Positive Spirit Infuses Formation of NRG Oncology

Just weeks before NRG Oncology’s application was submitted for participation in the National Cancer Institute’s new National Clinical Trials Network, the NSABP, RTOG, and GOG group chairs took time to reflect upon their aspirations for the new organization.

The Groups’ Synergies

An optimistic outlook and enthusiasm for NRG Oncology’s potential to carry forward and improve upon the practice-changing legacy of each individual group resonated throughout the chairs’ remarks. “We possess an esprit de corps that by moving forward together we can build upon each group’s unique strengths to create an even stronger organization,” says Philip J. DiSaia, MD, Gynecologic Oncology Group (GOG) Chair and professor and fellowship director of the Division of Gynecologic Oncology in the Department of Obstetrics at the University of California, Irvine.

A strong premise conveyed by the chairs is that the extensive clinical trial history and complementary nature of the scientific expertise brought together under NRG Oncology creates an international leader in clinical and translational research across seven major cancer disease sites. “NRG Oncology brings to the table very exciting, measurable, and definitive advantages. For example, we will expand an outstanding developmental therapeutics program,” remarks Norman Wolmark, MD, National Surgical Adjuvant Breast and Bowel Project (NSABP) Chair and professor of surgery at Temple University in Philadelphia, “and the depth and breadth of the combined tissue bank is an enormous benefit, especially as practice continues to evolve into providing more targeted therapy.”

The chairs concur that among NRG Oncology’s compelling attributes are extensive early-phase trial expertise; broad experience for carrying out combined-modality therapy trials; a prominence in women’s cancers, all cancers of the reproductive system, and cancers of the entire digestive system; and an intensive focus on head and neck and brain cancer. Additionally, each legacy group brings a track record of success in carrying out international trials. States RTOG Group Chair Walter J. Curran, MD, Executive Director of the Winship Cancer Institute of Emory University in Atlanta, “In many areas we are bringing together programs that will create new strengths, and in others we are combining programs that are already independently strong. As a leadership team, we are determined to continue to create a home for discovery and creativity in all of these areas.”

The Leadership Model

As allowed for in the National Clinical Trials Network program guidelines, the three chairs will serve as NRG Oncology PIs and share equal responsibility for executing the group’s research program. Additionally, the three PIs will hold the positions of NRG Oncology Foundation Board Chair, Presiding Chair, and Contact Chair on a rotating basis. Curran, DiSaia, and Wolmark, respectively, will be the first to serve in these positions.

“The level of collegiality,” remarks Wolmark, “has been unprecedented, certainly in my experience. The three of us have worked together diligently so that NRG Oncology will function as an integrated entity.”

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The NRG Oncology Foundation and Industry Collaboration

The recently established NRG Oncology Foundation, which will be administered equally by the three legacy groups, will be the recipient of governmental funds for conducting NCI- and state-sponsored research. The chairs all acknowledge that, because governmental funding alone will not support the robust research agenda planned, additional funding must be secured from industry and other governmental sources. “The NRG Oncology Foundation board will be composed of talented leaders who are dedicated to NRG Oncology’s mission and vision. Together we will look for opportunities to leverage resources and create new sources of revenue to run and execute trials,” says Curran.

A key rationale cited for the cooperative group program’s reorganization is a heightened emphasis on translational research. As Wolmark points out, “The enhanced capability, expertise, and infrastructure of NRG Oncology to carry out the NCI-sponsored program is essential for attracting new and expanded partnerships that cannot be ignored if we’re going to move the state of the art forward.”

All three groups have strong histories of working with industry, and DiSaia calls attention to the potential that each chair’s relationships have for attracting broader industry partnerships within NRG Oncology. “This is an important way we can support each other,” notes DiSaia, “especially now that the NCI embraces industry collaborations.”

Maintaining a Strong Member Loyalty

A group’s members are acknowledged as the organization’s backbone and key to future success. DiSaia likens cooperative group participation to a fraternity or sorority (“it doesn’t pay, but we do it because we love it”) and stresses the importance of keeping that sense of pride and accomplishment strong as the members move into the new configuration. The groups’ history of previously working together provides a strong foundation for a smooth integration. Says DiSaia, “We think we can improve upon what we’ve already been doing. We can answer questions that no one else can because of our volume and structure, and we can answer them in a very robust, scientific manner.” By building a vibrant organization, the chairs expect to maintain a strong member allegiance as well as to attract new investigators who want to join because they see the scientific program as interesting and exciting. Noting the commitment the groups have traditionally played in the stewardship of members’ careers—in academic medicine and in community practice—Curran comments, “We’re strongly advocating that NRG Oncology continues in that vein.”

The chairs share a desire to communicate to their members the enthusiasm present during the formulation of the response to NCI’s Funding Opportunity Announcement. “We are very eager to launch this unique group,” says Wolmark. “Yet by the same token, we are not abandoning what has brought us to our current point and what has been the force for our success.”

Benefits for Patients

At the core of all the face-to-face planning meetings, teleconferences, and e-mail correspondences that have taken place over the past 15 months has been the desire to emerge as one effectively operating group. “If we can run as one organization,” says Curran, “we can be extraordinarily successful in defining new and better ways of thinking about the diseases we’re studying and in taking care of patients.” DiSaia is encouraged that the women of this country will be gaining a better cancer research group that is ready to work on new early diagnosis strategies, better and less invasive treatment, and continued preservation of fertility and cosmetics. Wolmark echoes the enthusiastic sentiment, stating, “I am optimistic that we can achieve the aims we set out to accomplish and more rapidly change the standard of care to benefit the individuals to whom we have the greatest commitment, and those are our patients with cancer.”

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Until March 2014, when the NCI’s National Clinical Trials Network is expected to formally launch, NSABP, RTOG, and GOG are required by federal guidelines to operate separately under their existing grants. Although patience is required during the interim, NRG Oncology is poised to be a defining force in cancer research.
The NRG Oncology Web site Working Group (WWG) has established and registered an official Web site for the NRG Oncology cooperative group. Following an extensive search and selection process for a Web content management system that provides distributed, permissions-based access for posting content to the NRG Oncology Web site, the WWG chose DotNetNuke (DNN) Professional Edition 7.0.

“DNN is one of the topmost Web site content management systems adopted globally and has been in use for a decade in a wide variety of business sectors, including health care,” says Jeff Leong, an application developer at the ACR Clinical Research Center. “The NRG Oncology Web site will use the professional version of the software, which comes with all the coolest features that can translate into new and helpful functionality for end users at the research sites.”

A Web content management system allows publishing, editing, and modifying content, as well as maintenance from a central interface. Following initial configuration of a system, administration can be done through a browser-based interface that allows technical and non-technical users alike to make changes to the content easily.

RTOG Web site administrator Karan Boparai has significant experience managing Web site content using DNN, as RTOG launched a new Web site based on this technology in 2010. “With DNN I can add new Web site pages easily and redesign existing pages to add additional text, photos, and graphics without the use of any programming language. DNN’s modular framework provides a great deal of flexibility for Web site expansion,” says Boparai. Such ease of expansion is an especially desirable feature, because the NRG Oncology Web site is expected to grow significantly after its initial launch.

DNN will allow for simplified management of materials posted by appointed staff from each of the legacy groups. Boparai also reports that the security functionality allows her to assign privileges for staff to update specific pages. “Distributing the responsibility for posting approved content and materials, for example, protocols and publication citations, has resulted in faster Web site updates,” notes Boparai.

The physical location of the server and DNN software installation hosting the Web site is the office of the Gynecologic Oncology Group (GOG) in Buffalo, NY. Justin Dittmar, a GOG Technical Support Specialist and administrator for the NRG Oncology Web site, sees DNN and its hosted server environment as a “perfect fit” with the GOG’s virtualized server farm. “The physical infrastructure supporting the NRG Oncology’s DNN installation provides ample and scalable disk space and memory. This virtualized environment is also very reliable,” states Dittmar. “We were able to create a new NRG Oncology Web server and install the initial DNN package and supporting software in a total of just a few hours. The NRG Oncology DNN portal will be a collaborative effort among all three member groups, so it has been nice to kick off this relationship by working with other team members on the install and configuration process for the Web site,” concludes Dittmar.

Web site content and design are currently under development by the WWG and the Communications Working Group. Both groups will continue to relay communications to NRG Oncology members as important information is published to the new site.
NRG Oncology Network Group Statistics and Data Management Center Takes Shape

A major grant application in support of NRG Oncology pertains to statistical expertise for data management, data analysis, and statistical analysis of National Clinical Trials Network (NCTN) studies, including translational and ancillary studies. The three directors coordinating that function within RTOG, NSABP, and GOG recently shared their perspectives on the opportunities and challenges posed by the impending merger.

Combining Best Practices for Optimal Efficiency

“NRG will join three high-performing statistical and data management centers, each with a more than 40-year record of publishing papers of practice-changing research,” points out James Dignam, PhD, from the University of Chicago and group statistician for RTOG. “The legacy groups’ combined databases encompass examples of just about every kind of statistical problem.” All three directors look forward to the ability to choose the best processes of each of the three groups in developing methods for study design and analysis, and data collection and cleaning that their novel and broad expertise provides.

A surprising degree of similarity underlies the groups’ disease site-specific research, including a shared interest in incorporating the advances in cancer biology and bioinformatics that are a key aspect of modern clinical trials. “We all see the need,” comments Dignam, “to keep pace with the rapidly developing technology that has progressed from microarray data, to genomic data, and now to next-generation sequencing involving the interaction among gene products. NCI has taken a strong position of requiring a rigorous statistical validation process for all new biomarkers resulting from this research to ensure clinical relevance and utility.” The groups also share an interest in methodology research in areas such as competing risk analysis, prognostic modeling, and clinical trial monitoring and early termination issues. They are also interested in the streamlining and automation of routine trial summary reporting to allow for increased focus on scientific papers and forward-looking research planning.

In preparation for the March 2014 merger, the statistical directors have spent the last year coordinating the harmonization of procedures. John Blessing, PhD, from the Roswell Park Cancer Center and director of the GOG Statistical and Data Center, describes the collegial relationships brought to this enormous endeavor. “I sense a belief among those working on the grant application that ‘Boy, this is a hell of a challenge, but we have a hell of a team and we’ll make it work. Amidst the pressure of time-consuming meetings and conference calls, we’ve maintained respect for the accomplishments of each group and found ways to make necessary changes that are well thought out.”

The directors also share a leadership style that highly values collaboration. As Blessing explains, “The statisticians are fully integrated research partners, and the philosophy of an integrated team is embraced by the directors and members of all four statistical and data management center divisions: administration/operations, biostatistics and science, data management, and information technology. There is an aspect of family among our staff members, many of whom have extended longevity and experience, making the groups that much better.”

Integration Challenges and Strategies

The planning team faced the challenge of combining procedures to enable the three groups to operate as one cooperative group. Committees and subcommittees were established to harmonize SOPs encompassing protocol

continued
design, data monitoring committee management, annual report development, and interaction with disease site committees. Joe Costantino, DrPH, professor in the Department of Biostatistics at the University of Pittsburgh and director of the NSABP Biostatistical Center, is pleased by the progress already made toward this goal. “The work of these committees, which involved the statistical directors as well as the heads of information management and data management, was made easier by the earlier implementation of the Medidata Rave electronic data capture system, because all three groups were already using a standardized system,” notes Costantino.

There has also been a need to blend the processes being worked out in separate subcommittees so that the group comes together as a whole. According to Blessing, “Implementing combined SOPs that are clearly effective as they are written will help us to hit the ground running on Day 1 of the merger. However, some working groups need to wait for the completion of another group’s efforts before finalizing their SOPs. The audit working group, for example, couldn’t finalize its plan for auditing members until the definitions of membership status had been worked out.” Nonetheless, work continued with the intention of fine-tuning as necessary.

Much of the work to date has focused on visualizing a concept of how the groups will best work together and establishing an underlying structure to facilitate that operation. Viewing this as a work in progress, Blessing comments, “We’ve made good inroads and will make more during the next year when the groups interact with each other at our combined meetings.”

Striving to operate as a totally consolidated group in March 2014 is an unrealistic goal, according to the team. “Because of the groups’ differences in terms of physician mix, scientific questions, and trial design, some differences will necessarily persist,” acknowledges Dignam.

“Long-term challenges projected now might not be accurate in 14 months,” notes Blessing. “However, as we move from creating to actually being NRG Oncology, we can assume that challenges will generally relate to fine-tuning the structure or filling in the gaps.” Costantino agrees, stating, “We’ve come a long way in the merger process, but we won’t really be there until a couple of years into the combined system.”

Site Investigator Contribution
As plans for establishing the NRG Oncology Network Group Statistics and Data Management Center proceed, the statistical planners emphasize the goal of incorporating all research areas of the current three groups into a more efficiently operating cooperative group. Blessing comments, “Site investigators have exhibited their trust that we will emerge as a strong organization by continuing to enroll patients into clinical trials, and this is a key aspect of making the merger successful.”

Starting in January, roundtable discussions at the combined annual meeting will allow investigators an opportunity to provide feedback about plans for new processes and procedures. “This input will help us to make things the best we can as fast as possible,” concludes Costantino.

Working Group Helps Establish the Public Face of NRG Oncology
The NRG Oncology Communications Working Group (CWG), composed of members from the publications and communications sections of the three legacy groups, has conferred over recent months to select a logo design and color combination capable of projecting a positive and professional public face for the combined group. Additionally, the CWG has held a number of sessions devoted to the development of a tagline that would clearly and succinctly communicate NRG Oncology’s intention to produce research innovations and practice-changing results. The new logo appears in the banner of this newsletter and in the business card shown here. It will appear on stationery, on the new Web site, and in other communications, such as press releases, notices to research sites, memos, and poster and slide templates. The tagline (Advancing Research. Improving Lives.) will accompany the new logo in most instances.

The NRG Oncology Web site is currently in development, as discussed on page 3. The CWG is working with Biddle Design and Gemini Communications of Philadelphia and the NRG Oncology Web Site Working Group to arrive at an online home for NRG Oncology that will be user friendly and logical, combining the best elements of the three legacy group Web sites.

The CWG is also conferring on the communications strategies, methods, and logistics that NRG Oncology will use to communicate with members and the public and on ways that procedures used by the three legacy groups can be combined and refined to advantage.
Membership in NRG Oncology

NRG Oncology brings together an impressive roster of committed investigators who have been integral to the legacy groups’ success. Encouraging such high-level participation has been at the forefront in the design of the membership structure for the new group. Leadership has made every attempt to recognize the disparate, yet important, cultural and administrative differences that have historically defined membership across the three enterprises. Described below is the NRG Oncology envisioned membership structure.

Principal Investigator(s) – To recognize the contributions of our legacy member sites, NRG Oncology will allow sites to designate up to three principal investigators (PIs) at each site. The PIs must represent different medical specialties (e.g., medical oncology, surgery, radiation oncology, gynecologic oncology). One PI must be designated as the site contact.

Parent/Affiliate Designation – Each Affiliate Member or CCOP component can have only one parent site. A site within NRG Oncology that participates as an Affiliate Member in two or more of the legacy groups that comprise NRG Oncology will be required to designate one site as its parent site.

Affiliate Member/Main Member Designation – An institution that is currently an Affiliate Member site in one group may qualify as a Main Member in NRG Oncology if it is a Main Member in one of the three legacy groups that comprise NRG Oncology.

Membership Categories – NRG Oncology will have the following membership categories:

- **Main Member (includes CCOPs)**
  - Required to accrue at least 15 patients per year in treatment intervention studies through NRG Oncology and maintain satisfactory data timeliness and audit scores
  - Accurals from an Affiliate Member count towards the Main Member’s accrual requirement
  - Responsibilities with regard to Affiliate Members include 1) receive all per-case reimbursement for the Affiliate Member, 2) distribute all per-case reimbursement to the Affiliate Member, and 3) ensure acceptable Affiliate Member performance.

- **Voting Main Member**
  A Main Member that accrues at least 40 patients per year in treatment intervention studies through NRG Oncology, including accruals of its Affiliate Members, will be eligible to become a Voting Main Member. The initial designation of Voting Main Member will be based on legacy group accrual and scientific participation, with equal representation from each group. Beginning in 2015, the Voting Main Member designation will be based on NRG Oncology accrual.

- **Affiliate Member (includes CCOP components)**
  An Affiliate Member is required to accrue at least 3 patients per year in treatment intervention studies and maintain satisfactory data timeliness and audit scores. Affiliate Member accrual reimbursement is sent to the Main Member. An Affiliate Member is generally audited at the same time as the Main Member.

- **International Members**
  An International Member includes those institutions outside the United States or Canada and may become a Main Member and a Voting Member if it meets the patient accrual and other qualifications for those categories. An International Affiliate Member is required to accrue at least 7 patients per year and maintain satisfactory data timeliness and audit scores.

### Membership Roster Survey

To create an accurate and up-to-date membership roster, each site that is currently a main member of NSABP, RTOG, or GOG will receive a survey form to confirm the member’s NRG Oncology participation intention. Please return this survey as promptly as possible.

Questions concerning your current membership status can be addressed to the membership office of the appropriate legacy group (see table below).

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<th>Legacy Group</th>
<th>Department</th>
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<td>NSABP</td>
<td>Membership</td>
<td>Mary Ketner (<a href="mailto:mary.ketner@nsabp.org">mary.ketner@nsabp.org</a>)</td>
<td>412-330-4624</td>
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<td>Tivona Lemar (<a href="mailto:tlemar@gog.org">tlemar@gog.org</a>)</td>
<td>215-854-0770</td>
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