NRG Oncology General Session

The NRG Oncology Group Chairs, Drs. Curran, Mannel, and Wolmark, provided an overview of the recent NCTN grant submission, our current research efforts, along with updates from Membership, Publications, NRG Oncology NCORP, Statistical Data Management, and Tissue Banking.

NRG Oncology submitted its NCTN six-year competitive grant renewal applications in January 2018. The recently released peer review scores recognized NRG Oncology as an exceptional research organization. This is a great testament to the dedication of our member investigators and the staff in our Operations and Statistics and Data Management Centers. As we transition into the new grant period, NRG Oncology is restructuring its leadership to decrease the number of Deputy Group Chairs and reorganize some of its Committee Chairs. More information on leadership transitions can be found on page 3.

The new grant cycle will begin in March 2019. Through this grant, NRG Oncology’s mission continues to be to improve the duration and quality of lives of adults with specific cancers through the conduct of its science-driven, National Cancer Institute (NCI)-supported multi-institutional clinical trials. This will be achieved through the specific aims focused on medical technology, biomarker and biologic pathway-defined approaches, and precision oncology and immuno-oncology. More information on these updates can be found in the session slides on the NRG Oncology website.

NRG Oncology Scientific Session

The NRG Oncology Scientific Session, moderated by Publications Co-Chair Thomas Julian, MD, held on Friday, July 13th, shared with members our recent endeavors and reported results from multiple NRG Oncology trials. The final analysis of the CALOR Trial (NRG-NSABP B-37) confirmed that chemotherapy benefits patients with resected ER-negative isolated
Social Media Workshop

The NRG Oncology Communications Committee organized a Social Media Workshop in recognition of the increasing role that social media (SoMe) plays in personal and professional networking as well as daily life of many of our members and patients. As evidence of this, information coming from the NRG Oncology Semiannual Meeting is being crowdsourced to the world by members through the #NRG18 Twitter hashtag. The communications and networking tool of SoMe spans across demographics, age, race, ethnicity and social status and is increasing in use. The Social Media Workshop on July 13th aimed to educate, inform, as well as engage cancer providers, investigators, and patient advocates with this technology as a means of collaboration.

The SoMe Workshop was kicked off by Dr. Thomas Julian (@TBJulianMD), chair of the NRG Oncology Communications Committee who provided an overview of how NRG Oncology utilizes SoMe resources to communicate and collaborate with members and support the mission of the NCI. Dr. Merry Jennifer Markham (@DrMarkham) offered guidance to professionals interested in using SoMe as a tool for professional development and networking as well as providing a reputable voice in a sea of information. Dr. Michael Cowher (@MikeCowher) brought Dr. Markham’s recommendations into the real world with recommendations and guidance on the potential pitfalls and risks associated with SoMe use in a professional capacity and how to steer clear of problems. Dr. Thomas George (@TGeorgeMD) provided examples of how SoMe can be used to support patient engagement in clinical research, including novel initiatives that NRG is actively developing. Finally, Kara Smigel-Croker (@KaraSmigel), a communications specialist with the NCI, provided an inventory of the SoMe resources available through and used by the NCI. The workshop concluded with a panel-based tutorial on Twitter basics and functionality for those SoMe newbies in the crowd.

Digital Health Minisymposium

How do we break down the silos between healthcare provider and patient? How can we collect more patient-reported health data (PRHD) in real-time so we can be proactive in treating patients and improving outcomes? NRG Oncology’s Digital Health and Personal Connected Health Minisymposium included speakers from a variety of backgrounds who expanded on these questions and provided examples of successful integrations of patient-oriented technology and the collection of data related to side effects.

The Program Chair, Adam Dicker, MD, of Thomas Jefferson University Hospital’s Kimmel Cancer Center, explained that digital health is a rapidly-growing concept that considers the use of technology to deliver care and information to providers and patients or caretakers alike, taking advantage of platforms such as smartphones, sensors, personal computers, and apps. The information that can be collected from the patient could improve outcomes and efficiency, decrease costs, and help providers deliver care information in new ways. Dr. Dicker suggested the audience consider a question through the session: Can digital health training in oncology be useful in clinical trials?

As session speaker, Alexi Wright, MD, MPH of Harvard Medical School, suggested that clinicians miss approximately 50% of patient symptoms because patients spend most of their time outside of the medical system. How can we combat this so that patients are actively engaged in their treatment and able to report their outcomes in a more timely matter?

Amir Kishon, PhD, of RMDY Health Inc., expanded on the different platforms available to enhance engagement among patients through built-in trackers, connected devices, elearning, calendars and reminders, and chat and group features.

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NRG Oncology extended their appreciation to our outbound Deputy Group Chairs as we prepare to transition into a new committee leadership structure. Deborah Watkins Bruner, PhD, was honored for her service as Deputy Group Chair of Publications and Thomas Julian, MD, was recognized for his service as Deputy Group Chair of Communications. Harry D. Bear, MD, PhD, is assuming the role of Deputy Group Chair of NRG Oncology Publications and Communications. Dr. Julian will remain as the Chair of Communications Committee and Krishnansu Tewari, MD, will become the Chair of the Publications Committee.

Larry J. Copeland, MD, was recognized for his service and dedication as Deputy Group Chair of Research Integrity. Going forward, David S. Miller, MD, will be the Deputy Group Chair for Membership and the Integrity Officer for NRG Oncology.

J. Tate Thigpen, MD, is stepping down from his role as the Deputy Group Chair for the Concept Prioritization and Advisory Committee.

Under continuing direction of Mitch Machtay, MD, the Deputy Group Chair for Research, NRG Oncology’s new research center leaders will include Jame Abraham, MD, and Ronald Alvarez, MD, who will head the NRG Oncology Research Strategy Committee. Also, Maria Werner-Wasik, MD, will chair the new Protocol Operations Management Committee.

A special thank you was given by Dr. Wolmark to D. Lawrence Wickerham, MD: NRG Oncology announced that, in addition to stepping down as Deputy Group Chair of Membership, he will also retire from the group as of the end of the year. In addition to his Deputy Group Chair role, Dr. Wickerham is also a Co-Principal Investigator of NRG Oncology’s NCORP grant, where he heads its Steering Committee. Dr. Wickerham has been an integral part of NRG Oncology’s operations and we are deeply appreciative of his service to the group and his past service to NSABP. Click here to watch Dr. Wolmark’s tribute to Dr. Wickerham.

Digital Health Minisymposium (continued)

Heather Jim, PhD, of the Moffitt Cancer Center, provided an example of her team’s successes with implementing technology to help counter fatigue as a side effect on a trial. Dr. Jim’s team collected PRHD from patients and tailored their therapies to help them with their fatigue through many interventions such as Facetime-delivered therapy to help explain how they can manage their symptoms. S. Percy Ivy, MD, from NCI CTEP, had similar success with an app for the pilot study eCO (eCediranib-Olaparib) which used a mobile device to allow patients to check and record their blood pressure. By using this device, Ivy’s team was able to capture 98.2% of the required blood pressures electronically.

Paul Kluetz, MD, of the FDA and Bradford Hesse, PhD of NCI focused on integrating these platforms into the healthcare process, while remaining mindful of safety and efficacy along the way.

The recording of this session can be found here.

Congratulations to the NRG Oncology NCORP Pilot Grant Awardee

Nitin Ohri, MD
Department of Radiation Oncology
Montefiore-Einstein

Physical Activity Monitoring to Predict Hospitalization in Advanced Cancer Patients
NRG Oncology Gastrointestinal Cancer Committee Workshop

The NRG Oncology Gastrointestinal (GI) Cancer Committee Workshop on Saturday, July 14th provided NRG Oncology members with an overview of the currently available NCTN studies targeting GI cancers. The presentations were organized by disease and included key upcoming amendment changes and status updates. Additionally, GI Committee members shared some coming attractions related to NRG GI cancer trials that are in development. These presentations were interactive with opportunities for audience members and other speakers to provide insights and feedback and to share best practices on incorporating clinical research in their practice.

The agenda began with an overview of the Colorectal Cancer studies in the NCTN portfolio. Dr. Thomas George (GI Cancer Committee Co-Chair) introduced the speakers who covered the gamut of studies for patients with resectable rectal cancer and post-operative treatment for those with colon cancer. Importantly, NCTN studies for patients with metastatic disease are now focused on relatively infrequent molecular subtypes of cancers, specifically MSI-H/dMMR (NRG-GI004 aka COMMIT Study) and HER2+ (S1613). Based on the recent successful completion of studies in BRAF mutant colorectal cancers, these next generation targeted therapies for molecular subsets of patients leverage the ability of the NCTN to collectively identify and treat patients with relatively low frequency mutations that a single center or practice would otherwise have difficulty completing. A common theme across all presentations in this section recognized the increasingly tailored treatment options available for patients with colorectal cancer as a component of personalized oncology.

Dr. Chris Crane provided an overview of the Non-Colorectal Cancer studies active or being developed by NRG Oncology. Feedback was solicited on emerging concepts related to feasibility and site interest. These include novel immunotherapy interventions for curable esophageal cancer, biologic modifiers for advanced pancreatic cancer, and immunotherapy with radiation for incurable biliary cancers. The future directions for this diverse group of GI malignancies includes the testing of novel therapies, novel modalities of radiotherapy, and novel ways of overcoming treatment resistance.

Intervening on the Financial Toxicity of Cancer Care

Yousuf Zafar, MD, MHS, Associate Professor of Medicine and Public Policy at the Duke Cancer Institute was the keynote speaker for the Health Disparities Workshop on Friday, July 13th, at the NRG Oncology Semiannual Meeting. Dr. Zafar presented on the burden placed on patients as a result of the costs associated with medical care, especially in regards to cancer treatment. Dr. Zafar recommended some long-term solutions, which include policy changes to reduce unsustainable drug prices and promote innovative insurance models. He also suggested short-term or more immediate goals that could help patients in these situations.
NRG Oncology Scientific Session (continued)

locoregional recurrence of breast cancer. The results of the final overall survival analysis of an international trial (NRG-GOG 0218) evaluation bevacizumab for advanced ovarian cancer were also reported.

Other trials reviewed included, NRG-RTOG 0126, a phase III study comparing standard to dose escalated radiotherapy for patients with intermediate risk prostate cancer; the long-term results of NRG-RTOG 0236, a phase II trial on SBRT in inoperable stage I NSCLC; NRG-RTOG 9704 analysis of MLH1’s correlation to survival in patients with pancreatic cancer; and patient-reported toxicity for pelvic iMRt on NRG-RTOG 1203. Each presentation included a discussant and a question and answer segment followed the session.

NRG Oncology Gynecologic Translational Science Workshop

Disease Site Updates

Cervix
Co-Chair for Translational Science: Dmitriy Zamarin, MD
Protocol GOG 9929 is a phase I trial of sequential ipilimumab after chemoradiation for the primary treatment of patients with locally advanced cervical cancer. The trial has completed accrual and the clinical outcomes data were presented at ASCO 2017. Translational studies have now been completed on the peripheral blood collected from the patients pre- and on-therapy. Findings revealed expansion of CD4+ICOS+ and CD8+ICOS+ lymphocytes in response to chemoradiation, which persisted after administration of ipilimumab. There was in addition evidence of expansion of reactive HPV16 E6/E7 lymphocytes as well as expansion of CD4+PD-1+ and CD8+PD-1+ lymphocytes in response to chemoradiation. The latter provided a rationale for evaluation of chemoradiation in combination with PD-1/PD-L1 blockade, which will be explored in the upcoming NRG-GY017 study evaluating atezolizumab as an immune primer and in combination with chemoradiation in patients with locally advanced cervical cancer.

Ovary
Co-Chairs for Translational Science: Elizabeth Swisher, MD, and Rebecca Arend, MD
The Ovarian Committee talked about the changing landscape of upfront ovarian cancer treatment and how it would impact clinical trial design. The role of neoadjuvant therapy and its role in clinical trial design and translation research endpoints was reviewed. An interest in defining the role of HIPEC in ovarian cancer treatment led to a plan to create a subcommittee to discuss the ideal design of a HIPEC trial.

NCTN Navigator Update
Presenter: Heather A. Lankes, PhD, MPH
Since the launch of NCI’s NCTN Navigator on April 2, 2018, requests for biospecimens from many of NRG Oncology clinical trials must be submitted through Navigator. Please refer to the Navigator website for additional details, a list of available trials, and/or to begin the biospecimen request process. The Navigator Front Door Service (navigatorcontact@imsweb.com) is available to address any further questions or concerns regarding Navigator.

For biospecimen requests from trials not available in Navigator, follow the procedure outlined on the NRG Oncology Biospecimen Access webpage Prior to submitting a Feasibility Query Form, review the clinical trials from which biospecimens are being requested. NRG Oncology clinical trials (including biospecimen collections) may be reviewed on the NRG Oncology website, CTSU, and/or ClinicalTrials.gov.

Special Topic of Interest

cTNA Biospecimen Collection and Processing
Presenter: Douglas Levine, MD
Circulating tumor DNA (ctDNA) is derived from dividing and dying tumors. ctDNA has a range of applications, including cancer screening, molecular profiling, prognostication, detection of residual disease, monitoring response, and studies of clonal evolution. Most methods to measure ctDNA are focused on detecting previously known mutations at very

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NRG Oncology Gynecologic Translational Science Workshop (continued)

high sensitivity, or screening for unknown mutations at lower sensitivity. cT-DNA can be collected in EDTA tubes and processed within hours or collected in Streck tubes and stored at room temperature for up to two weeks. There is a trade-off between cost and convenience when considering which methods to use.

Work in Progress Presentation

GOG 0225
Study Chair: Cynthia Thomson, MD
GOG 0225 is a randomized trial of a diet and physical activity intervention versus health education control condition to test the hypothesis that a 24-month lifestyle intervention is associated with increased progression-free survival in women treated for stage II-IV ovarian cancer. The study has enrolled 1178 women with a recruitment goal of 1200. To date, 98% of women have consented to blood sampling and 82% have provided blood samples. These samples are being biobanked for analysis of several biomarkers, evaluating both adherence to the lifestyle intervention and biological indicators postulated to be in the causal pathway for disease progression (Glasgow Prognostic Score) or associated with comorbid disease (eg, glucose, insulin, lipids, etc.)

CTN/CRA Workshop-Educational Session

The morning session offered diverse and informative presentations ranging from NRG Oncology and Clinical Trials Support Unit (CTSU) operational updates to didactic overviews of the medical and scientific underpinnings of oncology research. NRG Oncology’s Senior Director, Kati Stoermer, shared her vision for NRG Oncology to harness the group’s passion, initiative, and depth of experience and talent to continue to pursue excellence in oncology research.

The NRG Oncology Headquarters and CTSU presentations detailed changes intended to improve data collection processes. Diana Lin reviewed updates to the AJCC staging manual and highlighted challenges related to these changes. Educational presentations on pathology and genomic profiling elucidated the foundational science that underpins the rationale for NRG Oncology research. Altogether, the workshop enhanced the skills to perform the functional components of clinical research and the knowledge to understand the rationale for these components.

The noon session focused on self-care with a Reiki therapy presentation by NRG Oncology coordinator, Judy Fannelli. Reiki therapy, an alternative stress reduction, healing, and symptom management approach, compliments the efforts of NRG Oncology to improve patients’ lives. The techniques introduced during the session are applicable to both health care providers and patients.

The afternoon educational format involved 28 content-specific round tables (seven 20-minute sessions) and provided an opportunity for attendees to ask content experts questions.

In summation, the CTN/CRA workshop was an immensely valuable educational experience that enhanced knowledge and practical skills. Presentations for the morning and lunch sessions and round table handouts are available on the NRG Oncology website in the Nurses & CRA’s tab. Login is required to view these documents.

#NRG18

Relive the NRG Oncology Semiannual Meeting on social media! Search #NRG18 to see photos and updates from the meeting.

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