NRG Oncology Semiannual Meeting
January 9-11, 2020
Marriott Marquis - Houston, Texas

Program Book
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It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Houston, Texas, January 9 - 11, 2020

NRG Oncology’s semiannual meetings seek to promote collaboration among our researchers and to provide first-rate educational sessions exploring recent advances in clinical and basic cancer research and exciting new directions of inquiry. We encourage our members to become actively engaged in the exchange of ideas and information in the establishment of criteria for rigorous review of our science, and in the educational opportunities including specific workshops convened by NRG Oncology experts.

This semiannual meeting offers an impressive agenda that includes: an enlightening symposium, general and scientific sessions, educational workshops, and committee meetings.

Meeting highlights include:

A day-long summer Symposium titled, “It’s a PARP World After All” with noted Oncologists and Scientists serving as speakers and moderators. The targeted audiences are members and non-members of the NRG research teams to include: Gynecologic Oncologists, Medical Oncologists, Radiation Oncologists, Pathologists, and other MDs engaged in oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, and other interested Allied Health professionals. The speakers will focus their presentations on the use of PARP inhibitors across solid tumor disease types. PARP inhibitors have demonstrated efficacy in ovarian, breast, prostate, and pancreatic cancer.

The use of PARP inhibitor (PARPi) therapy has ushered in a new era and dramatically changed the management of ovarian cancer as well as several different solid tumor malignancies. “It’s a PARP World After ALL” GOG Foundation Symposium provides an excellent opportunity to explore the use of PARPi in ovarian, cervical, endometrial, breast, prostate, and pancreatic cancers. The latest practice-changing clinical trial results will be provided and reviewed in context with challenging clinical practice scenarios in cancer patients treated with PARPi. This symposium activity will provide evidence-based perspectives regarding controversial topics in ovarian and breast cancer management. The information that will be provided has potential practice-changing implications that be translated into clinical arena immediately. Moreover mechanisms of resistance to PARPi as well as the latest information on combination PARPi combinations will be reviewed. Interactive case vignettes will help attendees to better identify, manage, and mitigate PARPi toxicity. Ongoing and planned pivotal clinical trials will be discussed and the future of clinical trial design in the era of PARPi therapy will be explore.

Thursday, January 9th at 8.00 am.

Protocol Support Committee will be hosting its annual “Introduction to Clinical Trials Workshop” on Thursday, January 9th beginning at 7:30 am.

The Second Annual Radiation Oncology Mini-Symposium is being held on Friday, January 10th at 8:00 am, titled “Artificial (AI) Intelligence and Machine Learning in Radiation Oncology.

The new Plenary session will feature updates from Group Chairs, followed by a scientific session on Friday, January 10, 2020 10:00 am - noon.

NRG Oncology will be holding a kick-off meeting for NRG-CC008, “A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers (SOROC)” on Friday, January 10th during the CPC Workshop at 2:30 pm. The protocol is anticipated to activate early 2020, and the session is open to all attendees.
Social Media Workshop Twitter 1 on 1 is scheduled for Saturday, January 11th 8:00 am – 9:00 am. Social media experts from the NRG Oncology Communications Committee can help you with the setup of your social media account and answer any question you have about social media use and best practices.

We are very excited about the research that will be discussed during NRG Oncology’s semiannual meeting and invite your input about how we can make future meetings as meaningful and productive as possible.

Welcome to Houston!
NRG Oncology Mission Statement

NRG Oncology seeks to improve the lives of cancer patients by conducting practice-changing multi-institutional clinical and translational research with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types.

For the Educational Objectives, we list the following:

• Inform the participants of the current state of clinical and basic oncologic research, particularly, but not exclusively as it relates to clinical trials.

• Provide participants with peer review critiques of progress (or lack of it) with the objective of self-improvement.

• Provide an opportunity to learn research administration and financial management in a cooperative group setting.

• Provide a forum for experts from diverse fields to improve research practices and patient management.

Disclosure Information

In compliance with ACCME regulations, The GOG Foundation, Inc., as the accredited provider of this activity, must ensure that anyone in a position to control the content of the educational activity has disclosed all relevant financial relationships with any commercial interest. All reported conflicts are managed by a designated official to ensure a bias-free presentation. Please see the complete disclosure list handout included with this program.
Accreditation Statement

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the Joint Providership of The GOG Foundation, Inc. and NRG Oncology.

The GOG Foundation, Inc. is accredited by the ACCME to provide Continuing Medical Education for physicians.

AMA PRA Category 1 Credits™

The GOG Foundation, Inc. designates this live activity for a maximum of 25.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CME/Certificate Instructions - NEW!

Attendees should receive a CME code for each session to be entered into the Program App, this code acknowledges your attendance.

To receive your CME certificate, you must complete the Meeting evaluation on the Program App. Evaluations must be completed by February 1, 2020. All certificates will be sent directly to you by email by the system. The sender will be jreese@gog.org.

Additional information will be available at the CME desk.

The GOG Foundation Inc. Continuing Medical Education (CME) Program Mission Statement

The purpose of The GOG Foundation, Inc. CME program is to provide and promote an infrastructure dedicated to enhancing the knowledge base of meeting participants and guests centered on the development, execution, analysis and application of GOG-supported clinical trials. To that end, the CME Program engages in these discussions member researchers and invited clinicians committed to reducing the risk and improving outcomes for women at risk for or afflicted with a gynecologic malignancy.

For questions or comments about this CME activity, please contact: Michelle N. Small, Director, Education Programs/CME Compliance of The GOG Foundation, Inc. at: msmall@gog.org.
**FINAL LISTING OF APPROVED CME CREDITS**

The following sessions/workshops have been approved to receive CME credits
Accredited by the GOG Foundation, Inc. in Houston, TX January 9-11, 2020

*AMA PRA Category 1 credits™*

<table>
<thead>
<tr>
<th>WORKSHOP AGENDAS</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
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<tbody>
<tr>
<td>Symposium – “It’s PARP World After All”</td>
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<tr>
<td><strong>WORKSHOP AGENDAS</strong></td>
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<tr>
<td>Brain Tumor workshop</td>
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<tr>
<td>Breast Cancer workshop</td>
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<tr>
<td>Breast Cancer Rare and Genetically Linked Subcommittee Workshop</td>
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<td>Canadian Members workshop</td>
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<tr>
<td>Cancer Care Delivery Research CCDR</td>
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<td>Cancer Prevention and Control workshop</td>
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<td>Cervix Cancer workshop</td>
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<tr>
<td>Gastrointestinal Cancer workshop (Not approved as of 12/16/2019, Disclosures not in)</td>
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<tr>
<td>Genitourinary Cancer workshop</td>
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<td>Gynecologic Cancer workshop</td>
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<tr>
<td>GYN Developmental Therapeutics workshop/Phase I</td>
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<tr>
<td>GYN Dev. Therapeutics/Phase I/Translational Science workshop</td>
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<td>Head and Neck Cancer workshop</td>
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<td>Immunotherapy and Immune Modulation workshop</td>
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<td>Lung Cancer workshop</td>
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<tr>
<td>Medical Oncology workshop</td>
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<tr>
<td>NRG Oncology Plenary Session</td>
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<tr>
<td>NRG Protocol Workshop G1004, G1002 and G1005</td>
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<tr>
<td>NRG Protocol Workshop: NRG BR003 and BR004</td>
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<tr>
<td>NRG Surgical Oncology workshop</td>
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<tr>
<td>Ovarian Cancer workshop</td>
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<tr>
<td>Patient Centered Outcomes Research (PCOR)</td>
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<tr>
<td>Pharmacy Subcommittee workshop</td>
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<tr>
<td>Radiation Development Therapeutics</td>
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<tr>
<td>Rare Tumor workshop</td>
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<tr>
<td>Social Media and Mobile Technology workshop</td>
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<tr>
<td>Translational Science workshop</td>
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<tr>
<td>Translational Science GYN</td>
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<tr>
<td>Translational Science Lung Cancer workshop</td>
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<td></td>
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<tr>
<td>Uterine Corpus Cancer workshop</td>
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**PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD’s**

<table>
<thead>
<tr>
<th>PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD’s</th>
<th>THURSDAY</th>
<th>FRIDAY</th>
<th>SATURDAY</th>
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</thead>
<tbody>
<tr>
<td>PSC-Introduction to Clinical Trials: Principles of Clinical Management</td>
<td>4.5</td>
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<tr>
<td>PSC Afternoon Breakout sessions</td>
<td></td>
<td>.75 for each Breakout session</td>
<td>3</td>
</tr>
<tr>
<td>PSC-Clinical Trial Nurse/Clinical Research Asoc Ed Session Roundtables</td>
<td></td>
<td></td>
<td>3.5</td>
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WHAT'S NEW?

- **CME credits**: New sign-in process for CME’s.
- **New mobile app**
- **Agenda book option**: When registering online you were asked if you would like a printed agenda book. *(Thank you to our Voting PI group for the suggestion to print less!)* If you answered no, you will not receive a printed copy when you receive your meeting badge. This question will be asked for all future registrations.
- **NRG Oncology Slide and Poster Templates** can be downloaded on the NRG Oncology website.
- **You asked! We delivered:**
  - **Protein** has been added to the general continental breakfasts located in Texan Foyer.
  - **Lactation Room** will be available to nursing mothers
- **Plenary Session**: Friday, Jan. 10th, 10am-12pm

Plenary session will replace the General Session and Scientific Session. The new format will start off with updates from the Group Chairs, followed by a scientific session. No other published meetings will be held during this time. To accommodate this change, many meetings have either shifted or moved completely. Meeting attendees should double check the agenda as standing meetings may have changed times!

- **New Meeting Registration System**: Choose "New Account Profile" when first registering. The account you created for this meeting will be used for all future meetings.
Stay up-to-date with updates and announcements from the NRG Oncology Semiannual Meeting 2020 on Twitter and Facebook.

Complimentary wifi is available for meeting attendees:
Network Login: nrgmeeting
Passcode: n1r2g345

JOIN The Conversation On Twitter: @NRGONC #NRG2020

https://www.facebook.com/nrgoncology/
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 am – 12:00 pm</td>
<td>Introduction to Clinical Trials: Principles of Clinical Trial Management</td>
<td>Texan ABC/4th Level</td>
</tr>
<tr>
<td>8:00 am – 1:45 pm</td>
<td>Imaging and Radiation Oncology Core (IROC) RT Focused Staff Meeting*</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>9:00 am – 12:00 pm</td>
<td>NRG DMC Panel A*</td>
<td>Liberty AB/2nd Level</td>
</tr>
<tr>
<td>2:00 pm – 4:00 pm</td>
<td>GYN Developmental Therapeutics/Phase 1/Translational Science Workshops</td>
<td>Texan E/4th Level</td>
</tr>
<tr>
<td>2:00 pm – 4:00 pm</td>
<td>Immunotherapy and Immune Modulation Workshop</td>
<td>Texan H/4th Level</td>
</tr>
<tr>
<td>3:00 pm – 5:00 pm</td>
<td>NRG-Harvard-Ohio State-Case Western R01 Grant Meeting*</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>4:00 pm – 5:15 pm</td>
<td>An Introduction to NRG Oncology: New Investigator Educational Session</td>
<td>Texas ABC/4th Level</td>
</tr>
<tr>
<td>4:00 pm – 5:30 pm</td>
<td>Translational Science Workshop</td>
<td>Texas FG/4th Level</td>
</tr>
<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Patient Centered Outcomes Research (PCOR) Workshop</td>
<td>Texan H/4th Level</td>
</tr>
<tr>
<td>4:30 pm – 6:30 pm</td>
<td>PSC Education &amp; Training Working Group*</td>
<td>Kingwood A/3rd Level</td>
</tr>
<tr>
<td>4:30 pm – 6:30 pm</td>
<td>PSC Mentorship Working Group*</td>
<td>Galleria/3rd Level</td>
</tr>
<tr>
<td>4:30 pm – 6:30 pm</td>
<td>PSC Protocol Review Working Group*</td>
<td>River Oaks/3rd Level</td>
</tr>
<tr>
<td>5:15 pm – 6:00 pm</td>
<td>New Investigators Mini-Reception</td>
<td>Texan ABC/4th Level</td>
</tr>
<tr>
<td>5:30 pm – 7:00 pm</td>
<td>PSC Quality Control Working Group*</td>
<td>Galveston A/2nd Level</td>
</tr>
<tr>
<td>5:30 pm – 8:00 pm</td>
<td>Translational Science Brain Cancer Subcommittee/Low-Grade Glioma Working Group</td>
<td>Sugarland/3rd Level</td>
</tr>
<tr>
<td>6:00 pm – 7:00 pm</td>
<td>Early Phase Trial Oversight Committee*</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>6:00 pm – 7:00 pm</td>
<td>Communications Committee*</td>
<td>Montrose/3rd Level</td>
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## Thursday, January 9, 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
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<tbody>
<tr>
<td>6:00 pm – 8:00 pm</td>
<td>NCORP Concept Review <em>(Invitation Only)</em></td>
<td>Hunter’s Creek/3rd Level</td>
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<tr>
<td>6:00 pm – 8:00 pm</td>
<td>NRG Oncology Japan Meeting</td>
<td>Liberty/2nd Level</td>
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<tr>
<td>6:00 pm – 8:00 pm</td>
<td>Ancillary Projects Committee*</td>
<td>Galveston B/2nd Level</td>
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# NRG Oncology Semiannual Meeting

**FINAL SCHEDULE**  
Marriott Marquis Houston  
Houston, Texas  
January 9 – 11, 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>6:30 am – 8:30 am</td>
<td>Continental Breakfast</td>
<td>Texan 4th Level</td>
</tr>
<tr>
<td>7:00 am – 5:00 pm</td>
<td>Exhibits</td>
<td>Texan 4th Level</td>
</tr>
<tr>
<td>7:00 am – 5:30 pm</td>
<td>Registration/CME/Information Desk</td>
<td>Texan 4th Level</td>
</tr>
<tr>
<td>8:00 am – 5:00 pm</td>
<td>IT Resource Room/Internet Café/Speaker Ready Room</td>
<td>Memorial 3rd Level</td>
</tr>
<tr>
<td>10:00 am – 11:00 am</td>
<td>General Coffee Break</td>
<td>Texan 4th Level</td>
</tr>
<tr>
<td>2:00 pm – 3:30 pm</td>
<td>General Coffee Break</td>
<td>Texan 4th Level</td>
</tr>
<tr>
<td>6:45 am – 9:00 am</td>
<td>Patient Advocates Meeting *</td>
<td>Galleria 3rd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>Digital Health Working Group</td>
<td>Houston 3/2nd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>GYN Cancer Committee Executive Session *</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>Local Regional Breast Cancer Subcommittee *</td>
<td>Montrose 3rd Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>Pharmacy Subcommittee</td>
<td>Hunter’s Creek 3rd Level</td>
</tr>
<tr>
<td>7:00 am – 8:30 am</td>
<td>Translational Science Breast Cancer Subcommittee</td>
<td>Texan B/4th Level</td>
</tr>
<tr>
<td>7:00 am – 9:00 am</td>
<td>Clinical Trials Nurse/Clinical Research Associate Subcommittees Combined Meeting *</td>
<td>Texan H/4th Level</td>
</tr>
<tr>
<td>7:00 am – 12:00 pm</td>
<td>GYN/RT Case Review</td>
<td>Memorial 3rd Level</td>
</tr>
<tr>
<td>7:30 am – 8:30 am</td>
<td>NRG SDMC Executive Committee *</td>
<td>Fort Bend AB 2nd Level</td>
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<tr>
<td>7:30 am – 9:30 am</td>
<td>NRG-BN006 Training Session</td>
<td>Houston 4/2nd Level</td>
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<tr>
<td>7:30 am – 9:30 am</td>
<td>Sarcoma Working Group</td>
<td>Sugarland 3rd Level</td>
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<tr>
<td>8:00 am – 9:00 am</td>
<td>Breast Cancer Rare and Genetically Linked Subcommittee Workshop</td>
<td>Houston 7/2nd Level</td>
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<tr>
<td>8:00 am – 9:00 am</td>
<td>Social Media and Mobile Technology Workshop</td>
<td>Montgomery 2/2nd Level</td>
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<tr>
<td>8:00 am – 9:00 am</td>
<td>Protocol Z10 Subcommittee</td>
<td>Montrose 3rd Level</td>
</tr>
<tr>
<td>8:00 am – 10:00 am</td>
<td>Cervix Cancer Workshop</td>
<td>Texan E/4th Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>Rare Tumor Workshop</td>
<td>Texan A/4th Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>Radiation Oncology Committee Meeting</td>
<td>Texan FG/4th Level</td>
</tr>
<tr>
<td>8:00 am – 12:00 pm</td>
<td>Pathology Workshop &amp; Review</td>
<td>Chambers 2nd Level</td>
</tr>
<tr>
<td>8:00 am – 9:30 am</td>
<td>Cancer Prevention and Control Committee Meeting</td>
<td>River Oaks 3rd Level</td>
</tr>
<tr>
<td>8:30 am – 9:30 am</td>
<td>Protocol Operations Management *</td>
<td>Kingwood A/3rd Level</td>
</tr>
<tr>
<td>9:00 am – 10:00 am</td>
<td>Member Site Accrual Best Practices</td>
<td>Texan C/4th Level</td>
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<tr>
<td>10:00 am – 12:00 pm</td>
<td>Plenary Session (Combined Scientific &amp; General Sessions)</td>
<td>Texan D/4th Level</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>Final Review of Contours from the NRG GU 2020 Nodal Atlas Update *</td>
<td>Kingwood B/3rd Level</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>GYN GTN Subcommittee</td>
<td>Texan B/4th Level</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>Older Adult Working Group</td>
<td>River Oaks 3rd Level</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>Pathology Committee</td>
<td>Chambers 2nd Level</td>
</tr>
<tr>
<td>12:00 pm – 1:00 pm</td>
<td>New Investigators Committee and Working Group *</td>
<td>Meyerland B/3rd Level</td>
</tr>
<tr>
<td>12:00 pm – 1:30 pm</td>
<td>Immunotherapy and Immune Modulation Workshop</td>
<td>Texan H/4th Level</td>
</tr>
<tr>
<td>12:00 pm – 2:00 pm</td>
<td>Neurosurgical Subcommittee</td>
<td>Harris 2nd Level</td>
</tr>
<tr>
<td>12:00 pm – 2:00 pm</td>
<td>NRG Oncology Foundation Board of Directors *</td>
<td>Hunter’s Creek 3rd Level</td>
</tr>
</tbody>
</table>

**Revised 12/16/2019**  

*Sessions for Committee Member*
# NRG Oncology Semiannual Meeting

## Final Schedule

**Marriott Marquis Houston**  
Houston, Texas  
January 9 – 11, 2020

**Revised 12/16/2019**  
*Sessions for Committee Member*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:30 pm – 2:00 pm</td>
<td>Radiation-Developmental Therapeutics Workshop</td>
<td>Houston 5-6/ 2nd Level</td>
</tr>
<tr>
<td>12:30 pm – 2:30 pm</td>
<td>Imaging Committee</td>
<td>Fort Bend AB/2nd Level</td>
</tr>
<tr>
<td>1:00 pm – 1:30 pm</td>
<td>Protocol 225 Information Session</td>
<td>Meyerland B/ 3rd Level</td>
</tr>
<tr>
<td>1:00 pm – 2:00 pm</td>
<td>NRG BR003 and NRG BR004 Workshops</td>
<td>Texan C/4th Level</td>
</tr>
<tr>
<td>1:00 pm – 2:00 pm</td>
<td>NRG-GU008 Kick-Off Session</td>
<td>Meyerland A/3rd Level</td>
</tr>
<tr>
<td>1:00 pm – 2:00 pm</td>
<td>NRG-GU1919 Team Meeting *</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>1:00 pm – 2:30 pm</td>
<td>Cancer Care Delivery Research Workshop</td>
<td>Houston 7/2nd Level</td>
</tr>
<tr>
<td>1:00 pm – 4:00 pm</td>
<td>Ovarian Cancer Workshop</td>
<td>Texan E/4th Level</td>
</tr>
<tr>
<td>1:00 pm – 4:00 pm</td>
<td>Uterine Corpus Cancer Workshop</td>
<td>Texan A/4th Level</td>
</tr>
<tr>
<td>2:00 pm – 3:00 pm</td>
<td>NRG GI004, GI002, and GI005 Workshop</td>
<td>Texan C/4th Level</td>
</tr>
<tr>
<td>2:00 pm – 3:00 pm</td>
<td>CTEP/NRG/Merck Meeting NRG-GY018/MK 3475-868 *</td>
<td>Kingwood A/3rd Level</td>
</tr>
<tr>
<td>2:00 pm – 3:00 pm</td>
<td>Translational Science Head &amp; Neck Cancer Subcommittee</td>
<td>Montgomery/2nd Level</td>
</tr>
<tr>
<td>2:00 pm – 3:30 pm</td>
<td>Publications Committee *</td>
<td>Montrose/3rd Level</td>
</tr>
<tr>
<td>2:00 pm – 4:00 pm</td>
<td>Translational Science GU Cancer Subcommittee</td>
<td>River Oaks/3rd Level</td>
</tr>
<tr>
<td>2:00 pm – 5:00 pm</td>
<td>Brain Tumor Core Committee *</td>
<td>Houston 1-2/2nd Level</td>
</tr>
<tr>
<td>2:00 pm – 6:00 pm</td>
<td>Clinical Trial Nurse/Clinical Research Associate Workshop - Educational Session</td>
<td>Texan FG/4th Level</td>
</tr>
<tr>
<td>2:30 pm – 4:30 pm</td>
<td>Medical Physics Subcommittee Meeting</td>
<td>Meyerland B/3rd Level</td>
</tr>
<tr>
<td>2:30 pm – 4:30 pm</td>
<td>Cancer Prevention and Control Workshop</td>
<td>Houston 7/2nd Level</td>
</tr>
<tr>
<td>2:30 pm – 6:00 pm</td>
<td>Breast Cancer Working Group *</td>
<td>Houston 5-6/2nd Level</td>
</tr>
<tr>
<td>3:00 pm – 4:00 pm</td>
<td>NRG-LU003 Information Session</td>
<td>Meyerland A/3rd Level</td>
</tr>
<tr>
<td>3:00 pm – 5:00 pm</td>
<td>Health Disparities Committee</td>
<td>Texan B/4th Level</td>
</tr>
<tr>
<td>3:00 pm – 6:00 pm</td>
<td>Head &amp; Neck Cancer Core Committee *</td>
<td>Houston 3/2nd Level</td>
</tr>
<tr>
<td>3:30 pm – 4:30 pm</td>
<td>NRG Oncology Human Research Committee *</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>4:00 pm – 5:00 pm</td>
<td>Radiation Oncology GYN Working Group</td>
<td>Texan A/4th Level</td>
</tr>
<tr>
<td>4:00 pm – 5:00 pm</td>
<td>VA/MTF Meeting</td>
<td>Fort Bend AB/2nd Level</td>
</tr>
<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Genitourinary Cancer Core Committee *</td>
<td>River Oaks/3rd Level</td>
</tr>
<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Translational Science GYN Workshop</td>
<td>Texan H/4th Level</td>
</tr>
<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Translational Science Lung Cancer Workshop</td>
<td>Montgomery/2nd Level</td>
</tr>
<tr>
<td>5:00 pm – 6:00 pm</td>
<td>Brain Tumor Workshop</td>
<td>Houston 1-2/2nd Level</td>
</tr>
<tr>
<td>5:00 pm – 6:00 pm</td>
<td>Veterans Radiation Oncology Consortium (VetROC)</td>
<td>Galleria/3rd Level</td>
</tr>
<tr>
<td>5:00 pm – 7:00 pm</td>
<td>Korean Gynecologic Oncology Group Meeting</td>
<td>Hunter's Creek/3rd Level</td>
</tr>
<tr>
<td>6:00 pm – 8:00 pm</td>
<td>NRG Oncology Welcome Reception</td>
<td>Texan D/4th Level</td>
</tr>
</tbody>
</table>
## Final Schedule

**NRG Oncology Semiannual Meeting**  |  Jan 2020  
---|---

### Saturday, January 11, 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>6:30 am – 8:30 am</td>
<td>Continental Breakfast</td>
<td>Texan Foyer/4th Level</td>
</tr>
<tr>
<td>7:00 am – 2:00 pm</td>
<td>Exhibits</td>
<td>Texan Foyer/4th Level</td>
</tr>
<tr>
<td>7:00 am – 3:00 pm</td>
<td>Registration/CME/Information Desk</td>
<td>Texan Foyer/4th Level</td>
</tr>
<tr>
<td>8:00 am – 1:00 pm</td>
<td>IT Resource Room/Internet Café/Speaker Ready Room</td>
<td>Memorial/3rd Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>General Coffee Break</td>
<td>Texan Foyer/4th Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>Surgical Oncology Workshop</td>
<td>Houston 5-6/2nd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>Canadian Members Meeting</td>
<td>Meyerland A/3rd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>NRG SDMC Data Management Working Group *</td>
<td>Kingwood A/3rd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>NRG SDMC Statistical Working Group *</td>
<td>Montrose/3rd Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>Medical Oncology Workshop</td>
<td>Texan C/4th Level</td>
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<tr>
<td>7:00 am – 8:30 am</td>
<td>Proton Working Group Meeting</td>
<td>Houston 1-2/2nd Level</td>
</tr>
<tr>
<td>7:00 am – 9:30 am</td>
<td>Protocol Support Committee Business Meeting *</td>
<td>Houston 3/2nd Level</td>
</tr>
<tr>
<td>7:30 am – 9:30 am</td>
<td>GI Colorectal Cancer Subcommittee *</td>
<td>Texan A/4th Level</td>
</tr>
<tr>
<td>8:00 am – 9:00 am</td>
<td>GYN Developmental Therapeutics/Phase I Workshops</td>
<td>Texan E/4th Level</td>
</tr>
<tr>
<td>8:00 am – 9:00 am</td>
<td>Twitter 101 Session</td>
<td>Meyerland B/3rd Level</td>
</tr>
<tr>
<td>8:00 am – 9:30 am</td>
<td>Safety Review Committee *</td>
<td>Kingwood B/3rd Level</td>
</tr>
<tr>
<td>8:00 am – 10:00 am</td>
<td>NCORP PI &amp; Administrators Meeting</td>
<td>Texan C/4th Level</td>
</tr>
<tr>
<td>8:00 am – 10:00 am</td>
<td>Genitourinary Cancer Workshop</td>
<td>Houston 4/2nd Level</td>
</tr>
<tr>
<td>8:00 am – 10:00 am</td>
<td>Head &amp; Neck Surgical Subcommittee</td>
<td>Houston 7/2nd Level</td>
</tr>
<tr>
<td>8:00 am – 10:00 am</td>
<td>Lung Cancer Core Committee *</td>
<td>River Oaks/3rd Level</td>
</tr>
<tr>
<td>8:30 am – 9:30 am</td>
<td>Chordoma Research Working Group *</td>
<td>Fort Bend AB/2nd Level</td>
</tr>
<tr>
<td>9:00 am – 10:00 am</td>
<td>Ovarian Cancer Workshop</td>
<td>Texan E/4th Level</td>
</tr>
<tr>
<td>9:00 am – 10:00 am</td>
<td>Cervix Cancer Workshop</td>
<td>Texan B/4th Level</td>
</tr>
<tr>
<td>9:00 am – 10:00 am</td>
<td>Uterine Corpus Cancer Workshop</td>
<td>Texan H/4th Level</td>
</tr>
<tr>
<td>9:00 am – 10:00 am</td>
<td>Quality Assurance Audit Meeting *</td>
<td>Kingwood A/3rd Level</td>
</tr>
<tr>
<td>9:00 am – 1:00 pm</td>
<td>Breast Cancer Workshop</td>
<td>Texan FG/4th Level</td>
</tr>
<tr>
<td>9:30 am – 11:30 am</td>
<td>GI Non-Colorectal Cancer Subcommittee *</td>
<td>Texan A/4th Level</td>
</tr>
<tr>
<td>10:00 am – 11:30 am</td>
<td>Membership Committee *</td>
<td>Montrose/3rd Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>Gynecologic Cancer Workshop</td>
<td>Texan E/4th Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>Lung Cancer Workshop</td>
<td>Texan 1-2/2nd Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>Head &amp; Neck Cancer Workshop</td>
<td>Houston 4/2nd Level</td>
</tr>
<tr>
<td>11:30 am – 1:00 pm</td>
<td>Gastrointestinal Cancer Workshop</td>
<td>Texan C/4th Level</td>
</tr>
<tr>
<td>12:00 pm – 1:00 pm</td>
<td>NRG-LU005 Study Update/Information Session <em>(Lunches will be provided to those who register for the session prior to December 17th)</em></td>
<td>Houston 1-2/2nd Level</td>
</tr>
<tr>
<td>12:00 pm – 1:00 pm</td>
<td>Voting Members PI Meeting *</td>
<td>Harris/2nd Level</td>
</tr>
<tr>
<td>12:30 pm – 5:00 pm</td>
<td>NRG-HN006 Surgeon Education/Training</td>
<td>Houston 4/2nd Level</td>
</tr>
</tbody>
</table>

*Sessions for Committee Member

**Revised 12/16/2019**
### Saturday, January 11, 2020

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:00 pm – 4:00 pm</td>
<td>Research Strategy Meeting *</td>
<td>Texan D/4th Level</td>
</tr>
<tr>
<td>4:00 pm – 5:30 pm</td>
<td>Executive Committee *</td>
<td>Galleria/3rd Level</td>
</tr>
</tbody>
</table>

*Sessions for Committee Member*
The Self-Service Resource Center will feature:

- Internet Access
- Email
- Printing
- Copier/Scanner

WIFI
Complimentary wifi is available for meeting attendees in all meeting rooms.

Network SSID: nrgmeeting
Passcode: n1r2g345

To email from the Resource Center, make sure you have access to Web-based email such as Yahoo Mail, Gmail, Outlook Web Access, or other proprietary Web-based mail services. Ask your network administrator or local computer support if you have Web-based mail access. You may contact support@nrgoncology.org prior to the meeting for more information.
NRG Oncology Translational Science Workshop

Held at the NRG Oncology January 2020 Semiannual Meeting
Thursday, January 9, 2020, 4:00-5:30pm
Room: Texan FG
Marriott Marquis - Houston, Texas

Session Speakers:

David Fuller, MD, PhD
MD Anderson Cancer Center
“Imaging & Informatics for Big Data in Multi-Site Trials: Innovation & Infrastructure”

Meenakshi Anurag
Baylor College of Medicine
“High Immune Tolerance Associates with Poor Clinical Outcomes in Liminal Breast Cancer”

Leisha Emens, MD, PhD
UPMC Hillman Cancer Center
“Biomarker-Driven Patient Selection for Breast Cancer Immunotherapy”

Program Co-Chairs:

Michael Birrer, MD, PhD
University of Arkansas for Medical Sciences

Adam Dicker, MD, PhD, FASTRO
Thomas Jefferson University

Matthew Ellis, MB, BCHIR, PhD
Baylor College of Medicine
NRG Oncology Digital Health Workshop

Held at the NRG Oncology January 2020 Semiannual Meeting
Friday, January 10, 2020, 7:00-8:00am
Room: Houston 3
Marriott Marquis - Houston, Texas

Aimed to help provide a conceptual framework for better mechanistic understanding of the pathways by which digital tools can impact cancer care.

Session Speakers:

Colin Carpenter, PhD
CEO of Siris Medical, Inc.
“Accelerating the prior authorization process with Siris - Artificial Intelligence”

Benjamin Kann, MD
Dana Farber Cancer Institute
“Deep Learning for Identification of Extranodal Extension in Head and Neck Cancer: The Path to Clinical Integration”

Benjamin Smith, MD & Stephen Grant, MD
MD Anderson Cancer Center
“Experience with user-centered design and implementation of an oncology-specific EHR”

Program Co-Chairs:

Adam Dicker, MD, PhD, FASTRO
Thomas Jefferson University

Sanjay Aneja, MD
Yale School of Medicine
NRG Oncology Social Media Workshop

Held at the NRG Oncology January 2020 Semiannual Meeting
Friday, January 10, 2020, 8:00-9:00am
Room: Montgomery AB
Marriott Marquis - Houston, Texas

Session Speakers:

Clifford Robinson, MD
Washington University School of Medicine in St. Louis
“Hashtag Oncology and Twitter for Beginners”
@SBRT_CR

Deanna Teoh, MD, MS
University of Minnesota
“The Doctor Is In: Engagement Through Social Media Platforms”
@DeannaTeoh

Dee Sparacio, MS
Kaleidoscope of Hope Ovarian Cancer Foundation, Women of Teal Blog
“Benefits and Support of Twitter Cancer Communities”
@WomenofTeal

Session Chairs:

Rebecca Previs, MD
Duke University
NRG Oncology Communications Committee Member
@BeccaPrevisMD

Thomas Julian, MD
Allegheny Health Network
NRG Oncology Communications Committee Chair
@TBJulianMD

#NRG2020 @NRGOnc
Social Media and Mobile Technology Workshop

Date: Friday, January 10, 2020
Start and End Time: 8:00 am to 9:00 am (CST)
Chair: Rebecca Previs, MD

Learning Objectives:
Following this activity, participants will be better able to:

1. Recognize the value that social media engagement may provide for oncology professionals, patients and policy.
2. Appreciate the different tools available via social media to reach an intended audience.
3. Recognize the potential benefits to professional development including clinical research of social media.
4. Understand how patients use social media and what researchers/physicians can learn from their patients from social media.

WORKSHOP AGENDA

A. 8:00 – 8:05 Welcome and Introduction Thomas Julian, MD & Rebecca Previs, MD
B. 8:05 – 8:20 Hashtag oncology and twitter for beginners Clifford Robinson, MD
C. 8:20 – 8:35 The doctor is in: engagement through social media platforms Deanna Teoh, MD
D. 8:35 – 8:50 Social media benefits and advocacy, a patient perspective Dee Sparacio, MS

QUESTIONS / DISCUSSION

There will be approximately ten minutes designated at the end for a question and answer session with the audience and speaker panel.

SURVEY

Please take a few minutes to complete the survey provided so that we may continue to improve.

SUPPLEMENTAL SESSIONS:

Please see the NRG schedule of Social Media Workshop 1-on-1s available during the meeting. This 1:1 workshop is a walk-in clinic to help the new or beginning user set up their accounts, obtain personalized instruction or receive help in navigating the apps and processes. No question is a stupid question.
NRG Oncology Plenary Session

NRG Oncology January 2020 Semiannual Meeting
Friday, January 10, 2020, 10:00am-12:00pm
Room: Texan D  -  Marriott Marquis - Houston, Texas

Session Speakers:

Samir N. Khleif, MD
Georgetown University
“Overcoming Immune Resistance, the Next Frontier”

Kristin Higgins, MD
Emory University

Ramez N. Eskander, MD
University of California, San Diego
“NRG-GY018: A phase III randomized, placebo-controlled study of pembrolizumab (MK-3475, NSC #776864) in addition to paclitaxel and carboplatin for measurable stage III or IVA, stage IVB OR recurrent endometrial cancer”

Jarushka Naidoo, MBBCh
Johns Hopkins University
“Immune-related Adverse Events: Innovation and Infrastructure”

Group Chairs & NCORP PI:

Walter J. Curran, Jr., MD
Emory University
“Outstanding Publications Awards & Leadership Recognition”

Robert S. Mannel, MD
The University of Oklahoma
Moderator

Norman Wolmark, MD
UPMC Hillman Cancer Center
“Bernard Fisher, MD Tribute”

Deborah W. Bruner, RN, PhD
Emory University
NRG NCORP Research Base PI
NRG Oncology Plenary Session

Date: Friday, January 10, 2020
Start and End Time: 10:00 am – 12:00 pm

Chairs: Walter J Curran, Jr., MD; Robert S Mannel, MD; Norman Wolmark, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Identify the basic biologic concept driving the immunotherapeutic approaches in relevant diseases and pathologies.
2. Understand the state of the art position of immunotherapy including immunotherapy resistance and overcoming the resistance in specific immune modulatory approaches, single agents or in combinations including immune modulators and standard therapy.
3. Discuss the future directions of the field.

WORKSHOP AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00 – 10:30 am</td>
<td>Welcome Outstanding Publications Awards Leadership recognition?</td>
<td>Walter J Curran, Jr., MD</td>
</tr>
<tr>
<td>10:00 – 10:30 am</td>
<td>NRG NCORP Research Base Report</td>
<td>Deborah W. Bruner, RN, PhD</td>
</tr>
<tr>
<td>10:30 – 10:50 am</td>
<td>Bernard Fisher, MD Tribute</td>
<td>Norman Wolmark, MD</td>
</tr>
<tr>
<td>10:50 am – Noon</td>
<td>Moderator</td>
<td>Robert S Mannel, MD</td>
</tr>
<tr>
<td>10:50 – 11:10 am</td>
<td>Overcoming Immune Resistance, the Next Frontier</td>
<td>Samir N Khrief, MD</td>
</tr>
<tr>
<td>11:20 – 11:30 am</td>
<td>NRG-GY018: A phase III randomized, placebocontrolled study of pembrolizumab (MK-3475, NSC #776864) in addition to paclitaxel and arboplatin for measurable stage III or IVA, stage IVB OR recurrent endometrial cancer”</td>
<td>Ramez N Eskander, MD</td>
</tr>
<tr>
<td>11:30 –11:50</td>
<td>Immune-related Adverse Events: Innovation &amp; infrastructure</td>
<td>Jarushka Naidoo, MBBCCh</td>
</tr>
</tbody>
</table>
NRG Oncology Twitter 1-on-1

Held at the NRG Oncology January 2020 Semiannual Meeting
Saturday, January 11, 2020, 8:00-9:00am
Room: Meyerland B
Marriott Marquis - Houston, Texas

Join us during two special sessions at the NRG Oncology Semiannual Meeting where social media experts from the NRG Oncology Communications Committee can help you with the setup of your social media account and answer any questions you have about social media use and best practices.

Rebecca Previs, MD
Duke University

Michael Cowher, MD
West Virginia University

Michelle Shepard
NRG Oncology

Angela LaPenta
NRG Oncology

Jon Kiddy
Roswell Park Comprehensive Cancer Center
Join us at the
Welcome Reception

January 10, 2020
6 pm - 8 pm
Texan D - 4th Level
Brain Tumor Workshop

Date: Jan 10 2020
Chair: Minesh P. Mehta, MD
Co-Chairs: Mark Gilbert, MD; Michael Vogelbaum, MD, PhD; Arnab Chakravarti, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Recognize critical aspects of developing and conducting a clinical trial in brain tumor therapy research in a cooperative group setting.
2. Identify, describe, and discuss the design and status of new clinical trials being planned and launched by the NRG on brain tumors, to enable potential contribution to protocol design vetting and/or effective patient enrollment in newly-launched studies.
3. Identify and describe the status of ongoing clinical trials being conducted by the NRG on brain tumors, to enable effective patient enrollment in and treatment on NRG trials, and proper collection, submission and/or evaluation of the required patient data.
4. Identify, describe, and analyze aspects of ongoing NRG clinical trials on brain tumors which are in need of special support and improvement, to enable effective patient enrollment in and treatment on NRG trials, and proper collection, submission and/or evaluation of the required patient data.
5. Identify and describe the results and publication status of brain tumor clinical trials recently completed by the NRG, so they can make informed decisions based on the state of the science regarding patient treatment, and they can relay study results to patients treated on these trials.
6. Identify and describe new forms of radiotherapy delivery and their use in NRG brain tumor trials.
7. Identify and describe systemic therapies, including chemotherapeutical drugs, hormonal strategies, biologic agents, and new classes of targeted therapies that may be used in conjunction with radiation therapy in brain tumor treatment, and the effectiveness of those agents as demonstrated in NRG clinical trials.
8. Identify and describe new developments in biologic and imaging science that can be used in translational research strategies to identify patient subgroups at risk for failure with existing treatments and identify new approaches for these brain tumor patients.

AGENDA:

1. Ongoing Studies:

<table>
<thead>
<tr>
<th>STUDY</th>
<th>NAME</th>
<th>DX</th>
<th>START</th>
<th>N</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BN 001</td>
<td>Hypofractionated Dose escalated Photon IMRT or PBT vs Conventional Photon Irradiation with Concomittant and Adjuvant Temozolomide</td>
<td>nGBM</td>
<td>10/14</td>
<td>Photon: 302/288; 41/30 for advanced imaging; Proton: 188/288</td>
</tr>
<tr>
<td>2</td>
<td>BN 003</td>
<td>Meningioma RT vs Obs</td>
<td>Menin</td>
<td>6/17</td>
<td>68/133</td>
</tr>
<tr>
<td>3</td>
<td>BN 005</td>
<td>LGG Photons vs Protons</td>
<td>LGG</td>
<td>8/17</td>
<td>25/120</td>
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<tr>
<td>4</td>
<td>CC 003</td>
<td>Phase II/III PCI WBRT +/- HA</td>
<td>SCLC PCI</td>
<td>12/15</td>
<td>172/172 and 7/132</td>
</tr>
<tr>
<td>STUDY</td>
<td>NAME</td>
<td>DX</td>
<td>START</td>
<td>N</td>
<td>COMMENTS</td>
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<tr>
<td>5</td>
<td>1071</td>
<td>NCCTG N0577/Endorsed Study: Phase III CODEL PFS endpoint. RT/PCV vs RT/TMZ, NI P3 study</td>
<td>G2/3 Glios</td>
<td>9/09</td>
<td>172/360</td>
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<td>6</td>
<td>CCTG CE.7</td>
<td>SRS vs. HA-WBRT</td>
<td>BM</td>
<td>11/206</td>
<td>Roberge/Gondi</td>
</tr>
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<td>7</td>
<td>Alliance A071401</td>
<td>Meningioma targeted agents, 3 arms (SMO, AKT, NF2)</td>
<td>Menin</td>
<td>8/15</td>
<td>40/56</td>
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<td>8</td>
<td>Alliance A071601</td>
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<td>Cranio</td>
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<td>9</td>
<td>Alliance A071801</td>
<td>Phase III SRS vs. SRT</td>
<td>Postop BM</td>
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<td>Brown</td>
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<tr>
<td>10.</td>
<td>EAF151</td>
<td>Imaging</td>
<td>GBM</td>
<td>43/165</td>
<td>Tsien</td>
</tr>
</tbody>
</table>

2. Closed Studies: 1119 closed after reaching accrual of 143/143.

3. Studies Activating soon:

<table>
<thead>
<tr>
<th>STUDY</th>
<th>NAME</th>
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<th>COMMENTS</th>
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<tr>
<td>1</td>
<td>BN 006</td>
<td>Phase II/III Toca511</td>
<td>GBM</td>
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<td>2.</td>
<td>BN 007</td>
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<td>3.</td>
<td>BN 008</td>
<td>ONC 201 for H3K27M Glioma</td>
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Breast Cancer Workshop Agenda

Date: Saturday, January 11, 2020
Start and End Time: 9:00 am – 12:00 pm
Chair: Eleftherios Mamounas, MD
Co-Chairs: Julia White, MD; Charles Geyer, MD; Matthew Ellis, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Identify and describe the design and status of new breast cancer clinical trials.
2. Identify and describe the status of ongoing breast cancer clinical trials.
3. Identify and describe new forms of radiotherapy delivery and their use in breast cancer trials.
4. Identify and describe systemic therapies, including chemotherapeutic drugs, hormonal strategies, biologic agents, new classes of targeted therapies, and immunotherapy that may be used in breast cancer treatment clinical trials.

WORKSHOP AGENDA

9:00 – 9:20 Welcome Norman Wolmark, MD
9:20 – 9:50 Report from the Breast Working Group Meeting Eleftherios Mamounas, MD Julia White, MD
9:50 – 10:50 SABCS Update
   NSABP B-42 10-Year Update Eleftherios Mamounas, MD
   BR005: Results of Primary Analysis Mark Basik, MD
10:50 – 11:05 NRG BR007 A Phase III Clinical Trial to Evaluate Omission of Post Lumpectomy Breast Radiation in Node-Negative Hormone Sensitive Breast Cancer with a Low Oncotype Recurrence Score Julie White, MD
11:05 – 11:15 NRG BR002 A Phase IIIR/III Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer Steve Chmura, MD, PhD
11:15 – 11:45 Immunotherapy Trials

**NRG BR004** A Randomized Phase III Trial of Paclitaxel/ Trastuzumab/ Pertuzumab/Placebo Compared to Paclitaxel/ Trastuzumab/ Pertuzumab/Atezolizumab in First Line HER2-Positive Metastatic Breast Cancer  
Charles Geyer, Jr., MD

**NSABP-59/GBG 96** A Randomized, Double-Blind, Phase III Clinical Trial of Neoadjuvant Chemotherapy with Atezolizumab or Placebo in Patients with Triple-Negative Breast Cancer Followed by Adjuvant Continuation of Atezolizumab or Placebo  

**NRG BR006** Phase III Trial to Evaluate Adjuvant Therapy of Pembrolizumab for TNBC with Residual Invasive Cancer or Positive Lymph Nodes After Neoadjuvant Chemotherapy  
Eleftherios Mamounas, MD

11:45 – 12:00

**NRG BR003** A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Weekly Carboplatin in Women with Node-Positive or High-Risk Node-Negative Triple Negative Invasive Breast Cancer  
Vicente Valero, MD
Breast Cancer Rare and Genetically Linked Subcommittee Workshop

Date: Friday, January 10, 2020
Time: 8:00 am – 9:00 pm
Chairs: Karen Daily, DO, Alexandra Thomas, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Identify and describe opportunities for trial concept development in rare and genetically-linked breast cancer.
2. Describe the association between NF1 and breast cancer as well as related therapeutic approaches.
3. Refine clinical trial design in Phyllodes tumors and indolent rare breast tumors.

WORKSHOP AGENDA

8:00 - 8:05  BR1901 (Metaplastic) Update  Alexandra Thomas, MD
8:05 - 8:35  NF1 and Breast Cancer  Matthew Ellis, MB BChir, PhD
8:35 -8:45  Phyllodes/Indolent Rare Breast Tumors Concept  Karen Daily, DO
Simona Shaitelmann, MD
8:45 –9:00  Committee Discussion  Alexandra Thomas, MD
Karen Daily, DO
- New trial proposals
- July 2020 meeting speaker suggestions

Date: Friday, January 10, 2020
Start and End Time: 1:00 pm – 2:00 pm

Learning Objectives
Following this activity, participants will be better able to:

1. Discuss the study design and key inclusion criteria of the clinical trials.
2. Discuss the clinical logistics of the clinical trials.

WORKSHOP AGENDA

1:00-1:15 Overview of NRG-BR004 Priya Rastogi, MD
A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer

1:15-1:30 Clinical Logistics Mary Pat Matisko, RN, BSN

1:30-1:40 Overview of NRG-BR003 Kristen Kotsko, RN, BSN
A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel With or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Breast Cancer

1:40-1:50 Clinical Logistics Kristen Kotsko RN, BSN

1:50-1:55 Questions/Discussion

1:55-2:00 Evaluation
Cancer Prevention and Control Workshop

Date: Friday, January 10, 2020
Start and End Time: 2:30 pm – 4:30 pm
Chairs: Lisa Kachnic, MD; Douglas Levine, MD
Vice Chairs: Deb Barton, PhD; Julie Bauman, MD

NRG CPC Committee Workshop

Learning Objectives
Following this activity, participants will be better able to:
1. Discuss proposed and ongoing NRG clinical trials on cancer prevention and control in each of the primary disease sites
2. Discuss proposed and ongoing NRG clinical trials on prevention and control in each of the four disciplines (disparities, chemoprevention, survivorship, and biomarkers and early detection)
3. Discuss multi-disciplinary aspects of ongoing and proposed clinical trials in each of the primary disease sites
4. Discuss promising translational research objectives and priorities for future clinical trials
5. Identify and prioritize areas of unmet need in cancer prevention research in each of the primary disease sites
6. Apply standards and procedures required to design, submit, and conduct a research protocol for support by the NRG

A. NRG-CC008 Kick off meeting – Douglas Levine, MD
B. Introduction & Review of Committee Aims

C. Review of Open Studies:
   - GOG 0278: Before/after Non-radical Surgery Physical Function and QOL (A. Covens)
   - NRG-CC003: Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC (V. Gondi), temporarily closed for analysis
   - NRG-CC004: Phase II Double Blind Dose Finding Trial of Bupropion vs. Placebo for Sexual Desire in Women with Breast or Gynecologic Cancer (D. Barton)
   - S0820: A Double Blind Placebo-Controlled Trial of Efornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III – Preventing Adenomas of the Colon with Efornithine and Sulindac (PACES) (J. Dorth, NRG Study Champion)
   - A211401: Reducing Surgical Complication in Newly Diagnosed Lung Cancer Patients Who Smoke (S. Lo, NRG Study Champion)
   - EA1151: Tomosynthesis Mammographic Imaging Screening Trial (TMIST) (E. Pisano)

D. Review of Approved Concepts & Protocols in Development:
   - NRG-CC005: FORTE – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (R. Schoen)
   - NRG-CC1928: Utility of Gonadotropin-releasing Hormone Agonists (GnRHa) to Protect Ovarian Reserve for Women Undergoing Chemotherapy (H. Burks)
   - Surgery and Chemotherapy vs. Chemotherapy Alone as Primary Treatment for Older Women with Advanced Staged Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Carcinomas (A. Ahmed)
   - NRG-CC1974: Stereotactic Radiosurgery (SRS) Versus Hippocampal-avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer (V. Gondi, C. Rusthoven)
   - Impact of Sentinel Lymph Node Mapping on Lymphedema Associated Impairment of Health Related Quality of Life in Endometrial Cancer (E. Tanner)

E. Other Updates
   - C. Xiao and K. Sturgeon – Pilot project update/report
Cancer Care Delivery Research (CCDR) Workshop Agenda

Date: Friday, January 10, 2020
Start and End Time: 1:00pm – 2:30pm
Co-Chair: Mary Cooley, PhD, RN
Co-Chair: Matthew F. Hudson, PhD, MPH
Call-in number: 1-866-670-5102, Passcode: 374778#

Learning Objectives
Following this activity, participants will be better able to:
1. Discuss proposed and ongoing NRG cancer care delivery research trials.
2. Discuss proposed and ongoing NRG cancer care delivery research trials and cross-cutting aims with disparities.
3. Identify and prioritize areas of unmet need in cancer care delivery research
4. Apply procedures required to design, submit, and implement a research protocol for support by the NRG

WORKSHOP AGENDA

Session I

A. Welcome and Committee Updates/Information
   SPEAKERS
   Mary Cooley, PhD; Matthew Hudson, PhD

B. Emerging Concepts
   SPEAKERS
   Mary Cooley, PhD; Matthew Hudson, PhD

C. Update on CCDR Pilot Awards
   a. PROTECT: Patient Reported Outcomes to Enhance Care on Treatment
      SPEAKER
      Alexi Wright, MD
   b. Physical Activity Monitoring to Predict Hospitalization in Advanced Cancer Patients
      SPEAKER
      Nitin Ohri, MD
   c. Rurality, neighborhood socioeconomic and environmental deprivation and patient-reported outcomes for men with cancer in RTOG 0415
      SPEAKER
      Jinbing Bai, PhD, MSN, RN

D. NCI CCDR updates
   SPEAKER
   Kate Castro, RN & Ann Geiger, MPH, PhD

E. Discuss symposium for the July meeting related to CCDR research; preparing applications from concept to implementation.
   SPEAKER
   Mary Cooley, PhD

F. NRG-CC007CD: “Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy” Update
   SPEAKER
   Ron Chen, MD, MPH

QUESTIONS / DISCUSSION
GYN Developmental Therapeutics/Phase I/Translational Science Workshop

Date: Thursday, January 9, 2020
Start and End Time: 2:00 PM – 4:00 PM
Chairs: Roisin O’Cearbhaill, MD (Developmental Therapeutics)
Michael Birrer, MD, PhD (Translational Science)
Translational Research Chair: Panagiotis Konstantinopoulos, MD, PhD (Developmental Therapeutics)
Co-Chairs: Floor Backes, MD (Phase II), Russell Schilder, MD (Phase I), Stephanie Gaillard, MD, PhD (Phase I)

Learning Objectives:
Following this activity, participants will be better able to:
1. Participants will become familiar with current status of translational research projects involving phase I and II studies that are under development or activated for accrual.
2. New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.
3. Participants will become familiar with the LOI Submission
4. Participants will become familiar ComboMATCH Trial
5. Recommendations for action by the GYN Developmental Therapeutics committee will be summarized. ATCH study.

WORKSHOP AGENDA
Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

Discussion Topic - Current priorities of the Committee
2:00 PM – 2:05 PM Introduction, Drs. O’Cearbhaill and Birrer. Welcome. Review of opportunities for new investigators.

2:05 PM – 2:10 PM Update on concepts from last meeting, Dr Backes: PI1915 Dr. Moxley, DT1951 Hensley, DT 1959 Hensley, DT 1953 Mahdi, DT1955 Geller, DT 1958 Gaillard, PI1966 Simpkins.

2:10 PM – 2:25 PM How to write a successful LOI, Charles Kunos, MD, PhD, Medical Officer and Coordinator, Investigational Therapeutics & Radiation, Investigational Drug Branch, CTEP

2:25 PM – 3:50 PM Review of new concepts
• 5-minute presentation of concept (by proposing investigator)
• Review of concepts

3:50 PM – 4:00 PM ComboMATCH study and discussion by committee of potential concepts, Dr. O’Cearbhaill (NRG Representative for the ComboMATCH study).

Concepts Approved from last meeting:
- **DT1951** Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Martee Hensley)
- **DT1953** Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ uterine serous or clear cell carcinomas and in HER2+ ovarian cancer (Haider Mahdi)
- **DT1955** A Phase II study of N-803 and Durvalumab in recurrent epithelial ovarian, fallopian tube and primary peritoneal cancer. (Geller) IIT to be conducted; larger trial may be reconsidered for NRG later.
- **DT1958** Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Stephanie Gaillard)
- **DT1959** Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Martee Hensley)
- **PI1966** A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Simpkins)
New Concepts:

QUESTIONS / DISCUSSION:

- **CV2005**: A Phase II Study of Combined chemo-immunotherapy with cisplatin-pembrolizumab and radiation for unresectable vulvar squamous cell carcinoma (Olapado Yeku)
- **DT2007**: A multicohort single-arm trial of DS-8201a, an anti-HER2 antibody-drug conjugate incorporating a DNA topoisomerase I inhibitor in patients with HER2-positive endometrial cancer (Kosei Hasegawa)
- **DT2010**: Phase II study of dasatinib in recurrent low grade endometrial stromal sarcoma (Lilian Gien)
- **DT2013**: CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corrine Doll)
- **OV2008**: A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)
- **OV2011**: Randomized Phase II trial comparing bevacizumab/abemaciclib versus bevacizumab/placebo for maintenance therapy in homologous recombination proficient ovarian cancer patients after first or second platinum sensitive recurrence (Camille Gunderson)
- **OV2015**: Randomized Phase II of Neoadjuvant Paclitaxel /Carboplatin +/- Bevacizumab versus Neoadjuvant Paclitaxel/Carboplatin + AVB500 +/- Bevacizumab in Ovarian, Tubal, Peritoneal carcinoma (Katherine Fuh)
- **PI2014**: A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)
- **UC1963**: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)
- **UC2009**: A Phase II Trial of Sapanisertib and Letrozole in Advanced, Recurrent, or Metastatic Endometrioid Endometrial Cancer (Sara Bouberhan)
Learning Objectives:
Following this activity, participants will be better able to:

1. Participants will become familiar with the current status of phase I and phase II studies that are under development and activated for accrual.
2. Participants will become familiar with the Phase I Membership application and the Phase I Program Procedure Manual.
3. Immune Therapy and Immune Modulation workshop will present an update from Thursday, July 18 and plan for integration and prioritization.
4. Integration and prioritization of studies will be reviewed and reference to Cervix/Vulva Cancer, Ovarian Cancer and Uterine Corpus Cancer workshops and the Translational Science workshop.
5. New phase I concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.

Review of Phase I Studies (Active, Under Development, and New Concepts):

8:00 AM - 9:00 AM  Russell Schilder, MD (Phase I); Stephanie Gaillard, MD, PhD (Phase I)
- Active
- Studies under development
- Closed studies
- New concepts: 5-minute presentation of concept (by proposing investigator)
- Review of concepts
- Discussion of Phase I Membership application and the Phase I Program Procedure Manual.

Review of Phase II Studies (Active, Under Development, and New Concepts):
8:45 AM – 9:00 AM  Floor Backes, MD
- Active
- Studies under development
- Closed studies
- New concepts

List of Studies

Under development:
- **NRG-GY022** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Taylor/ Beumer)
- **PI1915** A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Moxley)
- **NRG- GY021** A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Adams) safety lead-in
- **PI1966**, A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Simpkins)
• DT1959, Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Hensley)
• DT1958, Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Gaillard)
• DT1953, Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ serous endometrial cancers (Mahdi)
• DT1951, Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Hensley)

Active Phase I Studies (including safety lead-ins):
Cervical Cancer Studies:
• NRG-GY017 Anti PD-L1 (atezolizumab) as an immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer. (Jyoti Mayadev/Russell Schilder/Dmitriy Zamarin) Safety lead-in

Active Phase II Studies (including safety lead-ins):
Ovarian Cancer and Endometrial cancer studies:
• NRG-GY014 A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid/clear cell carcinoma of the ovary, and recurrent endometrioid endometrial adenocarcinoma (R Eskander) CTEP CRDL LOI. First stage completed accrual August 2019

Ovarian Cancer Studies (prior safety lead-in):
• NRG-GY007 A phase I/II study of ruxolitinib with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (R Burger) Phase II Active for accrual
• NRG-GY009 (PTMA/CRDL) A randomized, phase II/III study of pegylated liposomal doxorubicin and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab in platinum resistant ovarian cancer (R O’Cearbhaill) Phase II completed accrual May 2019
• NRG-GY012, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay) Prior DT safety review

Closed DT/Phase I studies:
Cervical Cancer
• 9926 A phase I evaluation of extended field radiation therapy with concomitant cisplatin chemotherapy followed by paclitaxel and carboplatin chemotherapy in women with cervical carcinoma metastatic to the para-aortic lymph nodes (C Boardman) Gyn Onc 2018
• 9929 A phase I trial of sequential ipilimumab after chemoradiation for the primary treatment of patients with locally advanced cervical cancer stages IB2/IIA with positive para-aortic lymph nodes only and stage IIB/IIIB/IVA with positive lymph nodes (J Mayadev/R Schilder) CTEP/CRDL. ASCO 2017 JAMA Onc 2019
• NRG-GY002 A phase II evaluation of nivolumab, a fully human antibody against PD-1, in the treatment of persistent or recurrent cervical cancer (A Santin) ASCO 2018 (A Santin) manuscript submitted
• 265 A phase II evaluation of ADXS11-001 in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix (W Huh) Safety lead in performed by Phase I subcommittee - completed. ASCO 2016 (Stage 1 of Phase II). SGO 2017
Endometrial Cancer Studies:
• **2290** A randomized phase II study with a safety lead-in to assess the antitumor efficacy of the MEK inhibitor trametinib alone or in combination with GSK2141795, an AKT inhibitor, in patients with recurrent or persistent endometrial cancer (S Westin) Closed after safety lead in. CTEP/CRDL. SGO 2016. Gyn Onc 2019
• **NRG-GY011**, A Randomized Surgical Window Pilot Investigation of the Relationship of Short Term Medroxyprogesterone Acetate Compared to Medroxyprogesterone Acetate Plus Entinostat on the Morphologic, Biochemical, and Molecular Changes in Primary Endometrioid Adenocarcinoma of the Uterine Corpus (Linda Duska)
• **NRG-GY008** A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA mutations (A Santin) manuscript submitted

Ovarian Cancer Studies
• **9923** A phase I study of intravenous carboplatin/paclitaxel or intravenous and intraperitoneal paclitaxel/cisplatin in combination with continuous or intermittent, CTEP supplied agent ABT-888 and CTEP supplied agent bevacizumab, in newly diagnosed patients with previously untreated epithelial ovarian, fallopian tube or primary peritoneal cancer (K Moore) CTEP/CRDL. ASCO 2015, Gyn Onc 2019
• **186G** A phase II randomized, double-blinded evaluation of oral everolimus (RAD001) plus bevacizumab vs. oral placebo plus bevacizumab in the treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (W Tew). No TR specimens collected. ASCO 2014 Gyn Onc 2018
• **186K** A randomized phase II study of cabozantinib versus weekly paclitaxel in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (U Matulonis). TR: BIQSFP, MET IHC – Center for Molecular Oncologic Pathology (CMOP) DFCI. Gyn Onc 2019
• **255** A phase II randomized, double-blind trial of a polyvalent vaccine-KLH conjugate + OPT-821 versus OPT-821 in patients with epithelial ovarian, fallopian tube, or peritoneal cancer who are in second or third complete remission (P Sabbatini). TR completed. ASCO 2016. SGO 2017. ESGO 2017. Gyn Onc 2019
• **NRG-GY003** Phase II randomized trial of nivolumab with or without ipilimumab in patients with persistent or recurrent ovarian, primary peritoneal or fallopian tube cancer (B Burger) IGCS 2018

QUESTIONS/DISCUSSION/EVALUATION
Gastrointestinal Cancer Committee Workshop Agenda

Date: Saturday, January 11, 2020
Start and End Time: 1:00 pm – 3:00 pm
Colorectal Chair: Thomas George, MD, FACP
Colorectal Co-Chair: Scott Kopetz, MD, PhD
Non-colorectal Chair: Christopher Crane, MD
Non-colorectal Co-Chair: David Ilson, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Appreciate the eligibility criteria and hypotheses being explored in current and upcoming GI Onc clinical trials

WORKSHOP AGENDA

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<th>Time</th>
<th>Discussion/Study Information</th>
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<tr>
<td>1:00PM</td>
<td>Introduction and Opening Remarks</td>
<td>Christopher Crane, MD Thomas George, MD</td>
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<td>1:05PM</td>
<td>CRC SUBCOMMITTEE – Review of Upcoming Trials</td>
<td>Thomas George, MD</td>
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<td>1:15PM</td>
<td>Active CRC Studies</td>
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<td>NRG-G1002 TNT Trial</td>
<td>Thomas George, MD</td>
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<td>S0820 (PACES) Efornithine &amp; Sulindac for polyp prevention after CRC</td>
<td>Jenny Dorth, MD</td>
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<td>NRG-G1005 cfDNA as a decision tool for stage II colon cancer treatment</td>
<td>Kyle Van Morris, MD</td>
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<td>A021502 (ATOMIC) MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab</td>
<td>Asha Dhanarajan, MD</td>
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<td>NRG-G1004/S1610 (COMMIT) MSI-H mCRC 1L Immunotherapy Study</td>
<td>Caio Rocha Lima, MD</td>
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<td>SOLARIS Vitamin D supplementation in untreated mCRC</td>
<td>Christina Wu, MD</td>
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<td>S1613 HER2 Amplified mCRC Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan</td>
<td>Marwan Fakih, MD</td>
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<td>NCTN Portfolio of NET Studies</td>
<td>Heloisa Soares, MD Walid Shaib, MD</td>
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<td>2:00PM</td>
<td>NON-CRC SUBCOMMITTEE</td>
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<td>RTOG 1112 Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma</td>
<td>Laura Dawson, MD</td>
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<td>NRG GI003 Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma</td>
<td>Ted Hong, MD</td>
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<td>EA2165 Nivolumab after Combined Modality Therapy in Treating Patients with High Risk Stage II-IIIB Anal Cancer</td>
<td>Paul Romesser, MD</td>
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<tr>
<td>Trial Code</td>
<td>Description</td>
<td>Principal Investigator</td>
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<td>S1815</td>
<td>A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers</td>
<td>Khalid Matin, MD</td>
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<td></td>
<td><strong>Review of Upcoming Trials</strong></td>
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<tr>
<td>NRG GI1426</td>
<td>Phase III Randomized Trial of Protons vs. Photons for Esophageal Carcinoma</td>
<td>Steven Lin, MD</td>
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<td>NRG 1824</td>
<td>Phase I trial of chemoradiation and telomolysin for inoperable esophageal and GEJ ACA</td>
<td>Geoff Ku, MD</td>
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<tr>
<td>NRG GI1976</td>
<td>GI1976 (1862) G.Ku RPh II study of tislelizumab and chemoradiation followed by adjuvant tislelizumab in PET chemotherapy locally advanced esophageal squamous</td>
<td>Geoff Ku, MD</td>
</tr>
<tr>
<td>NRG XXX</td>
<td>Ablative RT +/- checkpoint inhibition in IHCC</td>
<td>Ted Hong, MD</td>
</tr>
<tr>
<td>S1922</td>
<td>Randomized Phase II Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma</td>
<td>Mohamed Salem, MD</td>
</tr>
</tbody>
</table>
NRG Oncology Protocols GI004/GI002/GI005 Workshop

Date: Friday, January 10, 2020
Start and End Time: 2:00 pm - 3:00 pm

Presenters: Thomas George, MD, FACP
Caio Max S. Rocha Lima, MD
Van Morris, MD

Learning Objectives/Following this activity, participants will be better able to:

1. Discuss the study design and key inclusion criteria of the clinical trials.

WORKSHOP AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:00 pm – 2:20 pm</td>
<td>Overview of GI004</td>
<td>Caio Max S. Rocha Lima, MD</td>
</tr>
<tr>
<td>2:20 pm – 2:30 pm</td>
<td>GI002 Update</td>
<td>Thomas George, MD, FACP</td>
</tr>
<tr>
<td>2:30 pm – 2:50 pm</td>
<td>Overview of GI005</td>
<td>Van Morris, MD</td>
</tr>
<tr>
<td>2:50 pm – 3:00 pm</td>
<td>Question and Answer</td>
<td></td>
</tr>
</tbody>
</table>
Learning Objectives

Following this activity, participants will be better able to:

1. Recognize critical aspects of developing and conducting a clinical trial in genitourinary (GU) cancer therapy research in a cooperative group setting.
2. Identify and describe the design and status of new GU cancer clinical trials being planned and launched by NRG Oncology, to enable contribution to protocol design vetting and/or effective patient enrollment in newly-launched studies.
3. Identify and describe the status of ongoing GU cancer clinical trials being conducted by NRG Oncology, to enable effective patient enrollment in and treatment on these trials, and proper collection, submission and/or evaluation of the required patient data.
4. Identify, describe, and analyze aspects of ongoing NRG Oncology GU clinical trials which are in need of special support and improvement, to enable effective patient enrollment in and treatment on these trials, and proper collection, submission and/or evaluation of the required patient data.
5. Identify and discuss the results and publication status of GU cancer clinical trials recently completed by NRG Oncology, so they can make informed decisions based on the state of the science regarding patient treatment, and they can relay study results to patients treated on these trials.
6. Identify and describe new forms of radiotherapy delivery and their use in NRG Oncology GU cancer trials.
7. Identify and describe systemic therapies, including chemotherapeutic drugs, hormonal strategies, biologic agents, and new classes of targeted therapies that may be used in conjunction with radiation therapy in GU cancer treatment, and the effectiveness of those agents as demonstrated in NRG Oncology clinical trials.
8. Identify and describe new developments in biologic and imaging science that can be used in translational research strategies to identify GU cancer patient subgroups at risk for failure with existing treatments and identify new approaches for these patients.

WORKSHOP AGENDA

8:00 – 8:05  Opening Remarks and Update

8:05 – 8:45  Review of Active Trials

NRG GU002  Phi-III Adjuvant RT Following Radical Prostatectomy ± Adjuvant Docetaxel  Mark Hurwitz, MD

NRG GU005  Phase III IGRT & SBRT vs. IGRT & Hypofrax IMRT localized prostate cancer  Rod Ellis, MD

NRG GU006  Phase II R biomarker stratified trial with a lead in to phase III testing the benefit of salvage RT +/- apalutamide in patients with a low PSA pre-treatment.  Dan Spratt, MD

NRG GU007  Phase I/II R of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer  Zach Zumsteg, MD

RTOG 3506  Randomized Phase II Trial of Salvage Radiotherapy With Std vs Enhanced ADT (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features  Edwin Posadas, MD

SWOG/NRG 1806  Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer  Jason Efstathiou, MD

SWOG 1802  Local therapy for M1 prostate cancer, a SWOG study  Richard Valicenti, MD
<table>
<thead>
<tr>
<th>AGCT 1531</th>
<th>Phase III Study of Active Surveillance for Low Risk and A Randomized Trial of Carboplatin vs Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumours</th>
<th>Allan Covens, MD</th>
</tr>
</thead>
</table>

**8:45 – 9:35**  
**Review of Pending Studies**

<table>
<thead>
<tr>
<th>NRG GU008 (formerly GU1817)</th>
<th>Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial</th>
<th>Ronald Chen, MD, MPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECOG/NRG EA8185</td>
<td>Phase 2 Study of Bladder-Sparing ChemoradiationN with Durvalumab in Clinical Stage 3, node Positive URotheLial Carcinoma (INSPIRE)</td>
<td>Abhishek Solanki, MD MS</td>
</tr>
</tbody>
</table>
| NRG 1864 (developing concept) | Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing  
Treatment De-Intensification for Men with Lower Genomic Risk and Treatment  
Intensification for Men with High Genomic Risk | Paul Nguyen, MD; Oliver Sartor, MD |
| Alliance/ NRG (concept # TBD) | Phase III Trial of Androgen Deprivation Therapy and Abiraterone/Prednisone Alone or with 177Lu-PSMA-617 in Castration Sensitive Metastatic Prostate Cancer (mCSPC) | Oliver Sartor, MD |

**9:35 – 9:55**  
**Other issues**

- Translational Research
- Medical Oncology Update
- Urology Update
- New Business

**9:55 – 10:00**  
**Closing Remarks**
Cervix Workshop Agenda

Date: Friday, Jan 10, 2020
Start and End Time: 8:00am – 10:00 (Session I)

Date: Saturday, Jan 11, 2020
Start and End Time: 9:00am – 10:00 (Session II)

Chair: Charles A. (Trey) Leath, III, MD, MSPH
Co-Chair: Jyoti Mayadev, MD
Translational Co-Chair: Dmitriy Zamarin, MD, PhD

**Learning Objectives:**
Following this activity, participants will be better able to:

1. Discuss national and international priorities, goals and initiatives in the management of cervical cancer
2. Discuss currently active and developing NRG clinical trials on the prevention, diagnosis, and treatment of cervical and vulvar cancers
3. Discuss promising therapeutics in development and potential translational research objectives and strategies for future clinical trials
4. Apply standards and procedures needed to design, submit, (revise), and conduct a research protocol within the NRG
5. Outline both potential barriers and potential solutions to improve enrollment to NRG clinical trials in cervical and vulvar cancer to include international collaboration

**WORKSHOP AGENDA**

Session I: Friday Jan 10, 2020 (Scientific Developmental Focus) 10:00 am – 12:00 pm

A. Introduction (10:00 – 10:10)
   a. Welcome, committee membership and rotation plan and review of July 2019 minutes

B. Scientific updates (10:10 – 10:45)
   a) HPV related cancers: lessons from Head and Neck ca: Dr. Maura Gillison, MD, PhD
   b) Early Stage Cervical Cancer Surgical Mgmt and International Collaboration: Pedro Ramirez, MD
   c) Non-CTEP Relevant Cervical Cancer Trials
      a. GCIG (Dr. David Gaffney)
      b. GOG Partners (Dr. Leslie Randall)
   d) Previously committee approved/reviewed concepts – current updates and future directions
      o CV1922 (Ritu Salani): PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer
      o CV1923 (Brian Slomovitch): GROINS V3
      o UC1963: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)
      o PI1915 A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley) CTEP IND
C. **New proposed concepts**
   - **CIV2005**: A Phase II Study of Combined chemo-immunotherapy with cisplatin-pembrolizumab and radiation for unresectable vulvar squamous cell carcinoma (Olapado Yeku)

Session II Saturday February 9, 2019 (Operational management on-going NRG trials) 10:00 am–11:00 am

D. **Closed Studies**

Protocols: 101, 120, 205, 222, 141, 173, 179, 204, 206, 204, 233, 9806

E. **Active / Recently Completed Trials**
   a. **GOG-0724/RTOG0724**: Phase III trial randomized study of concurrent chemotherapy and pelvic RT with or without adjuvant chemotherapy in high-risk patients with early stage cervical carcinoma following radical hysterectomy. (Heidi Gray, Anuja Jhingran)
      i. Opened April 2009
      ii. Accrual 172/285 (60.4%)
   b. **GOG-0263**: Randomized clinical trial for adjuvant chemoradiation in post-operative cervical cancer patients with intermediate risk factors (Sang Young Ryu, Wui-Jin Koh)
      i. Opened April 2010
      ii. Amended Nov 2017 to decrease accrual from 534 to 360
      iii. Accrual 279/360 (79.7%)
   c. **GOG-0270**: Groningen International Study on Sentinel nodes in vulvar cancer (GROINSS-VII) – An observational study (Brian Slomovitz)
      i. NRG Opened January 2012; NRG target accrual 140
      ii. Amendment for treatment of SLN macro-metastatic disease
      iii. Amendment for IMRT approved July 2015 by GROINSS, NOT by CTEP
      iv. Accrual completed (NRG accrual 148)
   d. **GOG-0274**: A phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: GOG collaboration with the OUTBACK trial (ANZGOG 0902/GOG 0274 / RTOG 1174). (Kathleen Moore)
      i. Opened January 2012; NRG target accrual 500
      ii. Expanded target accrual to 900 patients
      iii. Accrual completed May 2017
      iv. Study closed 6/1/2017 – 924/900 accrued – NRG accrual 627
   e. **GOG-0278**: Evaluation of physical function and quality of life (QOL) before and after non-radical surgical therapy for stage IA1-IB1 (≤2cm) cervical cancer. (Al Covens)
      i. Opened October 1, 2012
      ii. PET imaging amendment approved July 2015
      iii. Accrual 161/220 (80.5%)
   f. **GOG-0279**: A phase II trial evaluating cisplatin and gemcitabine concurrently with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva. (Neil S. Horowitz)
      i. Opened July 2, 2012
      ii. Temporarily Closed June 15, 2015 after enrolling 28 in 1st stage
      iii. 2nd stage re-opened July 2016
iv. Accrual 36/52 total (69.2%)
g. **NRG-GY006**: A randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, stage II, IIIB, or IVA Cancer of the uterine cervix or Stage II-IVA vaginal cancer. (Trey Leath, Loren Mell)
   i. Opened January 15, 2016
   ii. Accrual 101/188 (53.7%)
   iii. Amendment to CTEP re: increase in accrual size and transition to Randomized phase 3

h. **NRG-GY017**: Phase I trial using anti PD-L1 (atezolizumab) as immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer. (Jyoti Mayadev)
   - Opened October 26, 2018

Reports from Other Committees and Groups

i. Publications Subcommittee
j. Patient Centered Outcomes Research Committee
k. Ancillary Data Committee
l. Cancer Prevention and Control
m. Rare Tumor Committee
n. Vaccine Subcommittee
o. Pathology Committee
p. Radiation Committee
q. SPORE Committee
r. Nursing
s. Medical Oncology
t. Patient/Community/Advocacy

F. Concluding Remarks and Wrap-up

   Next Semi-Annual Meeting

QUESTIONS / DISCUSSION
Gynecologic Cancer Workshop

Date: Saturday, January 11, 2020
Start and End Time: 10:00 am – 12:00 pm
Chair: Carol Aghajanian, MD
Co-Chairs: Paul DiSilvestro, MD & William Small, MD
Translational Science Co-Chair: Heather Lankes, PhD, MPH

Learning Objectives:
Following this activity, participants will be better able to:
1. Discuss the status and significance of new and ongoing clinical trials on the prevention, diagnosis, and treatment of gynecologic cancers.
2. Discuss promising translational research objectives and priorities for future clinical trials.
3. Apply standards and procedures required to design, submit and conduct a research protocol for support by NRG Oncology.
4. Assure strict quality control of gynecologic cancer clinical trials.

WORKSHOP AGENDA
I. General Business
   A. Call to order
   B. Approval of minutes from July 2019
   C. Symposia (Alvarez)
   D. Report from Health Disparities Committee (Brown)
   E. Report from HRC (Creasman)
   F. Report from Scientific Publications Committee (Tewari)

II. Committee Descriptions
Gynecologic Cancer Committee
Cervix/Vulvar Cancer Subcommittee
   • Cervical cancer – Randomized phase II, Phase II/III, Phase III
   • Vulvar cancer – Phase II, Randomized phase II, Phase II/III, Phase III

Ovarian Cancer Subcommittee
   • Ovarian cancer (Ovarian cancer = Fallopian tube cancer, Ovarian cancer, Primary Peritoneal Cancer)
     ➢ Neoadjuvant chemotherapy (NACT) – Randomized phase II
     ➢ Randomized phase II, Phase II/III, Phase III

Rare Tumor Subcommittee
   • Clear Cell Tumors
   • Germ Cell Tumors
   • Ovarian - Low Grade Serous
   • Ovarian - Mucinous
   • Ovarian - Stromal Tumors
   • Vulvar/Vaginal Melanoma

Uterine Corpus Cancer Subcommittee
• Endometrial cancer (Endometrioid, Serous, Clear Cell, Carcinosarcoma)
  ➢ Randomized phase II, Phase II/III, Phase III
• Uterine sarcoma (leiomyosarcoma)
  ➢ Randomized phase II, Phase II/III, Phase III
• Gestational trophoblastic neoplasm (GTN)

GYN Developmental Therapeutics Committee
• Early phase trials, Window of opportunity trials
  ➢ Cervical cancer
  ➢ Endometrial cancer
  ➢ Ovarian cancer
  ➢ Uterine sarcoma

GYN Phase I Subcommittee
• Safety lead-ins
• Phase I

Other NCTN Group Trials & Study Champions

S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors

AGCT1531, A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors. This is an Adolescent and Young Adult (AYA) Study: Available to COG and the Adult Groups
NRG Oncology Study Champion: Covens

AGCT1532, A Randomized Phase 3 Trial of Accelerated Versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-Risk Metastatic Germ Cell Tumors. This is an Adolescent and Young Adult (AYA) Study: It is available to COG and the Adult Groups
NRG Oncology Study Champion: Covens

EAE161, Perfusion CT to Predict Progression-free Survival and Response Rate in Bevacizumab and Paclitaxel Treatment of Platinum-Resistant, Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma. ECOG-ACRIN Study Available to Alliance, NRG, SWOG
Temporarily closed to accrual 3/20/2019
NRG Oncology Study Champions: Mannel/Schilder
III. **Cervix/Vulvar Cancer Subcommittee**

### New Concepts

a. **CV2005**: A Phase II Study of Combined chemo-immunotherapy with cisplatin-pembrolizumab and radiation for unresectable vulvar squamous cell carcinoma (Olapado Yeku)

b. **UC1963**: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

### Studies Under Development

a. **CV1912**, Phase II study of nelfinavir and chemoradiotherapy for locally advanced vulvar cancer (Lilie Lin)

b. **CV1922**, PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer (Ritu Salani)

c. **CV1923**, GROINS V3

d. **CV1962**, FIGO 2018 stage 1B2 (≥2cm - <4 cm) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (CoNteSSa) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F) (Allan Covens/Lauren Cobb)

e. **CV1964**, Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (Scott Glaser)

### Active Studies:

a. **RTOG-0724**, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy (Anuja Jhingran)

b. **GOG-0263**, Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Sang Young Ryu)

c. **GOG-0279**, A Phase II Trial Evaluating Cisplatin and Gemcitabine Concurrent with Intensity-Modulated Radiation Therapy (IMRT) for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva (Neil S Horowitz)

d. **NRG-GY006**, A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (Charles Leath)

### Rare Tumor Subcommittee – Mucosal Melanoma

### Studies Under Development

a. **DT1822**, A Randomized Phase II Trial of Adjuvant nivolumab with or without cabozantinib in patients with resected mucosal melanoma (Danielle Vicus) – Alliance lead group
1. **DT2010**: Phase II study of dasatinib in recurrent low grade endometrial stromal sarcoma (Lilian Gien)

**DT2013**: CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corrine Doll)

**Studies Under Development**

- **PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley)

**Active Studies**

- **NRG-GY017**, Anti PD-L1 (atezolizumab) as an immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer (Jyoti Mayadev/Dmitriy Zamarin)

**NCORP**

**Active Studies**

- **GOG-0278**, Evaluation of Physical Function and QoL Before and After Non-Radical Surgical Therapy for Stage IA1 (LVSI+) and IA2-IB1 Cervical Cancer (Allan Covens)

**Closed Studies (Primary manuscript NOT published):**

- 270 (GROINSS-V), THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174), 265, GY002

**Terminations:**

**IV. Ovarian Cancer Subcommittee**

**New Concepts**

- **OV2008**: A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)

- **OV2011**: Randomized Phase II trial comparing bevacizumab/abemaciclib versus bevacizumab/placebo for maintenance therapy in homologous recombination proficient ovarian cancer patients after first or second platinum sensitive recurrence (Camille Gunderson)

- **OV2015**: Randomized Phase II of Neoadjuvant Paclitaxel/Carboplatin +/- Bevacizumab versus Neoadjuvant Paclitaxel/Carboplatin + AVB500 +/- Bevacizumab in Ovarian, Tubal, Peritoneal carcinoma (Katherine Fuh)

**Studies Under Development**

- **OV1838/1839**, Copanlisib and Olaparib (Panagiotis Konstantinopoulos)

- **OV1913**, A randomized phase II trial of triplet therapy (PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy with olaparib/cediranib or durvalumab/cedirinib in women with platinum resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung-Min Lee)

- **OV1954**, Maintenance therapy after platinum based treatment of platinum sensitive recurrence in patients who received PARP inhibitor maintenance after upfront therapy (John Nakayama)

- **OV1960**, HIPEC
**Active Studies:**

a. **NRG-GY005**, A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS). (Jung-Min Lee)

b. **NRG-GY007**, A Phase I/II Study of Ruxolitinib with Front-Line Neoadjuvant and Post-Surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer. (Robert Burger)

c. **NRG-GY009**, A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer. (Roisin O’Cearbhaill)

d. **NRG-GY021**, A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Sarah Adams)

**Rare Tumor Subcommittee**

**New Concepts**

a. **RT2012**: Randomized Phase II, non-randomized Evaluation of Pembrolizumab with and Without Abemaciclib in Small Cell Carcinoma of the Ovary, Hypercalcemic Type (Camille Gunderson)

**Studies Under Development**

a. **RT1849**, A phase II trial of durvalumab and cediranib in recurrent ovarian sex cord stromal tumors (Danielle Vicus)

b. **RT1969**, A phase II trial of nivolumab, ipilimumab with sargramostim for recurrent clear cell ovarian cancer (Danielle Vicus)

**Active Studies:**


b. **NRG-GY016**, Randomized phase II evaluation pembrolizumab + epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)

c. **NRG-GY019**, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum. (Amanda Fader)

**GYN Developmental Therapeutics Committee - Ovarian Cancer**

**New Concepts**

a. **OV2008**: A Randomized Phase II trial of PARPi combinations in PARPi inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)

b. **PI2014**: A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)

**Studies Under Development**
a. **PI1966**, A phase IB/II study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Fiona Simpkins)

**Active Studies:**

a. **NRG-GY014**, A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid or clear cell carcinoma of the ovary, and recurrent or persistent endometrioid endometrial adenocarcinoma. (Ramez Eskander)

*Closed Studies (Primary manuscript NOT published):* 212, 268, 273, 281, 283, GY003, GY004

*Closed Studies (Primary manuscript published):* 186H*, 213, 239*, 252, 262

*patient on active treatment

**Terminations:** 218, 255

V. **Uterine Corpus Cancer Subcommittee**

**New Concepts**

a. **UC1963**: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

b. **UC2006**: Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer: Additional arm NRG-GY012 protocol (Hairder Mahdi)

c. **UC2009**: A Phase II Trial of Sapanisertib and Letrozole in Advanced, Recurrent, or Metastatic Endometrioid Endometrial Cancer (Sara Bouberhan)

d. **UC2019**: (UC1814R) A phase III randomized study of carboplatin, paclitaxel, atezolizumab, and ipatasertib plus ipatasertib and atezolizumab maintenance versus carboplatin, paclitaxel, ipatasertib and ipatasertib maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer. (Debra Richardson)

**Studies Under Development**

a. **UC1731**, Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study. (Katarzyna Jerzak/Helen Mackay/Linda Duska)

b. **NRG-GY020**, Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer. (Floor Backes)

c. **UC1926**, Randomized phase II trial of adjuvant therapy with either paclitaxel/carboplatin or everolimus/letrozole in stage III endometrial cancer with no residual disease. (Brian Slomovitz)

d. **UC1963**, A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

**Active Studies:**

a. **GOG-0238**, A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus. (Jonathan Micha Feddock)
b. **NRG-GY012**, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay)

c. **NRG-GY018**, A randomized phase III Placebo-Controlled Study of Pembrolizumab in addition to Paclitaxel and Carboplatin for Measurable Stage III Or IVA, Stage IVB or Recurrent Endometrial Cancer. (Ramez Eskander)

**GYN Developmental Therapeutics Committee – Uterine Corpus Cancer**

**New Concepts**

a. **DT2010**: Phase II study of dasatinib in recurrent low grade endometrial stromal sarcoma (Lilian Gien)

**Studies Under Development**

a. **DT1951**, Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Martee Hensley)

b. **DT1959**, Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Martee Hensley)

c. **DT1953**, Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) in HER2+ serous endometrial cancers (Haider Mahdi)

d. **DT1958**, Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Stephanie Gaillard)

**Active Studies:**

a. 

**Closed Studies (Primary manuscript NOT published):** 209, 261, 275, 286B, GY008, GY011

**Closed Studies (Primary manuscript published):** 188*, 249, 258

*patient on active treatment

**Terminations:** 210

**VI. Developmental Therapeutics Committee** (O’Cearbhaill, Backes, Konstantinopoulos)

**Studies Under Development**

a. **NRG-GY022 (DT1833)**, Assessment of carboplatin clearance predictors: a companion PK study to NCI sponsored clinical trials or standard of care treatments using carboplatin (Taylor/Beumer)

b. **MATCH COMBO**

**VII. Patient Centered Outcomes Research (PCOR) Committee Report** (Wenzel)

**VIII. Elderly & Special Populations Working Group and Cancer Care Delivery (Health Disparities Committee)** (Tew)

**IX. Translational Science Committee Report** (Birrer, Lankes)

**X. Cancer Prevention and Control Committee Report** (Walker)

**QUESTIONS / DISCUSSION**
Ovarian Workshop Agenda

Date: Friday, January 10, 2020  Saturday, January 11, 2020
Start and End Time: 1:00 pm - 4:00 pm  9:00 am - 10:00 am
Chair: Kathleen Moore, MD  Kathleen Moore, MD
Co-Chair: Robert Burger, MD  Robert Burger, MD
Translational Chair: Elizabeth Swisher, MD  Elizabeth Swisher, MD
Translational Co-Chair: Rebecca Arend, MD  Rebecca Arend, MD

Learning Objectives:
Following this activity, participants will be better able to:

1. Review the status of completed and ongoing NRG-GOG clinical trials on the treatment of ovarian cancer
2. Review the status of approved NRG-GOG concepts that are under development
3. Discuss emerging molecular selection for ovarian cancer and how this may inform clinical trial development
4. Apply standards and review procedures required to design, submit, and conduct a research protocol within NRG, including ancillary data proposals
5. Assure strict quality control of GOG/NRG clinical trials

WORKSHOP AGENDA
Note: The actual order of topics and discussion is subject to change, depending on availability of participants

A. Introduction
   • Review of learning objectives
   • Statements regarding potential conflict of interest
   • Committee membership updates

B. Summary of Key Discussion Items (from this Agenda)
   • Discussion of biomarkers in Gyn cancers  C. Aghajanian /H. Lankes
   • Discussion of molecular selection in ovarian cancer and impact on clinical trials/ TBD

C. Review of Closed Studies (not-terminated)
   • GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
   • GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman).
   • GOG0218 A Phase III trial of carboplatin and paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent bevacizumab (NSC #704865, IND #7921) followed by placebo, versus carboplatin and paclitaxel plus concurrent and extended bevacizumab, in women with newly diagnosed, previously untreated, stage III and IV epithelial ovarian, primary peritoneal or fallopian tube cancer (Robert A Burger).
• GOG0252 Phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma (Joan L Walker)
• GOG0262 A randomized phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III or IV epithelial ovarian, peritoneal or fallopian tube cancer (John K Chan)
• GOG0273 Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen) Modified dose dense cohort manuscript in draft form.
• GOG3001 A phase 3 randomized, double-blind, placebo-controlled, multi-center study of AMG 386 with paclitaxel and carboplatin as first-line treatment of subjects with FIGO stage III-IV epithelial ovarian, primary peritoneal or fallopian tube cancers (Amgen TRINOVA-3 NCT01493505) (Bradley J Monk)
• GOG3004 (SOLO1) A phase III, randomised, double blind, placebo controlled, multcentre study of olaparib maintenance monotherapy in patients with BRCA mutated advanced (FIGO stage III-IV) ovarian cancer following first line platinum based chemotherapy. (Paul A DiSilvestro and Kathleen Moore). Manuscript Oct 2018
• GOG3005 (AbbVie Study No.: M13-694) A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stage III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Rob Coleman). NEJM manuscript Oct 2019
• NRG-GY003 Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (Bob Burger) Presented IGCS 2018/manuscript submitted
• GOG0281 RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson). Presented at IGCS 2019

D. Review of Active Studies (all metrics are as of 11/2019)
• GOG0264 RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naive sex cord stromal tumors of the ovary (Jubilee Brown)
  o Activated 08FEB2010
  o Enrollment 58/128 (as of 11/19)
  o 1 event short of interim analysis
• NRG-GY004 Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Joyce Liu and Ursula Matulonis). Expanded overall accrual to 550 patients, closed to accrual 10-NOV-2017
  o Primary analysis expected Q1-2 2020
• NRG-GY005: A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory
Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Jung-Min Lee and Angeles Alvarez Secord)
- Suspended 17JUN2017 (n = 213) for analysis of randomized phase II component
- Re-opened to phase 3 without monotherapy olaparib arm 12/17/2018
- Reminder to sites regarding completion of scheduled QOL assessments
- Enrollment 362/562
- Discussion of feasibility given anticipated approval of PARPi beyond BRCA in front line? (Mike Sill/Jung Min Lee/Angeles Alvarez Secord)

- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer. Activated for Phase I accrual. (Robert A Burger)
  - 122/147
  - Discussion of impact of cross over to PARPi maintenance among patients completing chemotherapy proximal to new approvals? Do we need a similar amendment to what was done for BRCA associated cancers? (M Sill/Burger)

- NRG-GY009 A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Roisin O’Cearbhaill, Carol Aghajanian).
  - Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
  - Second-stage safety lead-in (all three arms) opened 14NOV2017
  - Group-wide activation 6/18/2018
  - Suspended at the end of phase 2 (May 2019)

- NRG-GY014 (DT1718) A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. (Ramez Eskander and David Hyman)
  - Activated 4/2019
  - Suspended 8/2019

- NRG-GY016 - phase 2 pembrolizumab + epacadostat (IDO inhibitor) in recurrent clear cell of the ovary (L Gien)
  - Activated Oct 2018/suspended for first phase accrual completion 4/2019
  - Amendment pending

  - Activated 8/26/19
  - 5/450

- NRG-GY021 Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams)
  - Activated Oct, 12 2019
  - Safety call will be coordinated through DT committee
NRG-GY022 (DT1833): Assessment of carboplatin clearance predictors: PK protocol to allow for extra sample collection and collection of demographic data, laboratory values, and outcome data. (Liz Villaruz/Jan Beumer) GYN Cancer Committee: 7/14/18
  - Activated 11/2019

AGCT1531 (RT1205) Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGiC, COG primary, Al Covens NRG)
  - Activated group-wide 30MAY2017
  - 254/1680

Ovarian Cancer Subcommittee
  E. Review of Approved Concepts under Development

- **OV1838/OV1839 PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib vs Standard Chemotherapy in Patients with Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)** LOI submitted 10/2018
  - Submitted to OTF 11/20 for Dec review

- **OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Ovarian Cancer (R Arend/ M Birrer/ K Moore)**
  - Concept submitted 11/2018
  - Ovarian Cancer task force review 12/18/18

- **OV1913 A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) vs doublet therapy (durvalumab and cediranib) in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung Min Lee)**
  - Approved by GCSC 9/19; awaiting confirmation of drug supply

- **OV1954 Treatment of platinum sensitive recurrence in BRCA mutated patients with olaparib with or without cediranib maintenance after upfront treatment with olaparib maintenance therapy. (Nakayama)**
  - Needs to be re-presented to committee

- **OV1960 A phase III randomized trial of heated intraperitoneal chemotherapy (HIPEC) with cisplatin at the time of interval cytoreductive surgery versus intravenous chemotherapy only followed by niraparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer. (Crispens)**
  - Submitted to OTF 11/20 for 12/2019 meeting

- **DT1955: N-803 and Durva recurr EOC, tubal and primary peritoneal (M Geller)**
  - For RSC 10/29/19

- **DT1907: Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial, fallopian tube and primary peritoneal cancer- (Floor Backes)**
On hold until Merck review received. If approved by Merck, RSC July 20, 2019

- P11966: Wee1 + ATRi in CCNE1 amplified ovarian and endometrial (Simpkins)
  - For RSC 10/29/19
- RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus) LOI. RSC review Feb ’19
  - RSCX 3/5/19
  - Awaiting submission of LOI pending feedback from CTEP
- RT1906: A randomized Phase II/III trial of chemotherapy versus pembrolizumab versus radiation therapy in the treatment of Stage IC 2,3 and II Ovarian or fallopian tube Clear Cell Carcinoma (John Farley)
  - Administratively disapproved due to feasibility

- RT1969: Nivolumab, Ipilimumab, Sargramostim in recurrent clear cell ovarian cancer (Vicus)
  - RSCX 11/25/19
- NRG-CC008 (CC1923) (NC1427) (CPC1206) A non-randomized prospective clinical trial comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers (SOROC) (Doug Levine). Submitted for NCORP review. Submitted to DCP

F. Review of New Concepts and Future Request for Proposals

- **OV2008**: A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)
- **OV2011**: Randomized Phase II trial comparing bevacizumab/abemaciclib versus bevacizumab/placebo for maintenance therapy in homologous recombination proficient ovarian cancer patients after first or second platinum sensitive recurrence (Camille Gunderson)
- **OV2015**: Randomized Phase II of Neoadjuvant Paclitaxel /Carboplatin +/- Bevacizumab versus Neoadjuvant Paclitaxel/Carboplatin + AVB500 +/- Bevacizumab in Ovarian, Tubal, Peritoneal carcinoma (Katherine Fuh)
- **PI2014**: A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)

**QUESTIONS / DISCUSSION**
Rare Tumor Workshop

Date: Friday, January 10, 2020
Start and End Time: 8:00 am - 10:00 am
Chair: Allan Covens, MD
Co-Chair: Jubilee Brown, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Discuss past, ongoing, and emerging NRG clinical trials on rare gynecologic cancers
2. Discuss promising translational research objectives and priorities for future clinical trials
3. Discuss rationale for triaging women with specific rare tumors to separate clinical trials including a “match” type trial.
4. Develop a strategy to study: Endometrial Stromal Sarcoma, Paget’s Vulva in a group-wide/intergroup NRG protocol

WORKSHOP AGENDA

Session I

A. Closed Studies

GOG-0187: A Phase II Study of Paclitaxel for Ovarian Stromal Tumors as First-Line or Second-Line Therapy (Homesley)

GOG-0239: A Phase II Trial of AZD6244 (NSC 741078, IND #77782) in women with recurrent low-grade serous carcinoma of the ovary or peritoneum (Farley)

GOG-0241: A Randomized Phase III Evaluation of Capecitabine and Oxaliplatin (XELOX) versus Carboplatin and Paclitaxel in Stage III-IV Mucinous Adenocarcinoma of the Ovary (Gershenson)

GOG-0241: A Randomized Phase III Evaluation of Capecitabine and Oxaliplatin (XELOX) versus Carboplatin and Paclitaxel in Stage III-IV Mucinous Adenocarcinoma of the Ovary (Gershenson)

GOG-0251: A Phase II Trial of NCI-supplied agent: Bevacizumab (rhuMAB VEGF) (NSC#704865, IND #7921) for recurrent sex cord-stromal tumors of the ovary (Brown)

GOG-0254: A Phase II Evaluation of SU11248 (Sunitinib Malate) in the Treatment of Persistent or Recurrent Clear Cell Ovarian Carcinoma (Chan)

GOG-0268: A Phase II Evaluation of Temsirolimus (CCI-779) in Combination with Carboplatin and Paclitaxel as First-Line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary (Farley)

NRG-GY001: A Phase II Trial of Cabozantinib in Women with Recurrent Clear Cell Carcinoma of the Ovary, Fallopian Tube, or Peritoneum (Farley)
GOG-0283: A Phase II Trial of DCTD-Sponsored Dasatinib (NSC #732517, IND #120636) in Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, and Endometrial Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression (Hyman)

GOG-0281: A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (GSK1120212) in Patients with Recurrent or Progressive Low-grade Serous Ovarian Cancer or Primary Peritoneal Cancer (David M Gershenson).

B. Presentation:

C. Active Studies

GOG-0264: A Randomized Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide and Cisplatin for Newly Diagnosed Advanced Stage and Recurrent Chemotherapy-Naive Sex Cord-Stromal Tumors of the Ovary (Brown)

AGCT1531: A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Covens)

CLEE011XUSIT: Phase II trial of letrozole + Ribociclib for women with recurrent low-grade serous carcinoma. (Slomovitz) GOG Partners

NRG-GY016: A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epacadostat (NSC #766086) in Recurrent Clear Cell Carcinoma of the Ovary (Gien)

NRG-GY019: A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Fader).

D. Proposed Studies/in development

RT1849: A Phase II Trial of Durvalumab and Cediranib in Recurrent Ovarian Sex Cord Stromal Tumours (Vicus). Approved for development.

DT1822: A Randomized Phase II Trial Of Adjuvant Nivolumab With Or Without Cabozantinib In Patients With Mucosal Melanoma. (Vicus) Alliance will lead.

RT1906 A randomized Phase III trial of carboplatin and paclitaxel chemotherapy versus cisplatin and radiation therapy followed by carboplatin and paclitaxel chemotherapy in the treatment of Stage IC 2, 3 and II Ovarian or fallopian tube Clear Cell Carcinoma (Farley)

RT1969 A phase II trial of Nivolumab, Ipilimumab with Sargramostim for recurrent clear cell ovarian cancer (Vicus)
E. **New concepts**

**RT2012**: Randomized Phase II, non-randomized Evaluation of Pembrolizumab with and Without Abemaciclib in Small Cell Carcinoma of the Ovary, Hypercalcemic Type (Camille Gunderson)

F. **Discussion Topics:**

a) “Match” trial for rare tumours
b) RFP: Low Grade Endometrial Stromal Sarcoma, Paget’s Vulva.

**QUESTIONS / DISCUSSION**
Uterine Corpus Workshop

Date: Friday, January 10, 2020
Start and End time: 1:00 pm – 4:00 pm (Session I)

Date: Saturday, January 11, 2020
Start and End time: 9:00 am – 10:00 am (Session II)

Chair: Matthew Powell, MD
Rad Onc Co-Chair: Ann Klopp, MD
Med Onc Co-Chair: Martee Hensley, MD
TR Co-Chair: Douglas Levine, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Discuss current and emerging research priorities of the Uterine Corpus Committee
2. Discuss proposed and ongoing NRG Gyn clinical trials on the prevention, diagnosis, and treatment of uterine corpus malignancies
3. Apply standards and procedures required to design, submit, and conduct a research protocol for support by NRG Oncology.

NOTE:
GTN subcommittee: FRIDAY 12:00-1:00 (Lead Neil Horowitz, MD)
GOG 210 Subcommittee: FRIDAY 8:00-9:00 (Lead David Mutch, MD)

Workshop Agenda

A. Introduction (Powell):

B. Review of Closed Studies [Sat AM Session]

1. **GOG0188**: Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [Gynecol Oncol 120(2): 185-8, 2011];

2. **GOG0209**: A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer (David Scott Miller to discuss) [Gynecol Oncol 125: 771-3, 2012] Submission

3. **GOG0210**: A Molecular Staging study of Endometrial Carcinoma (William T Creasman): Mutch in separate report

4. **GOG0249**: Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy doi:10.1016/j.ygyno.2014.07.078: Accepted JCO

5. **GOG0258**: A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma. (Daniela Matei)

6. **GOG0261**: A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naïve Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus

7. **GOG0275**: A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia (Julian C Schink to discuss)
8. **GOG0286** A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer *(Victoria L Bae-Jump to discuss)*

9. **NRG-GY008**: A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA and PIK3R1/R2 mutations *(A Santin)*; *Manuscript in development*; *(Backes to discuss)*

10. **NRG-GY011** (UC1406): A Randomized Surgical Window Pilot Investigation of the Relationship of Short Term Medroxyprogesterone Acetate (NSC #26386) Compared to Medroxyprogesterone Acetate Plus Entinostat (NSC #706995) on the Morphologic, Biochemical, and Molecular Changes in Primary Endometrioid Adenocarcinoma of the Uterine Corpus *(Duska to discuss)*

C. **Review of Active Studies**

1. **Endometrial Protocols**:
   a. **GOG0238**: A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus *(Bernard to discuss)*:
   b. **S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors *(Schink to discuss)*
   c. **GY012**: A Randomized, Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer *(Mackay/Bender/Rimmel)*. Additional arms added *(Rimel to discuss)*
   d. **GY018** (UC1710) Prospective randomized phase 3 trial of carboplatin and paclitaxel with or without pembrolizumab in the treatment of primary advanced stage (3 or 4) or recurrent endometrial cancer *(Eskander to discuss)*

D. **Review of Approved Concepts/Protocols**

1. **GOG-0210**
   a. **UC0905**: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 *(Mutch to discuss in 210 report)*
   b. **GOG-8032** *(UC1102)*: A clinico-pathologic analysis of high-grade uterine carcinomas (grade 3 endometrioid, serous, and clear cell carcinoma) and carcinosarcomas from GOG-0210 *(Richard Zaino/Ian Hagemann)*:
   c. **GOG-8040** *(UC1107)*: An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. *(Louise Brinton, Richard Zaino/Ian Hagemann)*:

2. **NRG TS008** *(UC1601)*: Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black Women with Endometrioid Endometrial and Uterine Serous Cancer *(L. Maxwell to discuss)*

3. **NC1603**: Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer *(Tanner to discuss)*

4. **UC1731**: Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study *(Jerzak/ Mackay/Duska to discuss)* N: 120 Stat: Sill; *Await preliminary data from GY011 before submitting to GCSC*. *(Duska to discuss)*
5. **UC1844** Efficacy of immunotherapy with immune checkpoint inhibitors in patients with deficient mismatch repair system or POLE mutated advanced stage or recurrent endometrial carcinoma: A randomized phase II/III trial (Mahdi) *(Mahdi to discuss)* Rejected by GCSC

6. **GY020 (UC1805)** Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Backes) N: 168 *(2:1 randomization)*. Stat: Sill *(Backes to discuss)*

7. **GY022 (DT1833)** Assessment of carboplatin clearance predictors: a companion PK study to NCI-sponsored clinical trials or standard of care treatments using carboplatin *(Taylor/Beumer)* N: 250 Stat: Miller *(Backes to discuss)*

8. **UC1926**: Randomized Phase II Trial of Adjuvant Therapy with either Carboplatin/Paclitaxel or Everolimus/Letrozole in Stage III Endometrial Cancer with No Residual Disease *(Slomovitz to discuss)*


10. **UC1968**: Molecular classification-directed care in endometrial carcinoma: a prospective cohort study (Temkin) Move to NCORP/Health Disparities

**E. Proposed studies:**

- **New Concepts**
- **UC2006**: Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer: Additional arm NRG-GY012 protocol (Haider Mahdi)
- **UC1963**: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino) Updated doc in packet.
- **UC2009**: A Phase II Trial of Sapanisertib and Letrozole in Advanced, Recurrent, or Metastatic Endometrioid Endometrial Cancer (Sara Bouberhan)
- **UC2019**: (UC1814R) A phase III randomized study of carboplatin, paclitaxel, atezolizumab, and ipatasertib plus ipatasertib and atezolizumab maintenance versus carboplatin, paclitaxel, ipatasertib and ipatasertib maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer. (Debra Richardson)

**F. Studies from Other Committees for Review:**

**G. New Business**

1. Update from GOG Foundation *(Slomovitz)*
2. Report from Subcommittee on Gestational Trophoblastic Disease *(Dr. Horowitz)*
3. Report from GOG0210 Scientific Advisory Board *(Mutch)* See 210 Subcommittee Report
4. Report from NRG radiation oncology GYN group *(Klopp)*
Head and Neck Workshop

Date: Saturday, January 11, 2020
Start and End Time: 10:00 am -12:00 pm
Chair: Quynh Thu Le, MD
Co-Chair: Erich Sturgis, MD-MPH; Stuart Wong, MD

Learning Objectives:
Following this activity, participants will be better able to:

1. Develop new head and neck cancer trials to be conducted through the NRG-Oncology network, specifically those testing (1) the addition of novel systemic therapies (chemotherapy, targeted therapy, immunotherapy) to radiation, (2) novel surgical or radiation approaches, (3) novel imaging approaches or (4) strategies to mitigate treatment related toxicity
2. Develop strategies to enable effective patient enrollment on these trials and proper collection, submission and/or evaluation of the required patient data.
3. Apply the results of completed NRG Oncology trials to daily treatment decision making in order to optimize patient care

WORKSHOP AGENDA

A. Actively Developing studies
   • HN006 Phase II-III SLN Biopsy vs. END in T1-2N0 oral cavity cancer  Stephen Lai, MD
   • HN007 Phase III Gem/cis vs. Gem/cis/Nivo in 1st line Rec/met NPC  Brigette Ma, MD
   • HN008 Phase I RT + DNA-PK inhibitor + Avelumab in High risk LA HNSCC  Maura Gillison, MD
   Michael Samuels, MD
   • Revised 1216 Phase III RT + cisplatin vs. RT+ docetaxel + cetuximab vs. RT + Julie Bauman, MD
     cisplatin + Atezo in resected high-risk stage III-IV HNSCC  Paul Harari, MD
     David Rosenthal, MD
   • HN1936 Chemo-immunotherapy selection to guide salvage surgery in rHNSCC enriched for PD1  Nabil Saba, MD
   • HN1937 Phase III HD vs. Weekly cisplatin in high risk LA HNSCC  Paul Harari, MD
   • HN 1935 Phase II-III RT vs. RT + PD1 in resected intermediate risk stage III-IV HNSCC  Stuart Wong, MD
   • Proposal 1: Phase II of T-DM1 +/- Atezo in metastatic Her2 amplified salivary duct cancer  Alan Ho, MD
   • Proposal 2: Phase III of observation vs. adjuvant IO in LA NPC with persistently detectable EBV DNA  Nancy Lee, MD

B. Review on active studies (list below)

C. Report on publications and protocol closed to active accrual  Quynh Le, MD

D. CCTG H&N Committee activities  John Waldron, MD
### E. Translational Research Program update
Neal Hayes, MD

### F. Surgical subcommittee update
Erich Sturgis, MD

### G. NCI Head and neck Steering Committee update
Christine Chung, MD

#### QUESTIONS / DISCUSSION

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<th>Actively accruing trials</th>
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<tr>
<td><strong>RTOG 1008</strong></td>
<td>Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIIR)</td>
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<td><strong>RTOG 1216</strong></td>
<td>RT-cisplatin vs. RT-Docetaxel + Cetuximab vs. cisplatin + Atezolizumab for “high risk” resected HNSCC (Phase IIIR)</td>
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<td><strong>NRG HN001</strong></td>
<td>Individualized NPC treatment based on post-RT EBV DNA (Phase III)</td>
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<td><strong>NRG HN004</strong></td>
<td>Phase II-IIIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC</td>
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<td><strong>NRG HN005</strong></td>
<td>Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer</td>
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<td><strong>RTOG 3507</strong></td>
<td>Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC</td>
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<th>Recently completed trial</th>
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<tr>
<td><strong>NRG HN003</strong></td>
<td>Phase I of Adjuvant Chemoradiotherapy +/- Pembrolizumab in High Risk, HPV(-) HNSCC</td>
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<td><strong>RTOG 3504</strong></td>
<td>Phase I of CRT +/- Nivolumab in intermediate/high risk HNSCC</td>
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<td><strong>NRG HN002</strong></td>
<td>Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good-Prognosis Advanced-Stage Oropharyngeal Cancer</td>
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<td><strong>RTOG 0912</strong></td>
<td>Phase IIR of Concurrent radiation + chemotherapy + pazopanib for Anaplastic Thyroid Cancer</td>
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<td><strong>RTOG 3501</strong></td>
<td>Phase IIR of CRT +/- Lapatinib in high risk stage III-IV HNSCC</td>
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<td><strong>RTOG 0920</strong></td>
<td>Phase III IMRT/IGRT + cetuximab for “intermediate risk” resected HNSCC</td>
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#### ECOG trials

| E3132 PORT +/- Cisplatin in intermediate risk pts with disruptive P53 mutation | Christine Chung |
| E3161: Intermediate risk HPV(+) HNSCC CRT +/- Nivo | Christine Chung/Nabil Sab |
| E3163 Sinonasal carcinoma | Nabil Saba |
Lung Cancer Workshop

Date: Saturday, January 11, 2020
Start and End Time: 10:00 am – 12:00 pm
Chair: Jeffrey Bradley, MD
Co-Chairs: Jessica Donington, MD, PhD and Martin Edelman, MD

Learning Objectives:
Following this activity, participants will be better able to:

1. Learn about ongoing clinical trials within the lung cancer committee.
2. Participate in feedback about ongoing and prospective trials.
3. Develop strategies to participate in these trials at your home institution.

4. Active Studies:
   a.) Lung-MAP SWOG S-1400 Saiama Waqar, MD
   b.) ALCHEMIST Trial Saiama Waqar, MD
   c.) RTOG 1308: Protons vs photons for St III NSCLC Xing Liao, MD
   e.) NRG CC003: Hippocampal avoidance brain Vinai Gondi, MD
   f.) LU002: Phase III chemo +/- SBRT for Stage IV Puneeth Iyengar, MD
   g.) NRG-LU003: NCI NRG ALK Master Protocol Shakun Malik, MD
   i.) NRG LU004 Phase I/II anti-PD1 concurrent with RT Steven Lin, MD
   h.) NRG/Alliance LU005 Limited-stage SCLC Kristin Higgins, MD
   j.) NRG LU006 Phase IIIR; Dose-painting IMRT for mesothelioma Andreas Rimner, MD
   k.) RTOG 3515 SBRT +/- durva for medically-inoperable Stage I Cliff Robinson, MD
   l.) SWOG S1914/NRG LU SBRT +/- neoadjuvant atezo for Stage I Charles Simone, MD
   m.) NRG LU007 Phase II/III ES-SCLC; chemo + atezo +/- RT Quynh Nguyen, MD

QUESTIONS / DISCUSSION
1.) EGFR/ALK Oligomet TS TKI +/- LCT (10 min) Elamin

2.) PII in St III - RT dose/fractionation trial (20 min) Higgins

3.) NRG CC1974: SCLC brain mets; SRS vs HA-WBI (20 min) Gondi

4.) PII in St III with safety run-in using N-803 after CRT (20 min) Lin

5.) Lung-MAP RadScopal (10 min) Nguyen
Patient Centered Outcomes Research (PCOR) Workshop

Date: Thursday, January 9, 2020
Start and End Time: 4:00 pm – 6:00 pm
Co-Chairs: Benjamin Movsas, MD; Patricia Ganz, MD; Lari Wenzel, PhD

Learning Objectives:
Following this activity, participants will be better able to:

1. Understand the importance of QOL compliance and data completeness
2. Analyze appropriate PRO and CER endpoints and instruments for use in NCTN Phase II and III clinical trials
3. Apply criteria for inclusion of PROs, CER, and PRO-CTCAE in NCTN Phase II and III clinical trials

WORKSHOP AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>4:00 – 4:30</td>
<td>Improving the Measurement of Individual and Group Change in FACIT-Fatigue in a Clinical Trial of Endometrial Cancer: an NRG Oncology Group/Gynecologic Oncology Group Study Comments/Audience Q &amp; A</td>
<td>David Cella, PhD</td>
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<td>4:30 – 4:45</td>
<td>PCOR Compliance Update Comments/Audience Q &amp; A</td>
<td>Ron Chen, MD</td>
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<td>4:45 – 4:55</td>
<td>Digital Health Update</td>
<td>Adam Dicker, MD</td>
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<td>4:55 – 5:40</td>
<td>Concepts in Development Protocols in Development</td>
<td>Patricia Ganz, MD</td>
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<td>Lari Wenzel, PhD</td>
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<td>5:40 – 5:50</td>
<td>NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates</td>
<td>Patricia Ganz, MD</td>
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<td>Lari Wenzel, PhD</td>
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<td>Laura Havrilesky, MD</td>
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<td>Jason Efstathiou, MD</td>
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<tr>
<td>5:50 – 6:00</td>
<td>Other Business</td>
<td>Patricia Ganz, MD</td>
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<td>Lari Wenzel, PhD</td>
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A. Active Studies
   1. Phase Ib Study To evaluate Neoadjuvant p53/MDM2 inhibitor combined with IMRT for Soft Tissue Sarcomas (Welliver/Wang)
   2. MGH/NRG: Phase I/II Trial of Preoperative Intensity Modulated Radiation Therapy (IMRT) For Retroperitoneal Sarcoma using a Simultaneous Integrated Boost (DeLaney/Wang)

B. New concept:
   1. Phase Ib Trial of Preoperative Zr-Bev Immuno-PET Guided Simultaneous Integrated Boost Radiation Therapy for locally advanced non-metastatic Soft Tissue Sarcoma of extremity and bodywall (Wolfson)

C. Developing Concepts:
   1. Phase II trial to investigate the role of peri-operative RT in desmoid tumors harboring CTNNB1 S45 mutation (Pollock/Welliver): Update only
   2. Registry to evaluate the safety and feasibility of treating sarcomas of the trunk with permanently implantable LDR CivaSheet (Krisha Howell and Dian Wang): Update only
   3. Registry to evaluate the efficacy of SBRT in treating sarcoma oligomet (Yen-Lin Evelyn Chen): Update only
   4. Phase II trial of Grid sarcoma by JW Snider, Majid Mohiuddin and Rob Griffin: Update only

D. Sarcoma TRP
   1. Preclinical studies for BMN673 clinical trial concept (updated by Meng Welliver and Brian Van Tine)
   2. Preclinical studies for Disulfram clinical trial concept (updated by Xinhui Wang)

E: New Business
Translational Science Workshop

Date/Time: Thursday, January 9, 2020
Start and End Time: 4:00 pm - 5:30 pm
Chair: Michael Birrer, MD, PhD
Co-Chairs: Adam Dicker, MD, PhD
Matthew Ellis, MB, BCHIR, PhD

Learning Objectives:
Following this activity, participants will be better able to:

1. To understand the emerging immunotherapy approaches to human cancers
2. To understand the immunotherapy trials being designed
3. To understand important biomarkers for patients receiving IO agents
4. To understanding ongoing proteomic research efforts
5. To better understand the translational research efforts of NRG Oncology.

WORKSHOP AGENDA

4:00 – 4:05 Opening Remarks and Introduction
Michael Birrer, MD, PhD
Adam Dicker, MD, PhD
Matthew Ellis, MB, BCHIR, PhD

4:05 – 4:20 CPTAC Updates
Matthew Ellis, MB, BCHIR, PhD (Baylor)

4:20 – 4:35 “Imaging & Informatics for Big Data in Multi-Site Trials: Innovation & Infrastructure”
David Fuller, MD, PhD (MD Anderson)

4:35 – 4:50 “High Immune Tolerance Associates with Poor Clinical Outcomes in Liminal Breast Cancer”
Meenakshi Anurag, Asst. Prof. (Baylor)

4:50 – 5:05 “Biomarker-Driven Patient Selection for Breast Cancer Immunotherapy”
Leisha Emens, MD, PhD (UPMC Hillman)

5:05 – 5:30 Closing Remarks and Discussion
Michael Birrer, MD, PhD
Adam Dicker, MD, PhD
Matthew Ellis, MB, BCHIR, PhD
Translational Science Brain Cancer Subcommittee and Low Grade Glioma Working Group

Thursday January 9th, 2020
Marriott Marquis, Houston, Texas
5:30 PM – 8:00 PM

Introduction
(Arnab Chakravarti, MD)

5:30 – 5:45
“The Utility of “Digital Twins” for Risk Stratification of CNS Malignancies”
(Sanjay Aneja, MD, Yale University)

5:45 – 6:00
“Identifying Genetic Risk Factors Using a SNP-Set Analysis of Genome-Wide Association Data- Example on ALS- Proposal for Gliomas”
(Prof. Dr. Pierre Robe, UMC Utrecht)

6:00 – 6:15
“NFKBIA Haploinsufficiency in Diffuse Glioma”
(Markus Bredel, MD, PhD, University of Alabama at Birmingham)

6:30 – 6:45
“miRNAs and GBM: Biomarkers & Mechanisms”
(Tiantian Cui, Ohio State University)

6:45 – 7:00
“Update of Correlative Endpoints within NRG/RTOG Low-Grad Glioma Trials”
(Erica Bell, PhD, Ohio State University)

7:00 – 7:15
“Assessing Circulating Tumor DNA in Pediatric Brain Tumors”
(Rameen Beroukhim, MD, PhD, Dana-Farber Cancer Institute)

7:15 – 7:30
“Update: Prognostic and Predictive RNA Biomarkers in NRG/RTOG 9802 & 9813”
(Jessica Fleming, PhD, Ohio State University)

7:30 – 7:45
“Reconstruct Three-Dimensional Chromosome Structures of Low Grade Glioma Using Infinium 450K Methylation Array”
(Wei Weng, Ohio State University)

7:45 – 8:00
Roundtable Discussions
Translational Science GYN Workshop

Date: Friday, January 10, 2020
Start and End Time: 4:00 pm – 6:00 pm
Chair: Michael Birrer, MD, PhD
Co-Chair: Heather Lankes, PhD, MPH

Learning Objectives:
Following this activity, participants will be better able to:

1. Understand GYN translational science conducted by NRG and discuss GYN translational science projects.
2. Understand the organization and operations of the NRG Biospecimen Banks.
3. Understand the NRG biospecimen access process.
4. Assure strict quality control of NRG clinical trials, including GYN translational science.

WORKSHOP AGENDA

4:00-4:05 Opening Remarks
   Biospecimen Bank/Translational Science Update
   Michael Birrer, MD, PhD
   Heather Lankes, PhD, MPH

   GYN Subcommittee Translational Science Updates
   • update on select trials approved at July 2019 meeting
   • summary of disease site January 2020 concept review, including issues raised

4:05-4:35 Ovarian Cancer Subcommittee
   Rare Tumor Subcommittee
   Rebecca Arend, MD
   Elizabeth Swisher, MD
   Gloria Huang, MD

4:35-5:05 Cervix/Vulva Cancer Subcommittee
   Dmitriy Zamarin, MD

5:05-5:35 Uterine Corpus Cancer Subcommittee
   210 Subcommittee
   Doug Levine, MD
   David Mutch, MD

5:35-5:55 GYN Developmental Therapeutics
   Panagiotis Konstantinopoulos, MD, PhD

5:55-6:00 Closing Remarks
   Michael Birrer, MD, PhD

New Concepts:

- **CV2005**: A Phase II Study of Combined chemo-immunotherapy with cisplatin-pembrolizumab and radiation for unresectable vulvar squamous cell carcinoma (Olapado Yeku)
- **OV2008**: A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)
• **DT2010**: Phase II study of dasatinib in recurrent low grade endometrial stromal sarcoma (Lilian Gien)
• **DT2013**: CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corrine Doll)
• **UC2006**: Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer: Additional arm NRG-GY012 protocol (Haider Mahdi)
Translational Science Lung Cancer Workshop Agenda

Date:     Friday, January 10, 2020
Start/End Time:  4:00 pm – 6:00 pm
Chair:     Bo Lu, MD, PhD

Learning Objectives:
Following this activity, participants will be better able to:
2. Use of ICIs in Treating Stage III NSCLC.

WORKSHOP AGENDA

Intro/Overview:     Bo Lu, MD, PhD

Speaker:      James Welsh (MD Anderson)
Presentation Title:  “Using Radiation to Overcome Immune Resistance”

Speaker:      Steven Lin (MD Anderson)
Presentation Title:  “Tankyrase as an Upstream Negative Regulator of LKB1 and Implications in Lung Cancer Immunotherapy”

Speaker:      Salma Jabbour (Rutgers)
Presentation Title:  “Checkpoint Inhibition in Stage III NSCLC”

Speaker:      Feng-Ming (Spring) Kong (Case Western)
Presentation Title:  “Deep-Machine Learning to Build Biomodel for Outcome Prediction”

Speaker:      Will Singleterry (IsoPlexis)
Presentation Title:  “Single Cell Proteomics Correlate with Immunotherapy Clinical Outcomes by Evaluating the Functional Changes of Immune Cell Subsets”

QUESTIONS / DISCUSSION
Health Disparities Committee
Friday, January 10, 2020
3pm-5pm
Agenda

Chairs: Chanita Hughes Halbert, PhD
Kate Yeager, PhD, RN, MS

Welcome/Announcements
- HD committee membership update

HDC Research Concepts/Protocol Updates

Clinical Trial Enrollment
- Health Disparity Resources & Support for NRG Committees/Protocols/Sites
- Statistics/Metrics
  - SDMC Reports
- Protocol Operations Management Committee (POMS)

CPC Grants- HDC support for:
- CC005/FOSTE
- CC008/Salpingectomy
- Other

NRG Communications Committee /Patient Engagement Working Group
- Website Patient Landing Pages
- Social Media
- NRG Member Communications

Education/Training/Mentorship
- HDC Workshop - July 2020 (Community Outreach/Engagement)

NRG Committee Reports - HDC Disease Site Liaisons

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<tr>
<th>Disease Site</th>
<th>Liaison</th>
<th>Alternate</th>
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<tr>
<td>Breast</td>
<td>Eleanor Walker</td>
<td>(Alternate: Kathie-Ann Joseph)</td>
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<tr>
<td>Brain</td>
<td>Na Tosha Gatson</td>
<td>(Alternate: Marianne Matzo)</td>
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<td>GI</td>
<td>Edith Mitchell</td>
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<td>GU</td>
<td>Mack Roach</td>
<td>(Alternate: Leon Hwang)</td>
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<tr>
<td>Gyn-Ovarian</td>
<td>Melissa Simon</td>
<td>(Alternate: Dana Chase)</td>
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<tr>
<td>Gyn-Cervix</td>
<td>Wendy Brewster</td>
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<tr>
<td>Gyn-Uterine</td>
<td>Anuja Jhingran</td>
<td>(Alternate: Marianne Matzo, Kathleen Darcy)</td>
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<td>Head &amp; Neck</td>
<td>Steven Chang</td>
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<tr>
<td>Rare Tumors</td>
<td>Mary Scroggins</td>
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<td>Lung (Thoracic)</td>
<td>Tom Simon</td>
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<td>Older Adult Working Group</td>
<td>William Tew</td>
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<td>Protocol Support Committee (PSC)</td>
<td>Tiffany Elsea, Donna White</td>
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NCORP Overview
- Cancer Prevention & Control (CPC)
- Cancer Care Delivery Research (CCDR)
- Patient Centered Outcomes Research (PCOR)

Other Business / Discussion
Imaging Committee Meeting Agenda

Date: Friday January 10, 2020
Start and End Time: 12:30pm – 2:30pm Central time
Chair Daniel Pryma, MD
Co-Chairs James Fink, MD, Amy Fowler, MD, PhD, Rathan Subramaniam, MD, PhD
Mark Rosen, MD, Ying Xiao, PhD, Feng-Ming (Spring) Kong, PhD, MD

MEETING AGENDA

12:30-12:35  Opening Remarks  Dan Pryma, MD
12:35-12:50  Report from IROC on Imaging QA in NRG trials  Mark Rosen, MD
12:50-1:00  Updates on Concepts near Development
  a. H&N  Rathan Subramanian, MD/ Min Yao, MD
  b. Brain  Tammy Benzinger, MD / Ashok Srinivasan, MD
  c. Breast  Heidi Umphrey, MD / Mohammad Eghtedari, MD
  d. Gyn  Katherine Maturen, MD / Aradhana Venkatesan, MD
  e. GI  Eric Tamm, MD
  f. GU  Ashesh Jani MD / Bill Hall, MD
  g. Lung  Michelle Ginsberg, MD
  h. Sarcoma  Dan Pryma, MD

1:00-1:30  HN006: PET/CT, Sentinel lymphoscintigraphy with SPECT/CT and Radiomic Analyses  Rathan Subramaniam, MD
1:35-1:50  Questions, comments, concerns & suggestions  Dan Pryma, MD
1:50-2:10  Discussion of BIQ for GU009 (GU1864)  Ashesh Jani, MD
2:10-2:30  Functional Imaging Correlates for LU1746  Dr. Steven Lin, MD
Medical Oncology Workshop

Date: Saturday, Jan 11, 2020
Start and End Time: 7:00 am - 8:00 am
Chairs: Corey Langer, MD; Deborah Armstrong, MD

Learning Objectives
Following this activity, participants will be better able to:

1. Address the role of biosimilars in current practice and clinical trials
2. Discuss initiatives to harmonize carboplatin dosing in NRG trials
3. Identify opportunities for biomarker specific, disease agnostic approvals by the FDA of new agents
4. Determine the role of NRG Med Onc in ongoing NCI Combo-MATCH and I-MATCH programs
5. Update therapeutic breakthroughs in major disease entities from ASCO 2019 and ESMO 2019
6. Provide salient updates on NRG clinical trial developments

WORKSHOP AGENDA

I. Introductions
   Corey Langer, MD; Deborah Armstrong, MD

II. Pharmacy Subcommittee
   A. Biosimilars – NRG Accommodations and Implications
   B. Carboplatin Dosing Harmonization and Position Paper
   C. Update on Protocol Drug Information Database/Forms and Review Process
   Judith Smith Pharm.D

III. Marker Specific, Disease Agnostic FDA Approvals
     Corey Langer, MD

IV. Combo MATCH
    Roisin Ocearbhaill, MD
    Stu Wong, M

V. I-MATCH
   Corey Langeer, MD

VI. Critical post-ASCO and ESMO updates
    Corey Langer, MD; Deborah Armstrong, MD

VII. Other business
     Corey Langer, MD
     Deborah Armstrong, MD

QUESTIONS / DISCUSSION
Pharmacy Subcommittee Workshop

Date: Friday, January 10, 2020
Start and End Time: 7:00 am – 8:00 am
Chair: Judith Smith, Pharm.D.

Learning Objectives:
Following this activity, participants will be better able to:

1. Compare and Contrast the efficacy, safety and cost of the recently approved FDA Biosimilar Ttastuzamb and bevacizumab biosimilars.
2. Discuss the clinical considerations of for substitution of biosimilars in clinical trials.
   a. Appreciate the logistics and financial implications of not allowing biosimilar substitutions.
3. Understand the rationale and benefits of standardizing drug information for research protocols.
4. Explain the primary aspects for standardizing patient variables for dosing carboplatin.
5. Discuss the role of standardization of pre-medication components.

WORKSHOP AGENDA

I. Introduction (2 min)
   a. Committee purpose and goals

II. CE Presentation: “Integration of the FDA-Approved Biosimilars into Clinical Trials setting: benefits and limitations” – Judith A. Smith, PharmD, BCOP, CPHQ (25 min)

III. Update on Placebo position statement (3 min)

IV. Planning to have updates from Disease State NRG Committee Meetings (10 min)
   a. Approval of standardized pre-medications for chemotherapy templates

V. Draft of Biosimilars Position/Policy review/discussion (15 min)

VI. Updates for CTEP Pharmacy Team (5 min)

VII. Action Items/Summary

QUESTIONS / DISCUSSION
Immunotherapy and Immune Modulation Committee Workshop

Date: Thursday, July 8, 2020 -
Start and end time: 2:00 PM – 4:00 PM
Chair: Samir N. Khleif, MD
Co-Chairs: Mark Einstein, MD
Arta Monjazeb, MD, PhD
Stephen Shiao, MD, PhD
Kristina Young, MD, PhD
Harry Bear, MD, PhD
Steven Finkelstein, MD, FACRO

Learning Objectives:
Following this activity, participants will be better able to:

1. Participants will become familiar with the current status of Immunotherapy studies that are under development or activated for accrual.
2. New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents (as appropriate).
3. Integration and prioritization of studies will be reviewed with reference to disease-site committees and the Committee on Experimental Medicine.
4. Recommendations for action by the Protocol Development Committee will be summarized.

New Concepts for Review and Discussion:

To be added

Active Protocols:

- **GOG 265**: ADXS11-011 in persistent/recurrent Cervical Cancer- (PI W. Huh)
- **NRG-GY002 (NCI LOI 9719)**: A phase II evaluation of nivolumab (BMS-936558), a fully human antibody against PD-1, in the treatment of persistent or recurrent squamous or non squamous cell carcinoma of the cervix. (Alessandro D. Santin M.D., Michael Frumovitz, MD, MPH)
- **NRG-GY003**: Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent High-Grade Serous Adenocarcinoma of Ovarian, Primary Peritoneal. Fallopian Tube or Endometrial Origin. (PI: Robert A. Burger, MD)
- **GY-016**: Phase 2 trial of pembro + epacadostat for recurrent clear cell ovary (PI Lilian Gien)
- **GOG-9929**: A Phase I Trial of Atezolizumab with Chemoradiation for the Primary Treatment of Patients with Stages IB2-IVA Cervical Cancer (PI Jyoti Mayadev, M.D.)
- **NRG GY017**: Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer (PI: Joyti Madayev)

Recently Reviewed Immunotherapy Concepts:

- **LU005**: Limited stage small cell lung cancer: A phase II/III randomized study of chemoradiation versus chemoradiation plus anti PD-1 immunotherapy (PI: Kristin Higgins, MD and Helen Ross, MD)
It activated on May 28th and ready to enroll

- **GY018**: Prospective randomized phase 3 trial of carboplatin and paclitaxel with or without pembrolizumab in the treatment of primary advanced stage (3 or 4) or recurrent endometrial cancer (Ramez N. Eskander, MD & Amanda N. Fader, MD) received final approval from CTEP and CIRB today, and it should be open and active to accrual shortly.

- **GY021**: A randomized phase II trial of olaparib + tremelimumab vs platinum-based physician choice chemotherapy in HRD+ and HRD- platinum sensitive recurrent ovarian cancer (PI: Sarah Adams, MD) CTEP approved and the NRG number is now GY021. Target activation 3Qtr2019. he study was submitted to CIRB last week. It was also selected for the CIMAC program for translational studies in collaboration with the MDACC team which I’m very happy about.

- **DT1831**: A Phase II study of combination pegylated liposomal doxorubicin with durvalumab in women with microsatellite stable recurrent endometrial cancer (PI: Bradley Corr MD) Protocol will not move forward

- **UC1844** Efficacy of second line immunotherapy with dual checkpoint inhibitors (CPI) vs. monotherapy in patients with deficient mismatch repair system or POLE mutated recurrent endometrial carcinoma: A randomized phase II trial (PI: Haider Mahdi, MD, MPH) Changed from a Phase 2 to a Phase 2/3 depending on the arm that is best in the phase II. Using Nivo in MSI EMCA. Discussion over whether this should be a bucket trial with other MSI tumors.

- **NRG RT1849** (PI Danielle Vicus) A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors.
  
  concept has successfully passed through RSC and a conf call with NCI is scheduled for next week

- **NRG-DT1911** (PI Dmitriy Zamarin) A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with paclitaxel and carboplatin in patients with recurrent platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer. the concept was approved by Research Strategy. Based on the feedback from the OTF and the overall lack of enthusiasm for nivolumab/carbo/taxol arm (based on negative data from Javelin 100), we decided to drop the arm. The trial has been modified to standard chemo+/ bev (or PARP maintenance per physician choice) vs. carbo/taxol/ipi/nivo. It is going for GCSC review next month. Keeping my fingers crossed.

- **NRG-RT1906** (PI John Farley) A randomized Phase II/III trial of chemotherapy versus pembrolizumab versus radiation therapy in the treatment of Stage IC 2,3 and II Ovarian or fallopian tube Clear Cell Carcinoma On hold

- **BN1855**: Randomized Phase III Open Label Study of Ipilimumab and Nivolumab vs Temozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-methylguanine DNA Methyltransferase) Glioblastoma. (PI: Andrew Lassman)
Submitted to BMSC for Review on February 14, 2019 meeting.

- **HN1854**: An open-label, placebo-controlled phase III study of cisplatin-gemcitabine with or without PD-1 inhibitor in the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma

  NRG is aiming for March HNSC review.

- **NRG-CV1908 (PI Scott Glaser sglaser@coh.org)** Incorporation of HPV Status and Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva

  Pending

- **NRG-OV1913 (PI Jung-Min Lee Leej6@mail.nih.gov)** A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab

  Pending

- **UC1814**: A phase III randomized study of carboplatin, paclitaxel, atezolizumab, and bevacizumab plus atezolizumab and bevacizumab maintenance versus carboplatin, paclitaxel, bevacizumab and bevacizumab maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer (PI: Debra L. Richardson, MD)

- **NRG-DT1907**: Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer (PI: Floor Backes, MD, Co-PI: David O’Malley)

- **NRG-BN1856**: A Phase III Trial of Ipilimumab + Nivolumab vs Ipilimumab + Nivolumab + Stereotactic Radiosurgery (SRS) for Melanoma Patients with ≤ 15 Symptomatic Brain Metastases (PI: Paul Spreduto, MD)

- **CV1964** Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (PI: Scott Glaser)

- **RT1969** A phase II trial of Nivolumab, Ipilimumab with Sargramostim for recurrent clear cell ovarian cancer (PI: Danielle Vicus)

- **LU1866**: Phase II Trial of Consolidation XRT + Immunotherapy for ES-SCLC (PI: James Welsh, MD; Stephen Chun)

- **DT1952** Phase II study investigating the efficacy of rationale combination immunotherapy in recurrent endometrial cancer with deficient mismatch repair system post progression on anti-PD1 therapy (PI: Haider Mahdi)
**Protocol Support Committee**  
Introduction to Clinical Trials: Principles of Clinical Trial Management

**Date:** Thursday, January 9, 2020  
**Start and End Time:** 7:30 am – 4:10 pm

**Facilitators:** Sharon Stockman BA, CCRP and Cindy Licavoli RN, BSN, MA

**Learning Objectives**

Following this activity, participants will be better able to:

1. Discuss NRG Oncology membership requirements
2. Describe the events leading up to the development of IRB’s
3. Describe the roles and responsibilities of the IRB relative to the performance of clinical research involving human subjects
4. Describe the roles and responsibilities of clinical research sites in following IRB regulatory and ethical requirements
5. Describe the processes to be followed by clinical research sites in adhering to IRB requirements
6. Describe the standard drug accountability procedures for NCTN trials
7. List resources for additional information regarding investigational drug
8. Describe the basic methodology of RECIST 1.1 and other response criteria used in NRG Oncology trials
9. Discuss RECIST 1.1 criteria as well as other response criteria used and identify methods of source documentation
10. Describe how to record the RECIST information to facilitate data submission
11. Identify proper forms of source documentation
12. Describe useful tools and methods to ensure timely and accurate data management in the clinical trial setting
13. Describe procedures for completion and submission of case report forms
14. Identify methods for screening patients for clinical trials
15. Identify the informed consent process according to federal regulations and local practices
16. Explain the clinical trial enrollment process
17. Navigate in the RAVE system
18. Utilize basic commands to key data into the RAVE system
19. Describe the key components of serious adverse event assessment including term selection, grading and attribution
20. Discuss the importance of QOL components to our trials
21.
22. Discuss protocol requirements for administration of chemotherapy, immunotherapy, radiation therapy and surgery
23. Discuss the nature of and preparation for NCI-mandated Quality Assurance Audits
24. Discuss the basics of pathology and translational research specimen requirements and submissions

**AGENDA**

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<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30am-7:40am</td>
<td>Welcome</td>
<td>Sharon Stockman, BA, CCRP &amp; Cindy Licavoli RN, MA</td>
</tr>
<tr>
<td>7:40am-7:55am</td>
<td>NRG Oncology Overview</td>
<td>Kati Stoermer, MSBA</td>
</tr>
<tr>
<td>7:55am-8:15am</td>
<td>NRG Membership</td>
<td>Mimi Passarelllo, MBA</td>
</tr>
</tbody>
</table>
8:15am-8:45 am  IRB’s: Who, What, Where, When and How  Lynne Lippmann, BA, CCRP
8:45 am-9:15 am  Serious Adverse Event Reporting  Sara McCartney, MS, RN
9:15 am-9:35 am  Investigational Drug Management  Nancy Knudsen, RN, BSN
9:35 am-9:50 am  Break
9:50 am-10:15 am  Medidata Rave  Joseph Mroziak
10:15 am-10:45 am  Quality Assurance Audits  Tamara McLaughlin, MHA, MPH
10:45 am-11:10 am  Pathology/Biospecimen Collections  Lisa Beaverson, BA, CCRP
                     Sandy DeVries, MA
11:10 am-11:40 am  RECIST  Mark Shahin, MD
11:40 am – 11:50 am  Mentorship Program  Nancy Fusco, RN, BSN
11:50 am – 12:00 p.m  QOL  Sharon Stockman, BA, CCRP
12:00 am – 12:05 pm  Morning Closing Remarks  Sharon Stockman, BA, CCRP
12:05 pm – 1:15 pm  Lunch (on your own)
1:15 pm – 4:10 pm  Afternoon Breakout Sessions- All sessions run concurrently (40 minutes/session)

**Topic**  
**Patient Screening and Enrollment**  
*Lead Facilitator*- Cindy Licavoli, RN, BSN, MA  
Joni Shortt, RN, BSN, CCRC
Tiffany Elsea, BA, CCRP

**Treatment Modalities in Clinical Trial Management**  
*Lead Facilitator*- Joyce Neading, RHIT, CTR  
Chrisann Winslow, RN, MSN
Karen Holeva, BS

**Data Management**  
*Lead Facilitator*- Lynne Lippmann, BA, CCRP  
Sue Eaton, CCRP
Whitney Jacobson, RN, BSN, CCRP

**Adverse Event Reporting**  
*Lead Facilitator*- Mary Smrekar, RN, MSN, CNP  
Donna White, RN, BSN, OCN
Alison Ivey, RN, MS, OCN, CCRP

4:10pm – 4:30pm  
Evaluation

QUESTIONS/DISCUSION
EVALUATION
Protocol Support Committee Workshop  
Education & Training Working Group (CLOSED)

Date: Thursday, January 9, 2020  
Start and End Time: 4:30 pm – 6:30 pm  
Chair: Susan Nolte, PhD, CRNP  
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
Working Group Facilitators: Karen Holeva, BS, Melinda Weiblen, BS

Learning Objectives
Following this activity, participants will be better able to:
1. Discuss alternative methods of education
2. Provide the PSC with potential topics and speakers for the 2020 Summer Meeting & 2021 Winter Meeting
3. Have a structured working group agenda

WORKSHOP AGENDA
1. Welcome
2. Announcements
3. Discuss progress of working group
   a. Conference Call Frequency
   b. Create Sub Groups
4. Discuss plans for Summer 2020 meeting
5. Suggestions for Winter 2021 meeting

QUESTIONS/DISCUSSION  
EVALUATION
Protocol Support Committee Workshop
Mentorship Working Group (CLOSED)

Date: Thursday, January 9, 2020
Start and End Time: 4:30pm – 6:30pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Working Group Facilitators Nancy Fusco RN, BSN, Sue Eaton CCRP

Learning Objectives:
Following this activity, participants will be better able to:

a. Identify potential new topics for the Introductory Materials
b. Discuss the development of mentor program tools
c. Review the effectiveness of the mentor program

Workshop Agenda:
**First hour: meeting with mentors

1. Roll call of Mentorship Working Group members and mentors
2. Update from Quality Control Working Group Liaison:
3. Announcements:
4. Mentor updates: Reports from mentors

**Second hour: Working Group members only for business meeting

5. Approval of minutes from most recent conference calls:
6. Review committee member number of participants:
7. Mentor Conference Call Reports: Sue and Mary
8. Review ongoing projects for the working group:
   a. Introductory Materials For NRG Oncology Research Clinical Trials Coordinators:
      i. Annual review: Review of sections assigned
      ii. Discuss new topics to include: Topic list
   b. Mentor working group documents:
      i. Review due in July of 2021
   c. Mentor Program:
      i. Development of Mentorship Program tools: New tools as needed
      ii. Lead/Second Lead mentor report
      iii. New updates regarding the program: Monitoring of effectiveness
      iv. Mentor/Mentee evaluations

9. Meeting Plan: Monthly conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

QUESTIONS/DISCUSSION
EVALUATIONS
Protocol Support Committee Workshop
Protocol Review Working Group (CLOSED)

Date: Thursday, January 9, 2020
Start and End Time: 4:30pm-6:30pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Working Group Facilitators Terry Thomas MS, CCRC, Nancy Knudsen RN, BSN

Learning Objectives
Following this activity, participants will be better able to:
1. Review current process of circulating protocols for review
2. Discuss the tracking form for the protocol working group reviewer responses
3. Discuss current method for updates and corrections of existing protocols
4. Discuss additional ways the working group can assist the protocol development teams.
5. Discuss the role the protocol review committee identifying issues and concerns for the other working groups like education and mentor to review/discuss
6. Discuss current procedures and approval with CTSU, protocol development and CIRB

WORKSHOP AGENDA
Call to order
Intro new members
Circulate Roster for approval and Protocol review Sheet
Intro Guests

Agenda Items
1. Review current Protocol review process.
2. Update from the Protocol Development team.
   a. Protocol template
   b. Protocol team discussion
   c. Development of standard protocol guidelines across NRG protocols
3. CIRB update
4. CTSU update
5. NRG regulatory
6. Update from Quality Control representative
7. Other business

QUESTIONS/DISCUSSION
EVALUATION
Protocol Support Committee Workshop
Quality Control Working Group (CLOSED)

Date: Thursday, January 9, 2020
Start and End Time: 5:30pm – 7:00pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Working Group Facilitators Joyce Neading CTR (retired), Michele Lacy RN, BSN, OCN

Learning Objectives
Following this activity, participants will be better able to:

1. Describe the role of the Quality Control Working Group’s relationship with the other PSC Working Groups.
2. Define the relationship between the Quality Control Working Group and the Quality Assurance/Audit Team.

Workshop Agenda
1. Review and approval of minutes from July 2019 meeting
2. Introductions/Welcome
3. Quality Assurance /Audit Team Liaison report/discussion
4. Working Group Liaisons report
   b. Education and Training Working Group – Robin Burgess
   c. Mentorship Working Group – Karyn Hart
5. Follow up on new projects
6. New Business

QUESTIONS/DISCUSSION
EVALUATION
Protocol Support Committee Workshop
Clinical Trial Nurse Subcommittee and Clinical Research Associate Subcommittee (JOINT MEETING/ CLOSED)

Date: Friday, January 9, 2020
Start and End Time: 7:00am – 9:00am
PSC Chair: Susan Nolte, PhD, CRNP
PSC Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
CTN Chair: Cindy Licavoli RN, BSN, MA,
CTN Co Chairs: Nancy Fusco RN, BSN, HeeSun Kim-Suh RN
CRA Chair: Sharon Stockman BA, CCRP
CRA Co-Chairs: Karen Holeva BS, Joyce Neading RHIT, CTR

Learning Objectives:
Following this activity, participants will be better able to:

1. Identify, describe and discuss aspects of RAVE Set-Up and how Committee Members can assist with review process
2. Identify, describe and discuss aspects of roles and responsibilities for the PSC Working Groups
3. Identify, describe and discuss the purpose and expectations of individual appointments to committees/working groups
4. Identify and discuss educational needs of both new and experienced CRAs/Nurses
5. Discuss the current activities of NRG Committees by CTN/CRA representatives

Agenda:
1. RAVE Overview and Discussion with Headquarters Representative(s)
2. Working Group Reports
   a. Protocol Review
   b. Education and Training
   c. Quality Control
   d. Mentorship
3. Discuss roles and responsibilities for appointments to NRG Oncology committees
4. Review Meeting Programs (Introduction to Clinical Trials)
5. Discuss meeting schedules and educational needs
6. Newsletter articles
7. Future meeting planning
8. Other business

QUESTIONS/DISCUSSION
EVALUATION
Protocol Support Committee Workshop
Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session

Date: Friday, January 10, 2020
Start and End Time: 2:00pm - 6:00pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Program Facilitators: Karen Holeva, BS, Melinda Weiblen, BS, Chrisann Winslow RN, MSN
Room:

Learning Objectives
Following this activity, participants will be better able to:

1. Describe tools on the CTSU website
2. Discuss the purpose of Institutional performance reports
3. To understand the role of patient reported outcomes (PROs) in cancer clinical trials
4. To understand the options for PRO assessment and analysis
5. To explore new frontiers in PRO assessment and opportunities for NRG Oncology to lead the way
6. Discuss the intersection of patient autonomy and the health care provider’s moral duty to render evidence-based care in the cancer research population
7. To recognize the caregiver’s role in leading nuanced compassionate discussions of how to best meet patients’ goals according to patients’ values (i.e what matter most to them)
8. To discuss the rationale for the request of non-medically indicated treatment & requests for violations of protocol care
9. To address the dual role of researcher/provider in clinical trials: an analysis of potential pressure for patient to receive “protocol driven” treatment
10. To identify moral distress in self or others which can contribute to (or result from) patient/family requests or “protocol specific” requirements
11. To identify breast cancer risk factors
12. To explain breast cancer pathology
13. To describe breast cancer diagnosis in relationship to treatment
14. To construct risk factors, pathology diagnosis and treatment in relationship to clinical trials

AGENDA

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<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
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<tbody>
<tr>
<td>2:00-2:10</td>
<td>Introduction/Welcome</td>
<td>Karen Holeva, BS</td>
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<tr>
<td>2:10-2:20</td>
<td>Welcome</td>
<td>Katie Stoermer, MSBA</td>
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<td>Executive Director, NRG Oncology</td>
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<td>2:20-3:00</td>
<td>Updates and information from CTSU</td>
<td>Amanda Fournier</td>
</tr>
<tr>
<td>3:00-3:25</td>
<td>Update on NRG Oncology QA Audits, monitoring and Institution Performance reports</td>
<td>Mimi Passarello, MBA</td>
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<tr>
<td>3:25-3:35</td>
<td>break</td>
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<tr>
<td>Time</td>
<td>Event</td>
<td>Presenter(s)</td>
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<tr>
<td>3:35-4:20</td>
<td>Patient reported outcomes: Why we do it and how we do it</td>
<td>David Cella, PhD</td>
</tr>
<tr>
<td>4:20-5:05</td>
<td>Ethics related to care of the Oncology research</td>
<td>Karen Iseminger PhD, ANP-BC, FNP</td>
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<td>Patient: moving concern to courage</td>
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<tr>
<td>5:05-5:50</td>
<td>Basics of Breast Cancer</td>
<td>Brenda Lee Steele BSN, RN, OCN, CCRC</td>
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<tr>
<td>5:50-6:00</td>
<td>Questions and evaluation</td>
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Radiation Development Therapeutics Workshop

Date: Friday January 10, 2020
Start and End Time: 12:30 pm - 2:00 pm
Chairs: Steven Lin, MD PhD and Sandip Patel, MD

Learning Objectives

Following this activity, participants will be better able to:
1. Critically appraise optimal statistical designs for phase I trials
2. Evaluate the landscape of early phase drug-radiation combination studies at the NRG

WORKSHOP AGENDA

I. Introduction
   A. General Business

II. Scientific Talk: Statistical Considerations for Designing and Conducting a Phase I Clinical Trial
   Pedro Torres-Saavedra, PhD
   15 min

III. Basket Trial concept under development: RadScopal trial
     James Welsh, MD
     10 min

IV. Disease Site Working Group Updates
   a. Sarcoma: DT001: A Phase IB Trial of Neoadjuvant AMG-232 Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma (STS) (Meng Welliver, MD)
      10 min

V. Disease Site Committee Updates
   a. Genitourinary (Committee Liaison: Chad Tang, MD)
      i. GU007— Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with INITIAL Phase I) (Pl: Dror Michaelson, MD)
      10 min
   b. Lung (Committee Liaison: Steven Lin, MD, PhD)
      i. LU004: Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined with MEDI4736 (Durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1)
      ii. New concept: Phase II randomized trial with safety run-in of consolidation N-803 after chemoradiation
      10 min
   c. GI-non colorectal (Committee Liaison: Terence Williams, MD)
      i. GI007: Phase I trial with expansion cohort of opb-301 (telomelysin) and definitive chemoradiation for patients with locally advanced esophageal and gastroesophageal adenocarcinoma who are not candidates for surgery (Pl: Geoffrey Ku, MD)
      10 min
   d. GI-colorectal (Committee Liaison: Theodore Hong, MD)
      i. GI002: A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer: Arm 3: AN0025
      10 min
   e. GYN (Committee Liaison: Jyoti Mayadev, MD)
      ii. New concept: Phase II Nelfinavir with radiation in vulvar cancer (Pl: Lillie Li, MD)
      10 min

QUESTIONS / DISCUSSION
Medical Physics Subcommittee Workshop Agenda

CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Date: Friday, January 10, 2010
Start and End Time: 2:30 pm – 4:30 pm
Chair: Ying Xiao, PhD
Co-Chairs Stanley Benedict, PhD

WORKSHOP AGENDA

2:30 – 2:35  Introductions / Subcommittee Updates  
Ying Xiao/Stanley Benedict, PhD

2:35 – 2:40  NCI Communications/NCTN Medical Physics  
Ceferino Obcemea, PhD

2:40 – 2:55  NRG QA Report  
- IROC Houston  
  Stephen Kry, PhD  
- IROC Philadelphia RT (Contouring & Dosimetry)  
  Ying Xiao, PhD  
- IROC Philadelphia Imaging  
  Mark Rosen, MD / Michael Boss, PhD

2:55 – 3:30  Disease Site Reports  
- Brain  
  Fangfang Yin fa/ Yunfeng Cui  
- Breast  
  X Allen Li / Jean Moran
- GI  
  Adam Yock / William Parker
- GU  
  Rajat Kudchadker / Robert Wallace
- GYN  
  Cecilia Lee / Hayeon Kim  
- H&N  
  Nataliya Kovalchuk / Ping Xia
- Lung  
  Martha Matuszak / Tim Solberg

3:30 – 3:40  Modality Technology Reports  
- Notable technologies  
  Zoufeng Li
- Monte Carlo Updates  
  Liyong Lin

3:40 – 4:15  Working Group and Other Updates  
- Adaptive QA  
  Carrie Glide-Hurst
- Deformable QA  
  Stan Benedict
- SBRT Practice Survey  
  Jason Sohn
- TRT Updates  
  Jacek Capala / Stan Benedict

4:15 – 4:25  Other Business/Discussions

4:25 – 4:30  Questions

4:30  Adjournment
### Proton Working Group Agenda

**CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)**

**Date:** Saturday, January 11, 2020  
**Start and End Time:** 7:00 am – 8:30 am  
**Chair:** Tom DeLaney, MD  
**Co-Chair:** Ted Hong, MD

#### WORKSHOP AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>7:00</td>
<td>Welcome/Introduction/ Moderator</td>
<td>Tom DeLaney, MD</td>
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<tr>
<td>7:05</td>
<td>Update on Proton Center Credentialing by IROC Houston</td>
<td>Paige Taylor, PhD</td>
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<tr>
<td>7:15</td>
<td>Protons in liver studies RTOG 1112 - Ph III Sorafenib +/- SBRT for hepatocellular ca (L. Dawson)</td>
<td>Laura Dawson MD, Ted Hong, MD</td>
</tr>
<tr>
<td>7:15</td>
<td>Protons in liver studies NRG-GI003 - Ph III Protons vs Photons for Hepatocellular Carcinoma</td>
<td>Laura Dawson MD, Ted Hong, MD</td>
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<tr>
<td>7:25</td>
<td>Brain Studies</td>
<td>Minesh Mehta, MD</td>
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<td>NRG-BN001 - Randomized Phase II Trial of Hypofractionated Dose- Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation w/ Concomitant /Adjuvant Temozolomide in Glioblastoma</td>
<td>Tom DeLaney, MD</td>
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<td></td>
<td>NRG-BN003 - Phase III Trial of Observation versus Irradiation for a Gross Totally Resected Grade II Meningioma</td>
<td>Tom DeLaney, MD</td>
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<tr>
<td></td>
<td>NRG-BN005 - A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas.</td>
<td>Tom DeLaney, MD</td>
</tr>
<tr>
<td>7:40</td>
<td>RTOG 1308 - Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable Stage II-IIIB NSCLC</td>
<td>Zhong Xing Liao, MD, Jeff Bradley, MD</td>
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<tr>
<td>7:50</td>
<td>NRG-HN001 - Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA): Addition of Protons</td>
<td>Annie Chan, MD, Tom DeLaney, MD</td>
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<td>7:55</td>
<td>Phase II/III Randomized Study of IMPT vs IMRT for Oropharyngeal CA</td>
<td>Steven Frank, MD</td>
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<tr>
<td>8:00</td>
<td>NRG-GI006 - Ph III Randomized Protons vs. IMRT Photon for Esophageal CA</td>
<td>Steven Lin, MD</td>
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<tr>
<td>8:10</td>
<td>PCORI (Patient-Centered Outcomes Research Institute) RADCOMP Breast Randomized Trial of Photons versus Protons</td>
<td>Shannon Macdonald, MD</td>
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<tr>
<td>8:15</td>
<td>COMPPARE (Comparative Study of Outcomes w/ Proton and Photon Radiation in Prostate Cancer) prostate Ca Study</td>
<td>Nancy Mendenhall, MD</td>
</tr>
<tr>
<td>8:20</td>
<td>Trial Proposal: SHIPP: Stereotactic Heavy Particles vs Protons vs Photons for Unfavorable Intermediate Risk Prostate Cancer</td>
<td>Mack Roach, MD</td>
</tr>
<tr>
<td>8:25</td>
<td>Other Business/Questions</td>
<td>Tom DeLaney, M.D.</td>
</tr>
</tbody>
</table>
Surgical Oncology Workshop

Date: Saturday, January 11, 2020
Start and End Time: 7:00 am – 8:00 am
Chair: John A “Drew” Ridge, MD, PhD
Co-Chairs: Nick Spirtos, MD
Thomas Julian, MD

Learning Objectives: Following this activity, participants will be better able to:

Following this activity, participant will be better able to:
1. Describe technological advances in surgical and radiation oncology for multiple NRG clinical disease sites.
2. Describe new approaches in medical oncology for multiple NRG clinical disease sites

Workshop Agenda

7:00 – 7:05 Welcome/Introduction /Approval of Minutes
7:05 - 7:15 Medical Oncology Update
7:15 – 7:25 Radiation Oncology Committee Update
7:25 – 7:55 Disease Site Liaison Reports (brief discussion of status with no more than a single slide)
   a. Brain
   b. Breast
   c. GI
   d. Gynecology
   e. Head and Neck
   f. Lung
   g. Urology

   *Liaison to provide a 5 minute update on latest surgical advancement

7:55 –8:00 Questions/Discussion
**An Introduction to NRG Oncology**  
*New Investigator Educational Session Agenda*

**Date:** Thursday, January 9, 2020  
**Start and End Time:** 4:00pm – 5:15pm, Brief Reception to Follow  
**Co-Chairs:** Elizabeth Gore, MD; Priya Rastogi, MD, Angeles Secord, MD  

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>4:00pm – 4:05pm</td>
<td>Introductory Remarks</td>
<td>Committee Co-Chairs</td>
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<tr>
<td>4:05pm – 4:15pm</td>
<td>NRG Oncology Update</td>
<td>Kati Stoermer</td>
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<tr>
<td>4:15pm – 4:30pm</td>
<td>NRG-GY018</td>
<td>Ramez Eskander, MD</td>
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<tr>
<td>4:30pm – 4:45pm</td>
<td>NRG NCORP</td>
<td>Lisa Kachnic, MD</td>
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<tr>
<td>4:45pm – 5:00pm</td>
<td>NRG Biospecimen Bank</td>
<td>Jeff Simko, MD</td>
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<tr>
<td>4:45pm – 5:00pm</td>
<td>NRG Ancillary Projects</td>
<td>Steven Waggoner, MD</td>
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<tr>
<td>5:15pm – 6:00pm</td>
<td>New Investigator Reception</td>
<td>To follow in same room</td>
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</table>
Canadian Members Meeting Workshop

Date:   Saturday, January 11, 2020
Start and End Time: 7:00 am – 8:00 am
Chair: Jean-Paul Bahary, MD
Co-Chairs: Andre Robidoux, MD; Al Covens, MD
NRG Oncology Operations: Kate Wiser (back-up representatives: Judy Langer and Erica Field)

Learning Objectives:
Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing NRG Oncology clinical trials available in Canada
2. Apply standards and procedures required to participate in a research protocol supported by NRG Oncology
3. Discuss the roles of the expanded Canadian Review Board for future clinical trials

WORKSHOP AGENDA

I. General
   Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest

II. Status of NRG Oncology trials open to accrual
   a. Accrual Update (June – December 2019)
      Discussion lead - NRG Oncology Regulatory

III. Optimizing accrual in Canada
   a. Discuss best practices for and barriers to optimizing accrual among Canadian sites
      Discussion lead - Canadian Members Co-Chairs

IV. New concepts and protocols
   a. CC008-A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROC] (Douglas Levine)

V. New Business, General Questions, Discussion, Next Meeting
   a. NRG and CCTG Membership Points Discussion

VI. Evaluation
AGENDA
NCORP PI & ADMINISTRATORS MEETING
SATURDAY, January 11, 2020
8:00 – 10:00 AM
Houston, TX

8:00 a.m.  Welcome  J. Walker, MD
8:05 a.m.  NCI NCORP Report  S. Russo, MD
8:15 a.m.  NCI CCDR Report  K. Castro, RN, MS
8:25 a.m.  Cancer Prevention and Control Committee/Overview of developing trials: NRG-CC005 and NRG-CC008  L. Kachnic, MD/D. Levine, MD
8:40 a.m.  Cancer Care Delivery Research Group  M. Cooley PhD, RN/M. Hudson, PhD, MPH
8:50 a.m.  Health Disparities Update  K. Yeager, RN, PhD/C. Hughes-Halbert, PhD
9:00 a.m.  Patient Centered Outcomes Research Committee  P. Ganz, MD
9:10 a.m.  Tips to increase interest and accrual NCORP site representatives
9:30  NCORP Credits and subcontract updates  Kati Stoermer
9:40 a.m.  Discuss Research Priorities at NCORP sites Q&A – Open Discussion
<table>
<thead>
<tr>
<th>NRG Main Member (Network)</th>
<th>CTEP ID</th>
<th>Accrued to NRG Studies and Credited to NRG</th>
<th>Accrued to Non-NRG NCTN Studies and Credited to NRG</th>
<th>Total</th>
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<td>Allegheny General Hospital</td>
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<td>AMITA Health Alexian Brothers Medical Center</td>
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<td>Arizona Center for Cancer Care-Peoria</td>
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NRG Oncology Winter 2020 Exhibitor Companies

NRG Oncology wishes to acknowledge the following exhibitors:

American College of Radiology
AstraZeneca
Best Medical International
Caris Life Sciences
Clovis Oncology, Inc.
Eisai Inc.
GSK
Imaging and Radiation Oncology Core (IROC) Group
Merck
OVARCOME
Prelude Dx™
Seattle Genetics
VBL Therapeutics
Xcision Medical Systems

Please take the time to visit the exhibit booths located in:

Texan Foyer - 4th Level

Exhibit hours are:

Friday, Jan 10, 2020 - 7:00 am - 5:00 pm
Saturday, Jan 11, 2020 - 7:00 am - 2:00 pm

Complimentary coffee, tea and soft drinks will be served in the exhibit area at specified times on each day that exhibits are open.
American College of Radiology

The American College of Radiology (ACR®) is a leading professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science, and professions of radiological care. ACR Accreditation and Appropriateness Criteria are the standards for safe imaging and patient care. The ACR’s 38,000 members include radiologists, radiation oncologists, nuclear medicine physicians and medical physicists. www.acr.org

Best Medical International

Best Medical International now encompasses a family of trusted companies and organizations with a proven track record of innovation, quality and service in external beam radiation therapy, brachytherapy and vascular brachytherapy solutions.

Caris Life Sciences

Caris Life Sciences® is a leading innovator in molecular science focused on fulfilling the promise of precision medicine through quality and innovation. The company’s suite of market-leading molecular profiling offerings assess DNA, RNA and proteins to reveal a molecular blueprint that helps physicians and cancer patients make more precise and personalized treatment decisions. Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Asia and other international markets. To learn more, please visit www.CarisLifeSciences.com or follow us on Twitter (@CarisLS).

Clovis Oncology, Inc.

Founded in 2009, Clovis Oncology (NASDAQ: CLVS) is a commercial stage biotechnology company focused on acquiring, developing and commercializing cancer treatments in the United States, Europe and other international markets.

Clovis’ product development programs generally target specific subsets of cancer, and the Company seeks to simultaneously develop, with partners, for those indications that require them, diagnostic tools intended to direct a compound in development to the patients most likely to benefit from their use.

GSK

GSK is focused on maximizing patient survival through transformational medicines. GSK’s pipeline is focused on immune-oncology, cell therapy, cancer epigenetics and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilizing modalities such as small molecules, antibodies, antibody-drug conjugates and cells, either alone or in combination. Please visit us at stand #11 for more information.

Merck

For more than a century, Merck has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. Today, Merck continues to be at the forefront of research to deliver innovative health solutions and advance the prevention and treatment of diseases that threaten people and animals around the world.

OVARCOME

Mission: To raise global awareness on ovarian cancer, to fund research in search of a cure, and to provide financial & psychosocial assistance to ovarian cancer patients in need. Ovarcome is inspired by the simple philosophy of support, love, and celebration of life.

Prelude Dx™

Prelude Dx, provider of DCISionRT®, a prognostic and predictive test for risk of recurrence and radiation therapy benefit for women diagnosed with DCIS, is pleased to provide information to help with individualized decision-making.

Seattle Genetics

Seattle Genetics, Inc. is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people’s lives. ADCETRIS® (brentuximab vedotin) utilizes the company’s industry-leading antibody-drug conjugate (ADC) technology and is currently approved for the treatment of multiple CD30-expressing lymphomas. Beyond ADCETRIS, the company has established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing or planned pivotal trials for solid tumors. Enfortumab vedotin for metastatic urothelial cancer and tisotum- ab vedotin for metastatic cervical cancer utilize our proprietary ADC technology. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies and targeted therapies to build a portfolio of programs for hematologic malignancies and solid tumors. The company is headquartered in Bothell, Washington, and has a European office in Switzerland. For more information on our robust pipeline, visit www.seattlegenetics.com and follow @ SeattleGenetics on Twitter.

Xcision Medical Systems

Xcision’s initial focus is on breast cancer, using stereotactic partial breast irradiation (S-PBI) to treat patients eligible for breast conserving therapy. The company’s first product, GammaPod™, is a new stereotactic radiotherapy system optimized for the treatment of breast cancer in one to five sessions. GammaPod has the potential to drive value in cancer care by dramatically shortening treatment times, improving patient reported outcomes, reducing side effects and obviating the need for surgery in select patients.
NRG Oncology Commercial Supporters

NRG Oncology would like to recognize and thank its commercial supporters for Independent Medical Educational Support associated with the 2020 Winter NRG Oncology Semiannual Meeting

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Pfizer
Seattle Genetics
Tesaro
Future NRG Oncology Semiannual Meetings

SAVE THE DATES

**July 16-18, 2020**
Marriott Marquis
Washington D.C.

**January 28-30, 2021**
Hyatt Regency New Orleans
New Orleans, LA

**July 22-24, 2021**
Philadelphia Marriott Downtown
Philadelphia, PA

**February 10-12, 2022**
Phoenix Convention Center
Phoenix, AZ

**July 21-23, 2022**
Hyatt Regency Chicago
Chicago, IL