the RTOG Biospecimen Resource, most recently with Jeffrey Simko, MD and Ken Aldape MD. He also serves as the pathology chair for several RTOG clinical trials and, in particular, has contributed to recent studies identifying the important role the human papilloma virus (HPV) plays in a subset of head and neck cancers. [Read Full Press Release](#)



Quynh-Thu Le, MD to Lead RTOG Head and Neck Committee

Quynh-Thu Le, MD (Sanford School of Medicine, Palo Alto) has been appointed Head and Neck Cancer Committee Chair for the Radiation Therapy Oncology Group (RTOG), an international National Cancer Institute (NCI)-funded clinical trials research group. Le is a professor and chair of the Department of Radiation Oncology at Stanford University where she has been engaged in leading both single and multicenter clinical trials and is a strong supporter of the conduct of RTOG head and neck cancer trials. “Offering our patients the opportunity to participate in RTOG’s progressive research investigating important questions about improving treatment strategies for patients with a head and neck cancer is very rewarding,” says Le who has been a member of the RTOG’s Head and Neck Cancer Committee since 2004 and will assume the chair role beginning in January 2012.

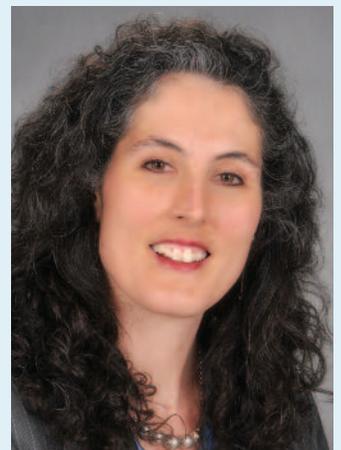
[Read Full Press Release](#)



Dr. Karen Knudsen Leads GU Grant Collaboration

RTOG’s Genitourinary (GU) Cancer Translational Research Program (TRP) Subcommittee is engaged in the development of a collaborative, multi-project cancer research initiative investigating the biology of locally advanced prostate cancer in the setting of curative management with resection and/or radiotherapy. GU TRP Subcommittee liaisons Alan Pollack, MD, PhD (University of Miami School of Medicine), and Felix Feng, MD (University of Michigan, Ann Arbor), challenged committee members to develop an NCI Program Project (P01) grant application. If successful, this grant would support an integrated, multi-project research program involving a number of independent investigators sharing common resources and infrastructure. Program Projects have a well-defined central research focus involving several disciplines or several aspects of one discipline.

The P01 grant collaboration is led by principal investigator (PI) Karen Knudsen, PhD, and co-PI Adam Dicker, MD, PhD, chair of RTOG’s Translational Research Program—both investigators are from Thomas Jefferson University in Philadelphia. The focus of the P01 application is to identify the molecular determinants of the DNA damage and the role of hormone therapy in locally advanced prostate cancer. Included are research projects led by investigators at the University of Michigan, Memorial Sloan Kettering Cancer Center, Cedars-Sinai Medical Center, and the University of California San Francisco.



People in the News (continued)**Genitourinary Cancer Committee Liaison for RTOG's TRP**

RTOG welcomes Felix Feng, MD (University of Michigan Medical School), as a new Genitourinary Cancer Committee liaison for its Translation Research Program (TRP). Dr. Feng's research interests include discovery and validation of biomarkers of radiation resistance in prostate and breast cancer and targeted radiosensitization of prostate, breast, and head and neck cancer in both preclinical and clinical settings. He joins Alan Pollack, MD, PhD (University of Miami Miller School of Medicine), in this role.

**Dr. Magliocco Joins Moffitt Cancer Center**

Anthony Magliocco, MD, FRCP, FCAP, chair of RTOG's Pathology Committee since 2010, recently joined the H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida as chair of Anatomic Pathology Department and executive director of Esoteric Laboratory Services. He is also adjunct professor of oncology, pathology and laboratory medicine at the University of Calgary where, prior to joining Moffitt Cancer Center, he served as director of pathology at the Tom Baker Cancer Centre where he established the core functional tissue imaging facilities along with a regional molecular analysis laboratory. Magliocco is also active in RTOG's Translational Research Program and serves on the Quality Control Committee.

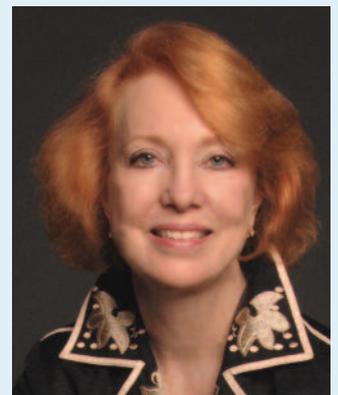
Contact Information: 813-745-2689; anthony.magliocco@moffitt.org

**Dr. Watkins Bruner, PhD, RN, FAAN Accepts Position at Emory University**

Deborah Watkins Bruner, PhD, RN, FAAN assumed a new position at Emory University in September 2011. Bruner holds a dual appointment as a professor of nursing at Emory's Nell Hodgson Woodruff School of Nursing and as associate director of cancer outcomes at Winship Cancer Institute of Emory University.

Bruner is chair of the RTOG Health Services Research and Outcomes Committee and also serves on other RTOG committee including the Symptom Management, Publications, and Genitourinary Committees. She moved from the University of Pennsylvania, where served as the Independence Professor in Nursing Education since 2006.

Contact information: 404-712-9695; deborah.w.bruner@emory.edu

**Gail Darling Joins RTOG Lung Cancer Committee as Surgical Oncology Co-chair**

Gail Darling, MD, FACS (Toronto General Hospital, Toronto, Ontario) has been appointed surgical oncology co-chair of the RTOG Cancer Lung Committee. Dr Darling is a professor of thoracic surgery and the Kress Family Chair in Esophageal Cancer at the University of Toronto where she also serves as the residency program director for thoracic surgery. Darling is also director of clinical research for thoracic surgery and director of the esophageal function laboratory at Toronto General Hospital.

Darling will work closely with committee chair Jeffrey D. Bradley, MD (Washington University, St. Louis, MO) and provide direction regarding the surgical components of RTOG lung cancer clinical trials. She will also serve as a member of the RTOG Surgical Oncology Committee chaired by Peter W.T. Pisters, MD, FACS (MD Anderson Cancer Center, Houston, TX).



RTOG Welcome and Congratulations

RTOG's recognition as an international leader in the conduct of adult oncology clinical trials is a result of hundreds of individuals stepping forward to support its research agenda. RTOG leadership is pleased to recognize a number of these contributors.

Welcome to New RTOG Member Institutions

FULL MEMBERS

University Hospitals of Cleveland
Janice A. Lyons, MD, Site Principal Investigator

US Oncology
Vivek S. Kavadi, MD, Site Principal Investigator

PROVISIONAL MEMBERS

Kaiser Permanente Santa Clara Medical Center
Samantha Seaward, MD, Site Principal Investigator

Memorial Sloan Kettering Cancer Center
Nancy Lee, MD, Site Principal Investigator

Ohio State University
Arnab Chakravarti, MD, Site Principal Investigator

Congratulations

RTOG/ACR FELLOWSHIP AWARDED

The Radiation Oncology Resident Training Fellowship is a collaborative project of RTOG and the American College of Radiology (ACR). This 5-day fellowship at RTOG headquarters in Philadelphia introduces residents to radiation oncology research. The RTOG Fellows participate in a 2-day RTOG Study Chair Education and Training Session and a subsequent 3-day program designed by the resident and RTOG leadership and staff to investigate more fully his or her area of interest in radiation oncology research.

Congratulations to the most recent fellowship recipients:

Roshan Prabhu, MD
 Emory University Winship Cancer Institute

Sinisa Stanic, MD
 University of California Davis

For more information about the fellowship, visit
www.rtog.org/Researchers/EducationTraining/RTOGACRResidentFellowship.aspx.

THE OUTSTANDING RESEARCH ASSOCIATE AWARD

The Outstanding Research Associate Award was established to honor a RTOG research associate who best exemplifies the values of professionalism, performance, compassion, and community service toward which all research associates aim.

Congratulations to the 2011 award recipient:

Marilyn Robinson, CCRP
 University of California San Francisco
 Nominated by Mack Roach, MD, Site Principal Investigator

Future RTOG Meeting Dates

2012

January 19-22, 2012
 Westin Peachtree Plaza Hotel, Atlanta GA

Information about the January 2012 meeting is now online at
[RTOG Meeting](#)

June 14-17, 2012
 Loews Philadelphia Hotel, Philadelphia PA

2013

January 2013 (TBD)
 Miami

June 13-16, 2013
 Loews Philadelphia Hotel, Philadelphia, PA

TOP-ACCRUING SITES*

Full & Provisional Institutions	# Accrued	CCOP Sites	# Accrued
Washington University	38	S.E. Cancer Control Consortium CCOP	44
Case Western	36	Christiana Care Health Services CCOP	26.5
McGill University	35.5	North Shore CCOP	20
University of Texas-MD Anderson Cancer Center	34	Toledo Community Hospital CCOP	19
US Oncology	34	Grand Rapids Clinical Oncology Program	18
Roswell Park Cancer Institute	27.5	Michigan Cancer Research Consortium CCOP	16.5
University of Utah Health Science Center	27	Beaumont CCOP	12.5
Emory University	26	John H. Stroger Hospital of Cook County MB-CCOP	11
Thomas Jefferson University Hospital	22	Cancer Research of the Ozarks CCOP	10.5
Princess Margaret Hospital	22	Montana Cancer Consortium CCOP	10.5

*January 1-May 31, 2011

RTOG's New Website Offers Workshop Videos

Videos of several workshops conducted at the RTOG Semiannual Meeting in June 2011 have been posted on the RTOG website (rtog.org). Information presented at the Quality of Life (QOL) and Comparative Effectiveness (CE) Workshop and the Cultural Competency and Recruitment Workshop are now broadly available to all RTOG investigators and others interested in the group's research activities via the website.

QOL and CE Workshop

The QOL and CE workshop was moderated by Benjamin Movsas, MD, RTOG Quality of Life Co-Chair, and Jason Efstathiou, MD, RTOG Comparative Effectiveness Committee Chair. It was developed to provide young investigators a primer on the methodology and processes for developing hypothesis-driven protocols and analyses for QOL and CE end points in radiation

"RTOG is a wonderful opportunity for young investigators to become involved in cutting-edge research and protocol development related to quality of life and comparative effectiveness. This workshop focuses on the key background and issues that will help young investigators in this regard."

BENJAMIN MOVSAS, MD
RTOG Quality of Life Co-Chair

oncology protocols. Guest speakers included Ann O'Mara, PhD, RN, FAAN, Program Director and Head of Palliative Care Research at the National Cancer Institute (NCI), who presented information about the institute's QOL and CE funding opportunities, and Priyanka Desai, MSPH, CPH, Research Associate at the Center for Medical Technology Policy, who gave a keynote presentation about CE research. Drs. Movsas and Efstathiou, along with five other RTOG investigators with extensive QOC and CE research experience, also provided presentations.

Thank you to all the investigators who contributed their time and expertise to this workshop. The funding for this video production was provided by the RTOG Foundation.

A list of the workshop topics and video links are available at www.rtog.org/Researchers/EducationTraining/QualityofLifeComparativeEffectivenessTraining.aspx.

Cultural Competency and Recruitment Workshop

The Cultural Competency and Recruitment Workshop was designed to present ideas and hold discussions about ways to increase cultural competency, improve communication with minority populations, and overcome potential barriers to clinical trial enrollment by Hispanic/Latino and African American patients. The workshop, led by Deborah Watkins Bruner, RN, PhD, FAAN, and Jessica Rearden, RN, MS, is part of a larger

Cultural Competency and Recruitment Training Program being conducted for RTOG physician investigators and clinical research associates (CRAs) who have primary contact with cancer patients related to study recruitment and performing informed consent discussions. The video content includes four modules:

- Module 1: Introduction to Cultural Competency
- Module 2: Recruitment of Minority Populations: Facts & Myths
- Module 3: Culturally Competent Communication
- Module 4: Overcoming Obstacles in the Recruitment of Minority Populations

Physicians and CRAs interested in viewing the videos of this workshop also have the opportunity to take part in an associated study that involves completing two Web-based surveys: one prior to the training, and one 3 months after the training. To view the videos and learn more about study participation, visit www.rtog.org/ResearchAssociates/EducationTraining/CulturalCompetencyandRecruitmentTraining.aspx.



"It was a wonderful experience to be part of such a novel and important program. RTOG and its members have a clear commitment to increasing cultural sensitivity related to the design and conduct of cancer clinical trials, and I believe this program is an important step in achieving that goal."

JESSICA REARDEN, MS, RN

This is a great opportunity to contribute to research on this important topic.

RTOG is pleased to acknowledge all the investigators, research associates, patient advocates, ACR/RTOG staff, and ePharmaSolutions who contributed their time and expertise to this workshop. The Pennsylvania Department of Health is also acknowledged for its funding of video production.

"The changing demographics of the United States along with our increasing number of international RTOG members make our attention and sensitivity to cultural differences imperative when considering clinical trial design, informed consent, patient questionnaires, and recruitment issues."

DEBORAH WATKINS BRUNER, RN, PHD, FAAN
RTOG Health Services Research & Outcomes Committee Chair

RTOG Publication Highlights



RTOG continues its strong publication record with the publication of 28 peer-reviewed manuscripts in calendar 2011 to date. Three recently published studies reported significant observations regarding the management of patients with either prostate cancer or lung cancer.

RTOG 9408: Combined Hormone Therapy and Radiation Therapy for Early-Stage Prostate Cancer

Published results (*N Engl J Med.* 2011;365:107-118) showed that short-term hormone therapy (androgen deprivation therapy [ADT]) given in combination with radiation therapy, compared with radiation therapy alone, for men with early-stage prostate cancer significantly increased their long-term survival and disease-free survival rates. This largest randomized trial of its kind enrolled nearly 2,000 men with low and intermediate risk of prostate cancer and followed their health status for 9+ years (1994–2001) at 212 centers in the United States and Canada. The addition of short-term ADT to radiation therapy significantly improved the overall survival rate at 10 years from 57% to 62% and was associated with 4% fewer prostate cancer-related deaths compared with the radiation therapy-alone arm (8% vs. 4% respectively). A particularly important finding was that the reduction in disease-specific deaths was accounted for mostly by the intermediate-risk study participants in the radiation therapy plus ADT arm (10% vs. 3% respectively, in the radiation therapy-alone arm at 10 years) while no reduction in deaths was seen among low-risk participants at 10 years.

RTOG 9410: Concurrent versus Sequential Chemotherapy and Radiation Therapy for NSCLC

In an article published online September 8, 2011 in the *Journal of the National Cancer Institute* (doi:10.1093/jnci/djr325), RTOG researchers reported that treating patients with locally advanced NSCLC with concurrent chemotherapy and radiation therapy significantly increased 5-year survival rates compared with treating patients with radiation therapy following chemotherapy.

...treating patients with locally advanced NSCLC with concurrent chemotherapy and radiation therapy significantly increased 5-year survival rates...

This phase III study is the largest randomized trial to confirm the importance of administering treatment concurrently rather than sequentially for this patient population. A total of 610 study participants at 153 institutions across North America were randomized to receive cisplatin-based chemotherapy in addition to radiation therapy administered sequentially (arm 1), once daily concurrently (arm 2), or twice daily concurrently (arm 3). The percentages of study participants confirmed still living at 5 years post-treatment in study arms 1, 2, and 3 were 10%, 16%, and 13%, respectively. Study participants experienced significantly worse acute side effects with concurrent therapy versus sequential therapy, particularly, severe esophagitis. However, reported late side effects were minimal and similar across the three study arms.

RTOG 0324: Adding Cetuximab to CRT for NSCLC

Intensive research in the past decade has focused on identifying molecular targets associated with NSCLC. One such study, “*A Phase II Study of Cetuximab (C225) in Combination with Chemoradiation (CRT) in Patients with Stage IIIA and IIIB NSCLC*,” was published in the June 10 issue of the *Journal of Clinical Oncology* (2011;29[17]:2312-2308). Seeking to determine the safety profile of the epidermal growth factor receptor (EGFR)-binding molecularly targeted therapy cetuximab in combination with CRT, the study enrolled 93 study participants from 42 RTOG centers between March 2004 and June 2005. Results demonstrated that the therapy is well tolerated by patients with inoperable stage III NSCLC, and the rate of severe side effects was commensurate with that reported with the same CRT regimen without cetuximab. The study results also showed better patient survival than observed in any previously reported RTOG stage III lung cancer trial (median survival, 22.7 months, 2-year survival rate, 49.3%).

The study results also showed better patient survival than observed in any previously reported RTOG stage III lung cancer trial.