NRG Oncology Semiannual Meeting

FINAL PROGRAM

JANUARY 25 - 27, 2018
PHOENIX CONVENTION CENTER, PHOENIX, ARIZONA
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It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Phoenix, AZ, January 25 - 27, 2018.

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 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, “Challenges in Design and Controls for Clinical Trials in Gynecologic Cancer” with noted Oncologists and Scientists serving as speakers and moderators. The speakers will focus their presentations on topics brought to light from recent clinical trials balanced against the expanding menu of therapeutic options and limited patient and financial resources. The perceived need to develop “me to assets” in overlapping treatment indications, particularly in the context of adequate and clinically-relevant controls, is profoundly limiting the potential throughput of the investigative progress. These and other topics will be addressed in an attempt to engage the audience in a discussion of the best next steps forward in clinical trials.

• A Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session will take place on Thursday – “Introduction to Clinical Trials: Principles of Clinical Trial Management”.

NRG Oncology research achievements will be featured during Friday’s Scientific Session, “NRG Oncology Research Review,” which will highlight the results of recently reported studies in ovarian and breast cancer as well as four recently activated trials in sarcoma and head and neck, lung, and prostate cancer.

At the NRG Oncology General Session on Friday, Group leadership will provide updates on topics of significance for our members and the research community.

We are very excited about NRG Oncology’s research potential and invite your input about how we can make future meetings as meaningful and productive as possible. Welcome to Phoenix!
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 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

NRG Oncology Semiannual Workshop CME Credits

Attendee sign-in sheets are located outside each CME session/workshop. Attendees must sign in as they enter the session. All sign-in sheets will be collected 30 minutes after the beginning of the CME session/workshop.

Evaluations/CME/Attendance Certificates

Overall evaluations are included in the Final Agenda Program Books. Print name clearly on the evaluation form as it appears on your badge. All evaluations must be submitted to CME department no later than six weeks after the completion of the meeting.

Attendees that have submitted their evaluation will receive a certificate by email with the total amount of credits received from the workshops for this meeting. (The symposium will not be included in the total) The correct email must be included on registration form.

If your name is not on the evaluation, you will not receive a certificate. Any questions regarding Evaluations/CME certificates may be directed to: jreese@gog.org

How to submit your evaluation:

Evaluations may be turned in at the CME desk after the completion of the meeting or sent via the following methods:

Mail: The GOG Foundation, Inc
      Attn: Lauren Shumaker
      2127 Espey Court #100, Crofton, MD 21114
E-mail: lcalhoun@gog.org.
Fax: 301-261-3972
Online: https://www.nrgoncology.org

Certificates will be emailed 4-6 weeks following the meeting.

NO EVALUATIONS WILL BE ACCEPTED AFTER: February 23, 2018.

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.
CONVERSE AND MEET

at the January 2018

NRG Oncology Semiannual Meeting

Stay up-to-date with updates and announcements from the NRG Oncology Semiannual Meeting 2018 on Twitter, Facebook and the Meeting App!

JOIN THE CONVERSATION ON TWITTER:@NRGONC

#NRG18

https://www.facebook.com/nrgoncology/

DOWNLOAD THE NRG ONCOLOGY MEETING APP

• Download EVENTSXD to your iOS, Android, Windows Phone or device to quickly access agendas, meeting room information and more!

• Sign up and login to select the NRG Oncology Semiannual Meeting from the list of meetings

• Access the Agenda and create your own personal agenda by tapping the green star to “favorite” specific sessions

WIFI

Complimentary wifi is available for meeting attendees:

Network Login: nrgmeeting   Passcode: n1r2g345
PHOENIX CONVENTION CENTER

WEST BUILDING  |  NORTH BUILDING

300 LEVEL
WEST BUILDING  |  NORTH BUILDING
45,200 SF West Ballroom  |  190,000 SF Exhibition Hall
Riser seating for 1,200

200 LEVEL
WEST BUILDING  |  NORTH BUILDING
21,000 SF Conference Center  |  43,000 SF Meeting Rooms
IACC Certified  |  192-Seat Lecture Hall

100 LEVEL
WEST BUILDING  |  NORTH BUILDING
27,200 SF Meeting Rooms  |  45,600 SF Ballroom
43,000 SF Meeting Rooms

LOWER LEVEL
WEST BUILDING  |  NORTH BUILDING
312,500 Total Combined SF Exhibition Hall
**Please be advised:**

All sessions/workshops in purple text will be held at the Hyatt Regency Phoenix – 122 N. 2nd Street

All sessions/workshops in red text will be held at the Sheraton Grand Phoenix – 340 N. 3rd Street

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am – 8:30 am</td>
<td>Symposium Breakfast</td>
<td>Convention-West 301AB/3rd Level</td>
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<tr>
<td>7:00 am – 6:00 pm</td>
<td>Registration/CME/Information Desk</td>
<td>Convention-West 301 Lobby/3rd Level</td>
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<tr>
<td>11:00 am – 11:15 am</td>
<td>Symposium Coffee Break</td>
<td>Convention-West 301AB/3rd Level</td>
</tr>
<tr>
<td>1:00 pm – 1:45 pm</td>
<td>Symposium Lunch</td>
<td>Convention-West 301AB/3rd Level</td>
</tr>
<tr>
<td>2:00 pm – 6:00 pm</td>
<td>IT Resource Room/Internet Café/Speaker Ready Room</td>
<td>Convention-West 104B/1st Level</td>
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<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Exhibit Setup</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>7:30 am – 4:30 pm</td>
<td>Introduction to Clinical Trials: Principles of Clinical Trial Management</td>
<td>Convention-West 301D/3rd Level</td>
</tr>
<tr>
<td>8:00 am – 1:00 pm</td>
<td>Imaging and Radiation Oncology Core (IROC) RT Focused Staff Meeting</td>
<td>Convention-West 106B/1st Level</td>
</tr>
<tr>
<td>8:00 am – 3:00 pm</td>
<td>Winter Symposium - “Challenges in Design and Controls for Clinical Trials in Gynecologic Cancer”</td>
<td>Convention-West 301AB/3rd Level</td>
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<tr>
<td>9:00 am – 12:00 pm</td>
<td>NRG DMC Panel A *</td>
<td>Convention-West 102B/1st Level</td>
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<tr>
<td>9:00 am – 1:00 pm</td>
<td>SOCR A Certification Exam</td>
<td>*Sheraton Hotel-Maryvale A/2nd Floor</td>
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<tr>
<td>12:30 pm – 1:00 pm</td>
<td>CCDR Leadership (Invitation Only)</td>
<td>Convention-West 213AB/2nd Level</td>
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<tr>
<td>1:00 pm – 2:00 pm</td>
<td>VisionTree Workshop</td>
<td>Convention-West 213C/1st Level</td>
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<tr>
<td>1:00 pm – 4:00 pm</td>
<td>CCDR Retreat (Invitation Only)</td>
<td>Convention-West 213AB/2nd Level</td>
</tr>
<tr>
<td>1:00 pm – 4:00 pm</td>
<td>NRG DMC Panel B *</td>
<td>Convention-West 213B/1st Level</td>
</tr>
<tr>
<td>1:15 pm – 4:10 pm</td>
<td>Introduction to Clinical Trials – Patient Screening &amp; Enrollment</td>
<td>Convention-West 210A/1st Level</td>
</tr>
<tr>
<td>1:15 pm – 4:10 pm</td>
<td>Introduction to Clinical Trials – Treatment Modalities</td>
<td>Convention-West 210B/1st Level</td>
</tr>
<tr>
<td>1:15 pm – 4:10 pm</td>
<td>Introduction to Clinical Trials – Data Management</td>
<td>Convention-West 210C/1st Level</td>
</tr>
<tr>
<td>1:15 pm – 4:10 pm</td>
<td>Introduction to Clinical Trials – Adverse Event Reporting</td>
<td>Convention-West 210A/1st Level</td>
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<tr>
<td>2:00 pm – 4:00 pm</td>
<td>Immunotherapy and Immune Modulation Workshop</td>
<td>Convention-West 211AB/2nd Level</td>
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<tr>
<td>2:30 pm – 4:00 pm</td>
<td>Comparative Effectiveness Research (CER) Committee *</td>
<td>*Hyatt Hotel-Remington A/2nd Floor</td>
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<tr>
<td>3:00 pm – 5:00 pm</td>
<td>Clinical Trials 101 – New Investigator Educational Session</td>
<td>Convention-West 210C/1st Level</td>
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<tr>
<td>3:00 pm – 5:00 pm</td>
<td>NRG-Harvard-Ohio State-Case Western R01 Grant Meeting*</td>
<td>Convention-West 106B/1st Level</td>
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<tr>
<td>4:00 pm – 6:00 pm</td>
<td>GYN Developmental Therapeutics/Phase 1/Translational Science Workshops</td>
<td>Convention-West 212ABC/2nd Level</td>
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<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Patient Centered Outcomes Research (PCOR) Workshop</td>
<td>Convention-West 211AB/2nd Level</td>
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<tr>
<td>4:30 pm – 6:30 pm</td>
<td>PSC Education &amp; Training Working Group *</td>
<td>*Hyatt Hotel-Russell ABC/2nd Floor</td>
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<tr>
<td>4:30 pm – 6:30 pm</td>
<td>PSC Mentorship Working Group *</td>
<td>Convention-West 210A/1st Level</td>
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<tr>
<td>4:30 pm – 6:30 pm</td>
<td>PSC Protocol Review Working Group *</td>
<td>*Hyatt Hotel-Borein A/2nd Floor</td>
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*Sessions for Committee Member*

Revised 1/8/18
### Thursday, January 25, 2018

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<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>5:00 pm – 7:00 pm</td>
<td>PSC Quality Control Working Group *</td>
<td>Convention-West 106B/1st Level</td>
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<tr>
<td>6:00 pm – 8:00 pm</td>
<td>NCORP Concept Review <em>(Invitation Only)</em></td>
<td>Convention-West 213AB/2nd Level</td>
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<tr>
<td>6:00 pm – 8:00 pm</td>
<td>NRG Oncology Japan Meeting</td>
<td>Convention-West 102B/1st Level</td>
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<tr>
<td>6:30 pm – 8:00 pm</td>
<td>Translational Science Workshop</td>
<td>Convention-West 105BC/1st Level</td>
</tr>
<tr>
<td>8:00 pm – 10:00 pm</td>
<td>Ancillary Projects Committee *</td>
<td>Convention-West 106B/1st Level</td>
</tr>
<tr>
<td>Time</td>
<td>Event</td>
<td>Location</td>
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<tr>
<td>6:30 am – 8:30 am</td>
<td>Continental Breakfast</td>
<td>Convention-West 301 Lobby/3rd Level</td>
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<tr>
<td>7:00 am – 5:00 pm</td>
<td>Exhibits</td>
<td>Convention-West 301 Lobby/3rd Level</td>
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<tr>
<td>7:00 am – 5:30 pm</td>
<td>Registration/CME/Information Desk</td>
<td>Convention-West 301 Lobby/3rd Level</td>
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<tr>
<td>7:00 am – 6:00 pm</td>
<td>IT Resource Room/Internet Café/Speaker Ready Room</td>
<td>Convention-West 104B/1st Level</td>
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<td>9:00 am – 1:00 pm</td>
<td>CTN/CRA Information Table</td>
<td>Convention-West 301 Lobby/3rd Level</td>
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<tr>
<td>10:00 am – 10:30 am</td>
<td>General Coffee Break</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>2:00 pm – 3:30 pm</td>
<td>General Coffee Break</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>6:45 am – 9:00 am</td>
<td>Patient Advocates Meeting *</td>
<td>*Hyatt Hotel-Borein B/2nd Floor</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>IROC RT/Imaging Credentialing Q&amp;A Session (1308, BN005, GI003)</td>
<td>Convention-West 101A/1st Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>GYN GTD Subcommittee</td>
<td>Convention-West 102B/1st Level</td>
</tr>
<tr>
<td>7:00 am – 8:00 am</td>
<td>GYN PDC Executive Session *</td>
<td>Convention-West 208B/2nd Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>Local Regional Breast Cancer Subcommittee *</td>
<td>Convention-West 105A/1st Level</td>
</tr>
<tr>
<td>7:00 am – 9:00 am</td>
<td>Clinical Trials Nurse/Clinical Research Associate Subcommittees Combined Meeting *</td>
<td>Convention-West 106A/1st Level</td>
</tr>
<tr>
<td>7:00 am – 9:00 am</td>
<td>Protocol 210 Subcommittee</td>
<td>Convention-West 213AB/2nd Level</td>
</tr>
<tr>
<td>7:00 am – 12:00 pm</td>
<td>GYN/RT Case Review</td>
<td>Convention-West 104B/1st Level</td>
</tr>
<tr>
<td>8:00 am – 9:00 am</td>
<td>NRG SDMC Executive Committee *</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>Ovarian Cancer Workshop</td>
<td>Convention-West 301C/3rd Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>Scientific Session – NRG Oncology Research Review</td>
<td>Convention-West 301D/3rd Level</td>
</tr>
<tr>
<td>8:00 am – 10:30 am</td>
<td>Translational Science Brain Cancer Subcommittee/Low-Grade Glioma Working Group</td>
<td>Convention-West 105BC/1st Level</td>
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<tr>
<td>8:00 am – 5:00 pm</td>
<td>GYN Chart Review *</td>
<td>*Hyatt Hotel-Remington A/2nd Floor</td>
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<tr>
<td>8:00 am – 5:00 pm</td>
<td>Pathology Workshop &amp; Review</td>
<td>*Sheraton Hotel-Ahwatuke AB/2nd Floor</td>
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<tr>
<td>9:00 am – 10:30 am</td>
<td>Cancer Prevention and Control Committee Meeting *</td>
<td>Convention-North 125AB/1st Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>International Members Meeting</td>
<td>Convention-North 126AB/1st Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>NRG BR003/NSABP B-55 and NRG BR004 Workshops</td>
<td>Convention-North 127AB/1st Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>NRG HN004 Workshop</td>
<td>Convention-West 101A/1st Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>Communications Committee</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>10:00 am – 12:00 pm</td>
<td>Health Disparities Committee</td>
<td>Convention-West 212ABC/2nd Level</td>
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<tr>
<td>10:00 am – 12:00 pm</td>
<td>Cervix Cancer Workshop</td>
<td>Convention-West 301C/3rd Level</td>
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<tr>
<td>10:00 am – 12:00 pm</td>
<td>Sarcoma Working Group</td>
<td>Convention-West 101C/1st Level</td>
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<tr>
<td>10:00 am – 12:00 pm</td>
<td>Imaging Working Group</td>
<td>Convention-North 131C/1st Level</td>
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<tr>
<td>10:30 am – 12:00 pm</td>
<td>Translational Science GYN Workshop</td>
<td>Convention-North 122ABC/1st Level</td>
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<tr>
<td>11:00 am – 12:00 pm</td>
<td>Protocol 225 Information Session</td>
<td>Convention-West 101A/1st Level</td>
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<tr>
<td>11:00 am – 12:00 pm</td>
<td>New Investigators Committee</td>
<td>Convention-West 101B/1st Level</td>
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</tbody>
</table>

*Sessions for Committee Member

Revised 1/8/18
**NRG ONCOLOGY SEMIANNUAL MEETING**

**FINAL AGENDA**
Phoenix Convention Center, Phoenix, Arizona
January 25 – 27, 2018

**Friday, January 26, 2018**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>11:00 am – 12:30 pm</td>
<td>Immunotherapy and Immune Modulation Workshop</td>
<td>Convention-West 211AB/2nd Level</td>
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<tr>
<td>11:00 am – 1:00 pm</td>
<td>Breast Cancer Rare &amp; Genetically-Linked Subcommittee Workshop</td>
<td>Convention-North 128AB/1st Level</td>
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<tr>
<td>11:00 am – 1:00 pm</td>
<td>Neurosurgical Subcommittee</td>
<td>Convention-West 105BC/1st Level</td>
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<tr>
<td>11:00 am – 1:00 pm</td>
<td>Elderly Working Group</td>
<td>Convention-North 126AB/1st Level</td>
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<tr>
<td>11:00 am – 1:00 pm</td>
<td>NRG Oncology Foundation Board of Directors *</td>
<td>Convention-West 213AB/2nd Level</td>
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<tr>
<td>11:30 am – 1:00 pm</td>
<td>NRG GI002 and NRG GI004 Workshops</td>
<td>Convention-North 127AB/1st Level</td>
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<tr>
<td>11:30 am – 1:00 pm</td>
<td>Cancer Care Delivery Research Session Workshop</td>
<td>Convention-North 124AB/1st Level</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>NRG Pharmacy Subcommittee</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>Pathology Committee *</td>
<td>*Sheraton Hotel-Ahwatukee AB/2nd Floor</td>
</tr>
<tr>
<td>1:00 pm – 2:00 pm</td>
<td>NRG Oncology General Session</td>
<td>Convention-West 301D/3rd Level</td>
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<tr>
<td>2:00 pm – 3:00 pm</td>
<td>Translational Science Head &amp; Neck Cancer Subcommittee</td>
<td>Convention-West 105BC/1st Level</td>
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<tr>
<td>2:00 pm – 3:30 pm</td>
<td>Publications Committee *</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>2:00 pm – 3:30 pm</td>
<td>Translational Science Breast Cancer Subcommittee</td>
<td>Convention-North 124AB/1st Level</td>
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<td>2:00 pm – 4:00 pm</td>
<td>Translational Science GU Cancer Subcommittee</td>
<td>Convention-North 126AB/1st Level</td>
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<td>2:00 pm – 4:00 pm</td>
<td>Rare Tumor Workshop</td>
<td>Convention-West 211AB/2nd Level</td>
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<tr>
<td>2:00 pm – 4:00 pm</td>
<td>Radiation Oncology Workshop</td>
<td>Convention-North 121ABC/1st Level</td>
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<tr>
<td>2:00 pm – 5:00 pm</td>
<td>Brain Tumor Core Committee *</td>
<td>Convention-North 132ABC/1st Level</td>
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<tr>
<td>2:00 pm – 6:00 pm</td>
<td>Clinical Trial Nurse/Clinical Research Associate Workshop - Educational Session</td>
<td>Convention-West 301AB/3rd Level</td>
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<tr>
<td>2:30 pm – 4:30 pm</td>
<td>Uterine Corpus Cancer Workshop</td>
<td>Convention-West 301C/3rd Level</td>
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<tr>
<td>2:30 pm – 5:30 pm</td>
<td>Cancer Prevention and Control Workshop</td>
<td>Convention-North 131AB/1st Level</td>
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<tr>
<td>3:00 pm – 6:00 pm</td>
<td>Head &amp; Neck Cancer Core Committee *</td>
<td>Convention-North 125AB/1st Level</td>
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<tr>
<td>3:30 pm – 6:30 pm</td>
<td>Breast Cancer Working Group *</td>
<td>Convention-North 124AB/1st Level</td>
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<tr>
<td>4:00 pm – 5:00 pm</td>
<td>NRG Oncology Human Research Committee *</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Medical Physics Workshop</td>
<td>Convention-North 128AB/1st Level</td>
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<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Translational Science Lung Cancer Subcommittee Workshop</td>
<td>Convention-West 105BC/1st Level</td>
</tr>
<tr>
<td>4:00 pm – 6:00 pm</td>
<td>Genitourinary Cancer Core Committee *</td>
<td>Convention-North 126AB/1st Level</td>
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<tr>
<td>5:00 pm – 7:00 pm</td>
<td>Korean Gynecologic Oncology Group Meeting</td>
<td>Convention-West 213AB/2nd Level</td>
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<tr>
<td>5:00 pm – 7:00 pm</td>
<td>Brain Tumor Workshop</td>
<td>Convention-North 132ABC/1st Level</td>
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<tr>
<td>6:00 pm – 8:00 pm</td>
<td>NRG Oncology Welcome Reception</td>
<td>Convention-North 221AB&amp;222ABC/2nd Level</td>
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</tbody>
</table>

*Sessions for Committee Member

Revised 1/8/18
### Saturday, January 27, 2018

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>6:30 am – 8:30 am</td>
<td>Continental Breakfast</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>7:00 am – 1:00 pm</td>
<td>IT Resource Room/Internet Café/Speaker Ready Room</td>
<td>Convention-West 104B/1st Level</td>
</tr>
<tr>
<td>7:00 am – 2:00 pm</td>
<td>Exhibits</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>7:00 am – 5:00 pm</td>
<td>Registration/CME/Information Desk</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>10:00 am – 11:00 am</td>
<td>General Coffee Break</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>12:45 pm – 3:00 pm</td>
<td>General Coffee Break</td>
<td>Convention-West 301 Lobby/3rd Level</td>
</tr>
<tr>
<td>6:30 am – 8:00 am</td>
<td>Surgical Oncology Workshop</td>
<td>Convention-North 124AB/1st Level</td>
</tr>
<tr>
<td>6:45 am – 8:30 am</td>
<td>Proton Working Group Workshop</td>
<td>Convention-North 121ABC/1st Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>Canadian Members Meeting</td>
<td>Convention-West 101A/1st Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>NRG SDMC Data Management Working Group</td>
<td>Convention-North 125AB/1st Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>NRG SDMC IT Working Group *</td>
<td>Convention-West 208B/2nd Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>NRG SDMC Statistical Working Group *</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>7:00 am – 8:00 am</td>
<td>Medical Oncology Workshop</td>
<td>Convention-North 127AB/1st Level</td>
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<tr>
<td>7:00 am – 9:00 am</td>
<td>Translational Science GI Cancer Subcommittee</td>
<td>Convention-North 122ABC/1st Level</td>
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<tr>
<td>8:00 am – 9:00 am</td>
<td>NRG BR005 Workshop</td>
<td>Convention-North 124AB/1st Level</td>
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<tr>
<td>8:00 am – 9:30 am</td>
<td>Safety Review Committee *</td>
<td>Convention-West 105A/1st Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>NCORP PI &amp; Administrators Meeting</td>
<td>Convention-North 127AB/1st Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>GYN Developmental Therapeutics/Phase I Workshops</td>
<td>Convention-West 301C/3rd Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>Genitourinary Cancer Workshop</td>
<td>Convention-West 105BC/1st Level</td>
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<tr>
<td>8:00 am – 10:00 am</td>
<td>Head &amp; Neck Surgical Subcommittee</td>
<td>Convention-West 211AB/2nd Level</td>
</tr>
<tr>
<td>8:00 am – 10:00 am</td>
<td>Lung Cancer Core Committee *</td>
<td>Convention-North 126AB/1st Level</td>
</tr>
<tr>
<td>9:00 am – 10:00 am</td>
<td>Quality Assurance Audit Meeting *</td>
<td>Convention-West 208B/2nd Level</td>
</tr>
<tr>
<td>9:00 am – 11:00 am</td>
<td>GI Colorectal Cancer Subcommittee *</td>
<td>Convention-North 122AB/1st Level</td>
</tr>
<tr>
<td>9:00 am – 12:00 pm</td>
<td>Protocol Support Committee Business Meeting *</td>
<td>Convention-North 125AB/1st Level</td>
</tr>
<tr>
<td>9:00 am – 1:00 pm</td>
<td>Breast Cancer Workshop</td>
<td>Convention-West 301A/3rd Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>Ovarian Cancer Workshop</td>
<td>Convention-West 301C/3rd Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>Cervix Cancer Workshop</td>
<td>Convention-West 211AB/2nd Level</td>
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<tr>
<td>10:00 am – 11:00 am</td>
<td>Uterine Corpus Cancer Workshop</td>
<td>Convention-West 212ABC/2nd Level</td>
</tr>
<tr>
<td>10:00 am – 11:30 am</td>
<td>Membership Committee *</td>
<td>Convention-West 105A/1st Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>Radiation-Developmental Therapeutics Workshop</td>
<td>Convention-North 124AB/1st Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>Protocol 225 Workshop</td>
<td>Convention-West 101A/1st Level</td>
</tr>
<tr>
<td>10:00 am – 12:00 pm</td>
<td>Head &amp; Neck Cancer Workshop</td>
<td>Convention-West 105BC/1st Level</td>
</tr>
<tr>
<td>11:00 am – 1:00 pm</td>
<td>GI Non-Colorectal Cancer Subcommittee *</td>
<td>Convention-North 122ABC/1st Level</td>
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<tr>
<td>Time</td>
<td>Session</td>
<td>Location</td>
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<tr>
<td>12:00 pm – 1:00 pm</td>
<td>Voting Members PI Meeting *</td>
<td>Convention-North 129AB/1st Level</td>
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<tr>
<td>1:00 pm – 3:00 pm</td>
<td>Gastrointestinal Cancer Workshop</td>
<td>Convention-North 127AB/1st Level</td>
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<tr>
<td>1:00 pm – 3:00 pm</td>
<td>Lung Cancer Workshop</td>
<td>Convention-West 105BC/1st Level</td>
</tr>
<tr>
<td>1:00 pm – 3:00 pm</td>
<td>Gynecologic Cancer Workshop</td>
<td>Convention-West 212ABC/2nd Level</td>
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<tr>
<td>2:00 pm – 3:00 pm</td>
<td>VA/MTF Meeting</td>
<td>Convention-North 126AB/1st Level</td>
</tr>
<tr>
<td>3:00 pm – 6:00 pm</td>
<td>Research Strategy Meeting *</td>
<td>Convention-West 102ABC/1st Level</td>
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</tbody>
</table>
The Resource Center will feature:

Assistance for IT-related issues, including, but not limited to the following:

- Medidata RAVE
- CTSU OPEN
- User Accounts

Available services include:

- Internet Access
- Email
- Printing

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.
Special Sessions/Events
NRG Oncology Semiannual Meeting /January 2018
Following this activity, participants will be better able to:

1. Understanding the protocol concept NRG-LU002
2. Explore the roles of secondary surgical cytoreduction and bevacizumab in women with ovarian cancer, and report the results of the bevacizumab component here.
3. Compare adjuvant chemotherapy with adriamycin (A) and cyclophosphamide (C) → weekly paclitaxel (WP), or docetaxel (T) and C with or without a year of trastuzumab (H) in women with node-positive or high-risk node-negative invasive breast cancer (IBC) expressing HER2 staining intensity of IHC 1+ or 2+ with negative FISH (HER2-Low IBC). Understanding the protocol concept in development
4. Understanding the protocol concept NRG-GU005
5. Understanding the protocol concept NRG-HN004
6. Understanding the protocol concept NRG-DT001

WORKSHOP AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 – 8:05 am</td>
<td>Welcome</td>
<td>Krishnansu Tewari, MD</td>
</tr>
<tr>
<td>8:15 – 8:20 am</td>
<td>Q&amp;A</td>
<td></td>
</tr>
<tr>
<td>8:20 – 8:30 am</td>
<td>Bevacizumab and paclitaxel-carboplatin chemotherapy and secondary cytoreduction in recurrent, platinum-sensitive ovarian cancer (NRG Oncology/Gynecologic Oncology Group study GOG-0213): a multicentre, open-label, randomised, Phase III trial.</td>
<td>Robert L Coleman, MD</td>
</tr>
<tr>
<td>8:30 – 8:35 am</td>
<td>Discussant</td>
<td>Carol Aghajanian, MD</td>
</tr>
<tr>
<td>8:35 – 8:40 am</td>
<td>Q&amp;A</td>
<td></td>
</tr>
<tr>
<td>8:40 – 8:45 am</td>
<td>NSABP B-47 (NRG Oncology): Phase III randomized trial comparing adjuvant chemotherapy with adriamycin (A) and cyclophosphamide (C) → weekly paclitaxel (WP), or docetaxel (T) and C with or without a year of trastuzumab (H) in women with node-positive or high-risk node-negative invasive breast cancer (IBC) expressing HER2 staining intensity of IHC 1+ or 2+ with negative FISH (HER2-Low IBC).</td>
<td>Louis Fehrenbacher MD</td>
</tr>
<tr>
<td>8:45 – 8:50 am</td>
<td>Discussant</td>
<td>William M Sikov, MD</td>
</tr>
<tr>
<td>8:50 – 8:55 am</td>
<td>Q&amp;A</td>
<td></td>
</tr>
<tr>
<td>8:55 – 9:05 am</td>
<td>NRG-GU005-Phase III IGRT and SBRT vs IGRT and hypofractionated IMRT for localized intermediate risk prostate cancer</td>
<td>Rodney J Ellis, MD</td>
</tr>
<tr>
<td>9:05 – 9:10 am</td>
<td>Q&amp;A</td>
<td></td>
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<tr>
<td>9:10 – 9:20 am</td>
<td>NRG-HN004- Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin</td>
<td>Loren K Mell, MD</td>
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<tr>
<td>Time</td>
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<td>Speaker</td>
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<tr>
<td>9:20-9:25 am</td>
<td>Q&amp;A</td>
<td></td>
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<tr>
<td>9:25-9:35 am</td>
<td>NRG-DT001- A phase IB trial of neoadjuvant AMG 232 concurrent with preoperative radiotherapy in wild-type P53 soft tissue sarcoma (STS)</td>
<td>Meng Xu Welliver, MD, PhD</td>
</tr>
<tr>
<td>9:35-9:40 am</td>
<td>Q&amp;A</td>
<td></td>
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<tr>
<td>9:50-10:00 am</td>
<td>Closing Discussion</td>
<td></td>
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</table>
Welcome to Phoenix!

Join us at the

NRG Oncology Welcome Reception

Friday, January 26, 2018
6 pm - 8 pm
North 221AB & North 222ABC
Workshops Agendas
NRG Oncology Semiannual Meeting
January 2018

See CME credit listing handout for list of workshops that have been approved for CME Credit Hours
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 chemotherapeutic 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>
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<tbody>
<tr>
<td>1</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>103/360</td>
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<td>2</td>
<td>1470 A071101</td>
<td>Randomized Phase II Trial of Bevacizumab +/- HSP vaccine in Patients with rGBM</td>
<td>rGBM</td>
<td>5/13</td>
<td>90/165</td>
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<tr>
<td>3</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; 12/30 for advanced imaging; Proton: 90/288</td>
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<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>4</td>
<td>BN 002</td>
<td>Phase I Study of Ipilimumab, Nivolumab, and the Combination in nGBM</td>
<td>nGBM</td>
<td>4/15</td>
<td>32/30</td>
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<td>5</td>
<td>NRG 1119</td>
<td>Phase II/II R+/- Lapatinib</td>
<td>BM Breast</td>
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<td>6</td>
<td>CC 001</td>
<td>Phase III WBRT+Memantine +/- HA</td>
<td>BM</td>
<td>7/15</td>
<td>446/510</td>
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<td>7</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 304</td>
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<td>8</td>
<td>0631</td>
<td>Phase II/III Image-Guided Radiosurgery/SBRT for Localized Spine Mets---RTOG CCOP Study</td>
<td>Spine Mts</td>
<td>8/09</td>
<td>390/395 (III: 344/352)</td>
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<td>9</td>
<td>Alliance A071401</td>
<td>Meningioma targeted agents, 3 arms (SMO, AKT, NF2)</td>
<td>Menin</td>
<td>8/15</td>
<td>39/56</td>
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<td>10</td>
<td>RTOGf 3508</td>
<td>IIR/III RT/TMZ +/- ABT 414 for nGBM</td>
<td>nGBM</td>
<td>9/15</td>
<td>358/720 1379 screened</td>
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<td>11</td>
<td>RTOGf 3503</td>
<td>Bev-refractory rec GBM PIIR</td>
<td>rGBM</td>
<td>5/16</td>
<td>1/85</td>
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<td>12</td>
<td>BN 003</td>
<td>Meningioma RT vs Obs</td>
<td>Menin</td>
<td>6/17</td>
<td>2/133</td>
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<td>13</td>
<td>BN 005</td>
<td>LGG Photons vs Protons</td>
<td>LGG</td>
<td>8/17</td>
<td>0/120</td>
</tr>
</tbody>
</table>
Breast Cancer Workshop Agenda

Date: Saturday, January 27, 2018
Start and End Time: 9:00 am – 12:00 pm
Chair: Eleftherios Mamounas, MD
Co-Chairs: Julia White, 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 – 9:30 Welcome/Update
Norman Wolmark, MD

9:30 – 10:00 Report from the Breast Working Group Meeting
Eleftherios Mamounas, MD
Julia White, MD

10:00 – 10:45 Immunotherapy Trials

NRG BR-004 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 BR-006 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

10:45 – 11:00 NRG BR-003 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

11:00 – 11:10 Olympia (NSABP B-55/Big 6-13) A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multicenter Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High-Risk HER2-Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy
Charles Geyer, Jr., MD
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:10 – 11:20</td>
<td>Clinical Trial Planning Meeting</td>
<td>Tom Julian, MD</td>
</tr>
<tr>
<td>11:20 – 11:30</td>
<td>NRG BR-005-A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy</td>
<td>Mark Basik, MD; Jennifer Delossantos, MD</td>
</tr>
</tbody>
</table>
| 11:30 – 11:40 | NRG BR-001 A Phase I Study of Stereotactic Body Radiotherapy (SBRT) for the Treatment of Multiple Metastases
NRG BR-002 A Phase IIR/III Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer | Steve Chmura, MD, PhD |
| 11:40 – 11:50 | NSABP B-51/RTOG 1304 A Randomized Phase III Clinical Trial Evaluating the Role of Post-mastectomy Chest Wall and Regional Nodal XRT and Post-lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy | Julia White, MD; Eleftherios Mamounas, MD |
| 11:50 – 12:00 | SWOG 1416 A Phase II trial of Cisplatin with or without Velaparib in Metastatic Triple Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer | Shannon Puhalla, MD |
Breast Cancer Rare and Genetically-Linked Subcommittee Workshop

Date: Friday, January 26, 2018
Start and End Time: 11:00 am - 1:00 pm
Chair: Alexandra Thomas

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

1. Identify and describe opportunities for to collaborate with pathology in supporting trials in rare tumors
2. Identify and describe opportunities for trial concept development in metaplastic breast cancer
3. Identify and describe opportunities for secondary analyses of NSABP trials and analyses in other large datasets
4. Identify and describe mechanisms by which to assess trial proposals on rare and genetically-linked breast cancers

WORKSHOP AGENDA

11:00 - 11:45 NSABP/NRG Pathology –Opportunities in Rare Tumors
   Peter Lucas MD, PhD
   Director of Pathology NSABP/NRG

11:45- 11:55 Discussion with Dr. Lucas

12:00- 12:10 Committee Updates
   ▪ Update from the Working Group
   ▪ Speakers for future meetings
   ▪ BR1703 Metaplastic Concept Update

12:10-12:20 Secondary analyses
   Karen Daily, DO
   ▪ Concepts which mine existing legacy or NRG data to build new knowledge on rare or genetically linked tumors
   ▪ Challenges to date
   ▪ Funding sources (possibility outside NCI?)

12:20-12:55 Trial Concepts
   ▪ Trial for pateints with germline mutations
     Anosheh Afghahi MD, MPH
   ▪ Neo-adjuvant trial concept
     Jayanthi Srinivasiah MD (tentative)
   ▪ Topics for which to develop RFP – Inflammatory; intersection with WG

12:55- 1:00 Committee Discussion
   ▪ Follow-up on previous discussions
   ▪ Future directions
Canadian Members Workshop

Date: Saturday, January 27, 2018
Start and End Time: 7:00 am – 8:00 am
Chair: Jean-Paul Bahary, MD
Co-Chairs: Andre Robidoux, MD; Al Covens, MD
NRG Operations: Erica Field (back-up representative – Katie Campbell and Judy Langer)

Learning Objectives:
Following this activity, participants will be better able to:
1. Discuss the status and significance of new and ongoing NRG clinical trials available to Canada
2. Apply standards and procedures required to participate in a research protocol supported by NRG Oncology
3. Discuss the roles of the Canadian Review Board for future clinical trials

WORKSHOP AGENDA

I. General
   a. Overview of Workshop Agenda and Disclosures and Potential Conflict(s) of Interest

II. Status of NRG Oncology trials open to accrual – discussion lead NRG Oncology Regulatory
   a. Accrual Update (March 2017 – December 2017)

III. Optimizing accrual in Canada - Discuss best practices for optimizing accrual among Canadian sites.
    Discussion lead
    a. Disease Sites of interest
    b. Review previously collected site data to support enrollment in these specific disease sites

IV. New concepts and protocols
    a. NRG-GU006: A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Salvage Radiotherapy with or without Enhanced Anti-Androgen Therapy with Apalutamide in Recurrent Prostate Cancer (Dan Spratt, MD)
    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
    c. Canadian Review Board – discussion lead

V. New Business, General Questions, Discussion
   a. Discussion lead

VI. Evaluation
Cancer Care Delivery Research (CCDR) Workshop Agenda

Date: Friday, January 26, 2018
Start and End Time: 11:30 am – 1:00 pm MST
Co-Chair: Debra Ritzwoller, PhD
Co-Chair: David Cohn, MD

Call-in number: 1-866-670-5102, Passcode: 321540#

WORKSHOP AGENDA

Session I

A. Welcome and information
   David Cohn, MD and Deb Ritzwoller, PhD
B. Brief introduction of new CCDR committee members
   a. Call for new committee members
C. NCI updates
   a. NCI approved concept updates
   TBD – (Ann Geiger, PhD or Kate Castro, RN)
D. Update on NCI CCDR Committees
   Deb Ritzwoller, PhD
E. Update on CCDR Pilot Awards
   Erin Hahn, MD
   b. PROTECT: Patient Reported Outcomes to Enhance Care on Treatment
   Alexi Wright, MD
F. NRG CCDR Concept updates
   a. Concepts in development
   b. NRG NCORP approved concept updates
   c. CCDR Committee approved concepts
G. Report from CCDR strategic planning meeting
   Debra Ritzwoller, PhD
H. NCORP submission dates
   a. Priorities for CCDR activities
I. New Business

QUESTIONS / DISCUSSION
Cancer Prevention and Control Workshop

Co-Chair: David S. Alberts, MD
Co-Chair: Lisa Kachnic, MD

Session I: Friday, January 26, 2018 11:00 am – 12:00 pm GOG-225 Informational Session
Session II: Friday, January 26, 2018 2:30 pm – 5:30 pm CPC Workshop
Session III: Saturday, January 27, 2018 10:00 am – 12:00 am GOG-225 Workshop

SESSION I – GOG-0225, Informational Session – CMEs are not provided
Friday, January 26, 2018 11:00 am – 12:00 pm
GOG-225: The Lifestyle Intervention for ovarian cancer Enhanced Survival (LIVES) Study
Presentations with a question and answer session

- David S. Alberts, MD, Regents Professor of Medicine, Pharmacology, Public Health and Nutritional Science, and Director Emeritus, University of Arizona Cancer Center
- Cynthia Thomson, PhD, RD, CSO, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona
- Tracy Crane, MS, RD, Research Specialist, Sr., LIVES Study Coordinator - Study co-chair and coordinator will be available to answer questions regarding ongoing study

SESSION II – NRG CPC Committee Workshop
Friday, January 26, 2018 2:30 pm – 5:30 pm
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. Introduction

B. Review of Open Studies:
- GOG-0225: Can Diet and Physical Activity Modulate Ovarian Cancer Progression Free Survival? (D. Alberts)
- GOG-0237: Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papillomavirus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC) (S-Y. Liao)
- GOG 0278: Before/after Non-radical Surgery Physical function and QOL
- NRG-CC001: Phase III Memantine and Whole Brain RT +/- Hippocampal Avoidance (P. Brown, V. Gondi)
- NRG-CC003: Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC (V. Gondi)
- 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)

C. Review of Concepts & Protocols in Development:
- NRG-CC005: FORTE – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (R. Schoen)
- A Randomized Trial of IADL-Based Dose-Adjusted Pegylated Liposomal Doxorubicin Every 28 Days with Bevacizumab 10 mg/kg Every 2 Weeks versus Standard of Care Dosing of Chemotherapy in Elderly Recurrent Ovarian Cancer Patients (D. Chase)
- A Three-Arm Cohort Study of Salpingectomy to Reduce the Risk of High-Grade Serous Carcinoma Among Premenopausal BRCA1 Carriers (D. Levine)
- Impact of Sentinel Lymph Node Mapping on Lymphedema and Health Related Quality of Life in Endometrial Cancer (E. Tanner)

D. Other Updates
- Alexia Alford: International Atomic Energy Agency’s (IAEA) work in body composition and energy expenditure assessments and potential for collaboration
- Dave Alberts: Tribute and celebration
  * Maria Prevatt, Setsuko Chambers, Ken Hatch and Janiel Cragun, U of AZ Cancer Center

SESSION III – CPC Training GOG-0225
Saturday, January 27, 2018 10:00 –12:00 am GOG-225 Workshop
GOG-0225: The Lifestyle Intervention for ovarian cancer Enhanced Survival (LIVES) Study
Training Objectives:
- “Hands on” anthropometric training will be available with live models
• Overview of the study instruments and data collection time points
• Introduction to study questionnaires
• Orientation to coaching for behavior change

Presentations:
  David S. Alberts, MD, Regents Professor of Medicine, Pharmacology, Public Health and Nutritional Science, and Director Emeritus, University of Arizona Cancer Center
  Cynthia Thomson, PhD, RD, CSO, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona
  Tracy Crane, MS, RD, Research Specialist, Sr., LivES Study Coordinator

QUESTIONS/DISCUSSION
EVALUATION
Cervix Cancer Workshop

Date:          Friday, Jan 26, 2018
Start and End time:  10:00 am – 12:00 pm (Session I)

Date:          Saturday, Jan 27, 2018
Start and End time:  10:00 am – 11:00 am (Session II)

Chair:         Bradley J. Monk, MD
Co-Chair:       Wui-Jin Koh, MD

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

- Discuss national and international priorities and initiatives in the management of cervical cancer
- Discuss active and developing NRG clinical trials on the prevention, diagnosis, and treatment of cervical and vulvar cancers
- Discuss promising developmental therapeutics and translational research objectives and strategies for future clinical trials
- Apply standards and procedures required to design, submit, and conduct a research protocol by the NRG
- Outline barriers and potential solutions to improve enrollment to NRG clinical trials in cervical and vulvar cancer, including international collaboration

Educational Need:
To provide an international forum for the development and monitoring of cooperative group clinical trials in cervical and vulvar cancers, with content and format based on evaluations from prior meetings.

WORKSHOP AGENDA

SESSION I:  Friday, Jan 26, 2017 (Scientific development focus)  10:00 am – 12:00 pm

A:  Introduction (10:00 – 10:10)

1.  Welcome, introduction of new members, and review of July 2017 minutes

B:  Scientific updates (10:10 – 10:45)

1.  Update from Gynecologic Cancer Intergroup (GCIC) meeting Nov 2017 (Brad Monk)
2.  Update on other cervix cancer clinical trials in progress (Brad Monk)
3.  Cervix Task Force update (Anuja Jhingran)

C:  Previously committee-approved/discussed concepts – current and future directions (10:45 – 11:30)

1.  NRG-GY017 (PI1727): 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)
2. **NRG CV1748** - Gronigen International Study on Sentinel Nodes in Vulvar Cancer – GROINSS VIII – A prospective phase II trial (SLN macroscopic +). (Brian Slomovitz)

3. **NRG CV1735** - Practice Changing Evaluation of Lymphedema and Quality of Life after Sentinel Lymph node Biopsy Only in Women with Early Stage Cervical Cancer. (Al Covens) Tabled from last meeting – pending information from GOG-0244

4. **CV1649** - A Randomized Phase II trial of cisplatin, paclitaxel and bevacizumab vs cisplatin, paclitaxel, bevacizumab, and anti-PD1 ligand in Stage IVB recurrent or persistent carcinoma of the cervix. (Katherine Moxley, Scott Richard) – transitioned to GCIG

5. **SWOG DART** (Dual Anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors) - Ipilimumab and Nivolumab. (Gyn Champion - Lilian Gien)

6. Radical treatment of oligometastatic cervix cancer. (Kim, Chino)

**D: New proposed concepts (11:30 – 12:00)**

1. **CV1807**: Phase I/II trial considering efficacy of concurrent immunotherapy with weekly cisplatin and radiation then maintenance immunotherapy vs weekly cisplatin and radiation in locally advanced cervical cancer. (Haider Mahdi)

**SESSION II: Fri, Jan 27, 2018 (Operational management of on-going NRG trials) 10:00 am – 11:00 am**

**E: Closed Studies**

Protocols: 101, 120, 205, 222, 141, 173, 179, 204, 206, 240, 233, 9806

**F: Active/Recently Completed Studies**

1. **GOG-0724/RTOG0724**: Phase III 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)
   a) Opened April 2009
   b) Accrual: XX/284

2. **GOG-0263**: Randomized Clinical Trial for Adjuvant Chemoradiation in Post-operative Cervical Cancer Patients with Intermediate Risk Factors (Sang Young Ryu, Wui-Jin Koh)
   a) Opened April 2010
   b) **Nov 2017 - Accrual target changed from 534 to 360**
   c) Accrual: XX/360

3. **GOG-0270**: Groningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-VII) An observational study (Brian Slomovitz)
   a) NRG Opened January 3rd, 2012; NRG target accrual 140,
   b) Amendment for treatment of SLN macro-metastatic disease
   c) Amendment for IMRT approved July 2015 by GROINSS, but NOT by CTEP
   d) Accrual completed (NRG accrual 148)
4. **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)
   - a) Activated January 9, 2012; NRG target accrual 500
   - c) Expanded accrual target to 900 total patients
   - d) Accrual completed 5/2017 (study closed 6/1/17) – 924/900 (NRG accrual 627)

5. **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)
   - a) Activated October 1, 2012.
   - b) PET imaging amendment approved July 2015
   - c) Accrual: XX/220

6. **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)
   - a) Activated July 2, 2012
   - b) Temporarily closed 6/15/2015, after enrolling 28 in 1st stage
   - b) 2nd stage re-opened July 2016 – accrual XX/25

7. **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. (Charles Leath, Loren Mell)
   - a) Activated Jan 15, 2016
   - b) Accrual: XX/188

8. **NRG-GY002**: Nivolumab in recurrent/metastatic cervical cancer (A Santin) – closed to enrollment

**G: Reports from Other Committees and Groups**

- a) Publications Subcommittee
- b) Patient Centered Outcomes Research Committee
- c) Ancillary Data Committee
- d) Cancer Prevention and Control
- e) Rare Tumor Committee:
- f) Vaccine Subcommittee
- g) Pathology Committee
- h) Radiation Committee
- i) SPORE Committee:
- j) Nursing
- k) Medical Oncology:
- l) Patient/Community/Advocacy

**H: Wrap up and questions**
# Gastrointestinal Cancer Workshop Agenda

**Date:** Saturday, January 27, 2018  
**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 clinical trials in GI Oncology

## WORKSHOP AGENDA

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<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<td>1:00 – 1:05</td>
<td><strong>Introduction and Opening Remarks</strong></td>
<td>Christopher Crane, MD Thomas George, MD</td>
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<tr>
<td>1:05 – 1:15</td>
<td><strong>CRC SUBCOMMITTEE - Review of Developing Trials</strong></td>
<td>Van Morris, MD</td>
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<td>1:15 – 2:00</td>
<td><strong>Active Studies</strong></td>
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<td><strong>N1048:</strong> Intergroup PROSPECT Trial</td>
<td>Thomas George, MD</td>
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<td></td>
<td><strong>NRG GI002:</strong> TNT Trial Update</td>
<td>Thomas George, MD</td>
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<td><strong>FR-2:</strong> A Phase II Study to Assess the Activity of PD-L1 Inhibition with Durvalumab after Chemo-Radiotherapy in Stage II-IV MSS Rectal Cancer</td>
<td>Thomas George, MD</td>
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<td><strong>SWOG S0820/PACES:</strong> Efllornithine &amp; Sulindac for polypl prevention after CRC</td>
<td>Jenny Dorth, MD</td>
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<td><strong>NRG GI004 / SWOG-S1610</strong> Colorectal Cancer Metastatic MSI-high Immuno-Therapy (COMMIT) Study</td>
<td>James Lee, MD PhD</td>
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<td><strong>FC-9:</strong> A Phase II Study of the Dual Immune Checkpoint Blockade with Durvalumab plus Tremelimumab Following Palliative Hypofractionated Radiation in Patients with Microsatellite Stable (MSS) mCRC</td>
<td>James Lee, MD PhD</td>
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<td><strong>S1613:</strong> A Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan in Advanced/mCRC with HER2 Amplification</td>
<td>Marwan Fakih, MD</td>
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<td><strong>A021502:</strong> Randomized MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab</td>
<td>Asha Dhanarajan, MD</td>
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<td>2:00 – 2:20</td>
<td><strong>NON-CRC SUBCOMMITTEE</strong></td>
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<td><strong>0848:</strong> A Phase III Trial Evaluation both Erolotinib and ChemoradiationAs Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma</td>
<td>Ross Abrams, MD</td>
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<td><strong>1112:</strong> 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><strong>NRG GI001:</strong> Ph II/III Chemo +/- Hypofractionated XRT intrahepatic cholangioca</td>
<td>Theodore Hong, MD</td>
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<td><strong>Alliance A021302:</strong> PET directed adjuvant gastric/GEJ</td>
<td>David Ilson, MD</td>
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<tr>
<td>2:20 – 3:00</td>
<td><strong>Review of Developing Trials</strong></td>
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<td><strong>NRG GI-1525:</strong> Concurrent (ADXS11-001) with SFU/MMC and radiation for locally advanced anal cancer</td>
<td>Lisa Kachnic, MD</td>
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<td><strong>NRG GI003:</strong> Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma</td>
<td>Ted Hong, MD</td>
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<td></td>
<td>Phase II study of durvalumab and PET-guided chemo for GEJ adenocarcinoma followed by adjuvant durvalumab/ tremelimumab</td>
<td>Geoffrey Ku, MD</td>
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Genitourinary Cancer Workshop Agenda

Date: Saturday, January 27, 2018
Start and End Time: 8:00 am – 10:00 am
Chair: Howard Sandler, MD
Co-Chairs: Leonard Gomella, MD; Oliver Sartor, MD; William Shipley, MD

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 – 9:05 Review of Active Trials

RTOG 0924 Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial
Hans Chung, MD

RTOG 0926 A Phase II Protocol for Patients with Stage T1 Bladder Cancer to Evaluate Selective Bladder Preserving Treatment by Radiation Therapy Concurrent with Radiosensitizing Chemotherapy Following a Thorough Transurethral Surgical Re-Staging
William Shipley, MD

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

NRG GU003 A Randomized Phase III Trial of Hypofractionated versus Conventional Post-Prostatectomy IGRT/IMRT
Mark Buyyounouski

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

NRG GU006 Phase IIIR biomarker stratified trial with a lead in to phase III testing the benefit of salvage RT +/- ARN-509 in patients with a low PSA pre-treatment.
Felix Feng, MD
### 9:05 – 9:35  Review of Pending Studies

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Description</th>
<th>Principal Investigators</th>
</tr>
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<tbody>
<tr>
<td>NRG 1708</td>
<td>Update of high-risk localized strategies, clinical trial development</td>
<td>Dror Michaelson, MD, PhD</td>
</tr>
<tr>
<td>NRG GU004/Alliance</td>
<td>Phase III Study: Radium-223 + Androgen Deprivation vs. Androgen Deprivation Therapy Alone in Patients Ineligible or Refusing Docetaxel</td>
<td>Albert Chang, MD, PhD; Oliver Sartor, MD</td>
</tr>
<tr>
<td>NRG 1623</td>
<td>Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial</td>
<td>Ronald Chen, MD, MPH</td>
</tr>
<tr>
<td>NRG 1604</td>
<td>Renal met SBRT</td>
<td>Dror Michaelson, MD, PhD</td>
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<tr>
<td>NRG/SWOG</td>
<td>Local therapy for M1 prostate cancer, a SWOG study</td>
<td>Richard Valicenti, MD</td>
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<td>NRG GUxx/SWOG</td>
<td>Bladder Immune Strategy</td>
<td>Jason Efstathiou, MD</td>
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<tr>
<td>NRG Foundation 3506</td>
<td>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</td>
<td>Edwin Posadas, MD; Felix Feng, MD</td>
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### 9:35 – 9:55  Other issues

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

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<td>Medical Oncology Update</td>
<td>Oliver Sartor, MD</td>
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<td>Urology Update</td>
<td>Leonard G. Gomella, MD</td>
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<tr>
<td>New Business</td>
<td>Group</td>
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### 9:55 – 10:00  Closing Remarks
Gynecologic Cancer Workshop

Date: Saturday, January 27, 2018
Time: 1:00 pm – 3:00 pm
Chair: Carol Aghajanian, MD
Co-Chair: Ronald Alvarez, MD & William Small, MD
Translational Co-Chair: Heather Lankes, PhD

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 2017
   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

**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

**Rare Tumor Trials - NCTN**
- **S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors
  - Fibromixoma and low grade mucinous adenocarcinoma (pseudomyxoma peritonei) – appendix and ovary
  - Non-epithelial tumors of the ovary (germ cell tumors, mullerian mixed tumor, adenocarcinoma)
  - Trophoblastic tumor (choriocarcinoma)
  - Adenoid cystic carcinoma
  - Vulvar cancer
  - Not otherwise categorized (NOC) rare tumors – after discussion with Study Chairs

**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*

**III. Cervix/Vulvar Cancer Subcommittee**

**Studies Under Development**
- **CV1748**, GROINS V3 (Brian Slomovitz)

**Active Studies:**
- **GOG0263**, 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)
- **RTOG/GOG 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)
- **GOG0278**, Evaluation of Physical Function and QoL Before and After Non-Radical Surgical Therapy for Stage IA1 (LVS1+) and IA2-IB1 Cervical Cancer (Allan L Covens)
- **GOG0279**, 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)
- **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 (Charles Leath)

**New Cervix/Vulvar proposals:**
- **CV1807**: Phase I/II trial of Efficacy of concurrent immunotherapy with weekly cisplatin and radiation then maintenance immunotherapy vs weekly cisplatin and radiation in locally advanced cervical cancer. (Haider Mahdi)

**Closed Studies:** 240, 270, THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174)

**Terminations:**

**Rare Tumor Subcommittee**
Studies Under Development

a. **RT1531**, A randomized phase II trial of Temozolomide and Cisplatin versus Pembrolizumab in patients with completely resected mucosal melanoma. (GYN Chair: Danielle Vicus, GI Chair: Chris Barker, H&N Chair: Min Yao, TS Chair: Samir Khleif)

GYN Developmental Therapeutics Committee - Cervical Cancer

Studies Under Development

a. **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)

Active Studies:

Closed Studies: 9926, 9929, 265, GY002

Terminations:

Translational Science

a. **NRG GY TS012**: Glycan and Glycoprotein Biomarkers of Para aortic Lymph Node Metastases in GOG221 Specimens. (Doris Benbrook)

IV. Ovarian Cancer Subcommittee

Studies Under Development

a. **GY015**: A randomized phase II study of neoadjuvant chemotherapy (NACT) +/- metformin (concurrent and maintenance) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (S. Diane Yamada)

b. **OV1719**: A randomized phase II trial of olaparib + tremelimumab vs platinum-based physician choice chemotherapy in HRD+ and HRD- platinum-sensitive recurrent ovarian cancer. (Sarah Adams)

Active Studies:

a. **GY004**: A 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). *Closed to non-Japanese sites 11.10.17*

b. **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). *Temporarily closed to accrual 6/16/17*

c. **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)

d. **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)

New Ovarian proposals:

a. **OV1812**: Assay-guided therapy for recurrent ovarian cancer (David O’Malley)

Closed Studies: 212, 213, 218, 252, 262, 273

Terminations:

Rare Tumor Subcommittee

Studies Under Development

a. **RT1507**, A phase II trial of Cediranib in recurrent ovarian sex-cord stromal tumors. (Danielle Vicus)
b. **GY016**, Randomized phase II evaluation pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)

c. **RT1713**, A Randomized Phase II, Three-Arm Trial of Paclitaxel/Carboplatin Compared to 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/David Gershenson)

**Active Studies:**


b. **GOG0281**, A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (GSK 1120212) in Patients with Recurrent or Progressive Low-Grade Serous Ovarian Cancer or Peritoneal Cancer. (David Gershenson)

**Closed Studies:** 239, 241, 254, 268, 283, GY001

**Terminations:**

GYN Developmental Therapeutics Committee - Ovarian Cancer

**Studies Under Development**

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

b. **UC1731**, Exemestane and entinostat in low grade gynecologic malignancy: a phase II study. (Katarzyna Jerzak/Helen Mackay)

**New DT Ovary proposals:**

a. **OV1810**: A Randomized Phase II trial of reducing chemotherapy cycles accompanied by PARPi in platinum-sensitive recurrent ovarian and fallopian tubal cancer. (Se Ik Kim)

b. **OV1811**: A Randomized Phase II/III trial of PARPi and bevacizumab combined treatment with PARPi maintenance versus conventional carboplatin and paclitaxel chemo with PARPi maintenance as front line setting in patients with primary ovarian, peritoneal and fallopian tubal cancer. (Jae-Weon Kim)

**Closed Studies:** 9923, 170R, 186G, 186H, 186K, 255, 260, 280, GY003

**Terminations:**

NCORP

a. **NC1427**, Premenopausal BRCA 1/2 Carriers – Risk Reducing Salpingectomy (Douglas Levine)

b. **CC1720**, Elderly Platinum-Resistant Ovarian Cancer Patients (Chase)

**Translational Science**

a. **TS1514**, ImmunoScore determination as predictive biomarkers for clinical outcome in GOG0262 population. (Samir Khleif)

b. **NRG GY TS013**, Biomarker Discovery to Direct Bevacizumab Therapy in Ovarian Cancer – Blood based Angiome Profiling in samples from women enrolled on the Gynecologic Oncology Group (GOG) 0218 trial (Angeles Secord)

c. **NRG GY TS###**, Evaluation of clear cell histologic subtypes of ovarian and uterine malignancies with anti-PD-L1 and anti-PD1 immunohistochemical staining and correlation with stage and survival. (Jill Alldredge)

**V. Uterine Corpus Cancer Subcommittee**

**Studies Under Development**
a. **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)

b. **UC1644**, A Randomized Phase II Study of Letrozole Versus Observation in Patients with newly diagnosed Uterine Leiomyosarcoma (Brian Slomovitz)

c. **UC1710**, A randomized phase II/III study of carboplatin and paclitaxel with or without immune check point inhibitor as initial therapy for measurable stage 3 or 4A, stage 4B or recurrent endometrial cancer. (Ramez N. Eskander)

d. **UC1744**, Randomized Phase II Study of Conventional versus Hypofractionated Pelvic RT for adjuvant treatment of endometrial cancer with endpoint of toxicity (Camille Gunderson/ Mark Bernard)

**Active Studies:**

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. (Jonathan Micha Feddock)

b. **GOG0286B**, A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer. (Victoria Bae-Jump)

**Closed Studies**: 184, 188, 209, 210, 249, 258, 261, 275, 277

**Terminations**:

GYN Developmental Therapeutics Committee - Endometrial Cancer

Studies Under Development

a. **GY013**, A pre-operative window pharmacodynamics trial of Triapine in uterine corpus serous adenocarcinoma (Sarah Temkin)

b. **PI1716**, A window of opportunity study of preoperative immunotherapy and brachytherapy in clinically localized endometrial cancer with microsatellite instability. (Matthew Harkenrider/William Small)


d. **DT1737**, Phase I/II study of megestrol acetate, entinostat, and SGI-110 in advanced, persistent, or recurrent endometrial carcinoma. (Carolyn McCourt)

**New corpus proposals**:

a. **UC1805**: A Randomized Phase III Trial of Radiation +/- checkpoint inhibitor for high intermediate risk mismatch repair deficient (dMMR) endometrial cancer (Floor Backes)

b. **UC1808**: Phase II Efficacy of primary immunotherapy alone or combined immunotherapy and chemotherapy vs. chemotherapy alone in patients with advanced stage or recurrent endometrial cancer (Haider Mahdi)

c. **UC1809**: Randomized Phase III Trial of adjuvant doxorubicin plus olaratumab (DO) versus gemcitabine plus docetaxel followed by doxorubicin (GDD) in uterus-limited high-grade Leiomyosarcoma. (Loggers)

d. **DT1806**: Gemcitabine and Wee1 Inhibitor in persistent or recurrent endometrial malignancy: a phase II study (Megan McDonald)

**Active Studies**:

a. **GY008**, A Phase II Evaluation of Copanlisib (BAY 80-6946), a Selective Inhibitor of PI3KCA, in Patients with Persistent or Recurrent Endometrial Carcinoma Harboring PIK3CA Hotspot Mutations. (Alessandro Santin). *Temporarily closed to accrual*

b. **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)
Closed Studies: 86P, 229O
Terminations:

Translational Science
a. **UC1506**, Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine)
b. **NRG GY TS008 (UC1601)**, Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black versus White Women with Endometrioid Endometrial Cancer and Uterine Serous Cancer. (L.Maxwell)
c. **NRG GY TS001**, The Relationship of Racial Genetic Admixture and its Association with High Risk Endometrial Cancer Outcomes. (Rod Rocconi)
d. **NRG GY TS###**, Expression of L1CAM in serum and metastatic samples of recurrent and advanced stage endometrial cancer patients. (Thanh Dellinger)
e. **NRG GY TS###**, Immunoscore in Endometrial Cancer: Analysis of a cohort from GOG 210 (Debra Richardson)

VI. **Patient Centered Outcomes Research (PCOR) Committee Report** (Wenzel)
   Active Studies: 213, 278
   Closed Studies: 147, 184, 199, 209, 212, 218, 240, 249, 252, 258, 259, 262, 267, 9902
   Terminations:

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

VIII. **Translational Science Committee Report** (Birrer)
   Active Studies: 8011, 8013, 8015, 8016, 8020, 8023, 8024, 8025, 8028, 8031, 8034, 8036, 8039, 8042
   Closed Studies:
   Terminations:

IX. **Cancer Prevention and Control Committee Report**
   Active Studies: 225, 237, 278
   Closed Studies: 199, 214, 244, 8199
   Terminations:
GYN Developmental Therapeutics/Phase I/Translational Science Workshop

Date: Thursday, January 25, 2018
Start and End Time: 4:00 PM – 6:00 PM
Chairs: Roisin O’Cearbhaill, MD (Developmental Therapeutics) and 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); Jyoti Mayadev, MD (Phase I, RT)

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

1. Participants will become familiar with current mechanisms for development of clinical and translational research within National Clinical Trials Network (NCTN).
2. 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.
3. New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.
4. Recommendations for action by the GYN Protocol Development committee will be summarized.

WORKSHOP AGENDA

Thursday, January 25, 2018
Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting
4:00 PM – 4:10 PM Introduction, Drs. O’Cearbhaill and Birrer
4:10 PM – 4:30 PM Setting the Bar: Current Concepts in Development of Combination Pharmacotherapy, Dr. Michael Maitland
4:30 PM – 4:45 PM CTEP Early Drug Development Update, Charles Kunos, MD, PhD, Medical Officer and Coordinator, Investigational Therapeutics & Radiation, Investigational Drug Branch, CTEP
4:45 PM – 5:00 PM Ovarian Germ Cell Tumors, Memorial Sloan Kettering Cancer Center, Make an IMPACT Program, Dr. Marina Stasenko
5:00 PM – 5:30 PM Classification of Prospectively Collected Endometrial Cancers into Clinically Relevant Subgroups using Massively Parallel Sequencing and Immunohistochemistry, Dr. Deborah DeLair
5:30 PM – 6:00 PM Review of new concepts
   • 5-10 minute presentation of concept (by proposing investigator)
   • Review of concept

New Concepts:

1. **DT1806**: Gemcitabine and Wee1 Inhibitor in persistent or recurrent endometrial malignancy: a phase II study (Megan McDonald, David Bender, Kim Leslie)
2. **CV1807**: Phase I/II trial of Efficacy of concurrent immunotherapy with weekly cisplatin and radiation then maintenance immunotherapy vs weekly cisplatin and radiation in locally advanced cervical cancer. (Haider Mahdi)
3. **UC1808**: Phase II Efficacy of primary immunotherapy alone or combined immunotherapy and chemotherapy vs. chemotherapy alone in patients with advanced stage or recurrent endometrial cancer (Haider Mahdi)

GYN Developmental Therapeutics/Phase I Workshop
Date: Saturday, January 27, 2018
Start and End Time: 8:00 AM – 10:00 AM
Chair: Roisin O’Cearbhaill, MD (Developmental Therapeutics)
Co-Chairs: Floor Backes, MD (Phase II), Russell Schilder, MD (Phase I); Jyoti Mayadev, MD (Phase I, RT)
Learning Objectives:
Following this activity, participants will be better able to:

1. Participants will become familiar with the current status of phase I, phase II studies that are under development and activated for accrual.
2. Immune Therapy and Immune Modulation workshop will present an update from Thursday, January 25, 2018 (2:00 – 4:00 PM) and plan for integration and prioritization.
3. 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.
4. Recommendations for action by the GYN Cancer Committee will be summarized.

Saturday, January 27, 2018
Review of Phase I Studies (Active, Under Development, and New Concepts):
8:00 AM - 9:00 AM  Russell Schilder, MD
- Active
- Studies under development
- Closed studies
- New concepts

Review of Phase II Studies (Active, Under Development, and New Concepts):
9:00 AM – 9:15 AM  Cervical Cancer (Kathleen Moore, MD)
- Active
- Studies under development
- Closed studies
- New concepts

9:15 AM - 9:30 AM  Endometrial Cancer (Matthew Powell)
- Active
- Studies under development
- Closed studies
- New concepts

9:30 AM – 9:45 AM  Ovarian Cancer (Robert Coleman, MD)
- Active
- Studies under development
- Closed studies
- New concepts

9:45 AM – 10:00 AM  Sarcomas (Roisin O’Cearbhaill, MD)
- Active
- Studies under development
- Closed studies
- New concepts

List of Studies
Active/Soon to be 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) – CTEP CRDL LOI

Endometrial Cancer Studies:
- PI1716 A window of opportunity study of preoperative immunotherapy and brachytherapy in clinically localized endometrial cancer with microsatellite instability (Matthew Harkenrider/William Small) – CTEP CRDL LOI
• DT1737 Phase I/II study of megestrol acetate, entinostat, and SGI-110 in advanced, persistent, or recurrent endometrial carcinoma (Carolyn McCourt)

Ovarian Cancer Studies:
• 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) Safety lead in 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) Safety lead in Active for accrual

Closed 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)
• 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

Endometrial Cancer Studies:
• 229O 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 GS1211795, an AKT inhibitor, in patients with recurrent or persistent endometrial cancer (S Westin) Closed after safety lead in. CTEP/CRDL. SGO 2016

Ovarian Cancer
• 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 Bell-McGuinn) CTEP/CRDL. ASCO 2015

Cervical Cancer Phase II:

Recurrent/metastatic disease

Closed Studies
• 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) Both stages of accrual complete
• 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 Phase II:

Chemotherapy naïve
• UC1733, A phase II, prospective randomized open blinded end-point (PROBE) study of the use of combination pegylated liposomal doxorubicin with atezolizumab in women with recurrent endometrial cancer and MMR deficiency (Dr. Bradley Corr)

Window of Opportunity Studies
• 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-GY013 A window of opportunity pharmacodynamic trial of triapine in uterine corpus serous adenocarcinoma (Sarah Temkin)
• PI1749, Surgical Window of Opportunity Study of Abemaciclib and Letrozole versus Letrozole for Estrogen+, Progesterone + Endometrial Cancer. (Emma Barber/Daniela Matei). CTEP CRDL LOI

Recurrent/metastatic disease
• **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)

Closed Studies

Ovarian Cancer Phase II:

Multi Disease Site:

• **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

• **UC1731**. Exemestane and entinostat in low grade gynecologic malignancy: a phase II study (Drs. Katarzyna Jerzak and Helen Mackay)

Closed studies:

• 170R A phase II evaluation of dalantercept, a novel soluble recombinant activin receptor-like kinase 1 (ALK-1) inhibitor receptor-fusion protein, in the treatment of persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (R Burger)

• 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

• 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. SGO 2016

• 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

• 260 A phase II evaluation of elesclomol sodium and weekly paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (B Monk)

• **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)

QUESTIONS/DISCUSSION/EVALUATION
Head and Neck Cancer Workshop

Date: Saturday, January 27, 2018
Start and End Time: 10:00 am – 12:00 pm
Chair: Quynh-Thu Le, MD
Co-Chairs: Erich Sturgis, MD-MPH; Stuart Wong, MD, Andy Trotti, MD

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

1. Recognize critical aspects of developing and conducting a clinical trial in head and neck cancer therapy research in a cooperative group setting.
2. Identify and describe the design and status of new head and neck clinical trials being planned and launched by the NRG, 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 head and neck cancer clinical trials being conducted by the NRG, 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 discuss aspects of ongoing NRG head and neck cancer clinical trials 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 head and neck cancer clinical trials completed by the NRG, so the learner 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 systemic therapies, including chemotherapeutic drugs, biologic agents, immunotherapy and new classes of targeted therapies that may be used in conjunction with radiation therapy in head and neck cancer treatment, and the effectiveness of those agents as demonstrated in NRG clinical trials.
7. Identify and describe new developments in biologic and imaging science that can be used in translational research strategies to identify head and neck cancer patient subgroups at risk for failure with existing treatments and identify new approaches for these patients.

WORKSHOP AGENDA
10:00 – 10:10 Report on publications and protocol closed to active accrual
Quynh-Thu Le, MD

10:10 – 10:30 Review of Active Studies

RTOG 0920 IMRT/IGRT + cetuximab for “intermediate risk” resected HNSCC (Phase III) Mitchell Machtay, MD
RTOG 1008 Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR) Cristina Rodriguez, MD
RTOG 1216 RT-cisplatin vs. RT-Docetaxel vs. RT-Docetaxel + Cetuximab for “high risk” resected HNSCC (Phase IIR-III) David Rosenthal, MD

NRG HN001 Individualized NPC treatment based on post-RT EBV DNA (Phase III) Nancy Lee, MD
NRG HN003 Phase I of Adjuvant Chemoradiotherapy +/- Pembrolizumab in High Risk, HPV(-) HNSCC Julie Bauman, MD, MPH
RTOG 3504 Phase I/IIIR of CRT +/- Nivolumab in intermediate/high risk HNSCC Maura Gillison, MD, PhD
NRG HN004 Phase IIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC Loren Mell, MD

10:30-10:40 Review of recently completed study
NRG HN002 Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good-Prognosis Advanced-Stage Oropharyngeal Cancer Sue Yom, MD
RTOG 0912  Concurrent radiation + chemotherapy + pazopanib for Anaplastic Thyroid Cancer (Phase II-R)  Eric Sherman, MD

RTOG 3501  Phase II R study of CRT +/- Lapatinib in high risk HNSCC  Stuart Wong, MD

10:40 – 11:30  Review of developing studies

RTOG 3507  Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC  Stuart Wong, MD

NRG 1707  Phase IIR involved field RT +/- systemic therapy for good risk HPV(+) cancer  Sue Yom, MD

MD NRG 1706  Clinically N0 Oral cavity cancer: ND vs. sentinel node biopsy  Steve Lai, MD

?  Phase I lead-in and Randomized Phase 2 trial of DNA-PK inhibition or cisplatin with PD-L1 checkpoint blockade and IMRT in stage 3-4 local-regionally advanced HPV-negative HNSCC  Maura Gillison, MD, PhD

NRG/HN 1647  RT +/- PD1 inhibition for high risk cutaneous SCC (Phase IIR)  Christine Chung, MD, PhD

NRG 1726  Phase 1 - PD1 + CTLA4 inhibition + SBRT in patients with oligometastasis  Allen Chen, MD

RT 1531  A randomized phase II trial of Temozolomide and Cisplatin versus Nivolumab + Ipi in patients with completely resected mucosal melanoma - GYN, H&N, Anal Canal Cancers  Danielle Vicus, MD

11:30 – 11:50  Presentations & Updates

Translational Research Program update  Neil Hayes, MD, PhD

HNSC update  Robert Ferris, MD, PhD

11:50 – 12:00  New Business

CTV delineation atlas  Quynh-Thu Le, MD
NRG Oncology Health Disparities Committee
Friday, January 26, 2018
10:00 am – 12:00 pm
Agenda

Tri-Chairs: Carol Brown, MD; Elise Cook, MD, MS; Kate Yeager, PhD, RN, MS

10:00-10:05 am Welcome/Announcements

10:05-10:45 am Disease Site and Other Committee Liaisons

- Communications Committee-Patient Advocate Working Group-HDC representative – Anuja Jhingran, Kate Yeager
- Protocol Support Committee (PSC) representative to the HDC– TBA
- HDC Disease Site Liaisons-
  - The role of the HDC Disease Site Liaisons in awareness presentations to disease site/other committees.
  - Ways to assist disease site committees/PI in concept/protocol development related to health disparities
  - Disease Site Committee Updates

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*Disease Site Committee Liaison to HDC

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Elderly Working Group                         William Tew
Cancer Prevention & Control (CPC)             Sandra Brooks
Patient Centered Outcomes Research (PCOR)    Dana Chase
NCORP                                         Carol Brown

10:45-11:30 am Working Groups Updates
- 2018 goals – review of and future plans
  - Clinical trial enrollment - TBA
    - Working Group Leader
  - Education/training/mentorship - Kathie Ann Joseph
    - HDC Workshop - July 2018
    - HDC Mentor Program
    - New Investigator Collaboration
- Training collaboration with Protocol Support Committee (PSC) and Patient Advocate Committee (PAC)
- Training for NRG Oncology and Committee chairs

- **Health disparities research** - Electra Paskett
  - *NRG Recruitment Survey Manuscript* – Elise Cook, Electra Paskett & Kate Yeager

  Socioeconomic/demographic information collection on NRG Oncology trials
  - *Alliance Pilot Study Update* - Electra Paskett

- **Statistics/metrics** - Reena Cecchini
  - SDMC Reports
  - Summary & dissemination of reports to Disease Site Liaisons/Committee
  - Posting Information on NRG website

11:30 - 11:40 am  **Presentations at July 2018 NRG Meeting**
- Scientific Session, General Session, Select Disease Site Committee Meetings, Protocol Support Committee (PSC—e.g. nurses, CRAs, support staff, other?)
- General overview (e.g. slides, talking points)
- Disease site committees (e.g. general overview, SDMC reports)

11:40 – 11:50 am  **NCTN Grant Submission- Future Plans**
- Collaborations
- Co Leaders
- HDC webpage (workshops, slides, recommended health disparity minority, accrual and retention resources e.g. websites, journals, etc.)

11:50 am - 12:00 pm  **Other Business / Discussion**

12:00 pm  **Adjournment**

**Future Meetings**

- Monthly Tri-Chair calls—first Thursday of every month.
- HDC Working Group (WG) Conference Calls—As determined by WG Leaders
- Committee Conference Calls—Dates to be determined
- Future NRG Oncology Meetings:

  **July 12 - 14, 2018**
  Philadelphia Marriott - Downtown
  Philadelphia, PA
  **HDC Workshop-TBA**

  **February 7 - 9, 2019**
  Phoenix Convention Center
  Phoenix, AZ

  **July 18 - 20, 2019**
  Philadelphia Marriott - Downtown
  Philadelphia, PA
  **HDC Workshop-TBA**

  **January 9 - 11, 2020**
  Marriott Marquis
  Houston, TX
International Members Workshop

Date: Friday, January 26, 2018
Start and End Time: 10:00 am – 11:00 am EST
Chairs: Ben Corn, MD; Stephan Bodis, MD
NRG Operations: Erica Field

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing NRG clinical trials available to International sites
2. Apply standards and procedures required to participate in a research protocol supported by NRG Oncology
3. Discuss the role of PI’s role to review NRG schemas/summaries for future clinical trials

I. General
   a. Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest
   b. News from NRG leadership for intl. members

II. Status of NRG trials open to accrual – Erica Field

III. Optimizing accrual - Discuss best practices for optimizing accrual among International sites – Ben Corn and Stephan Bodis
   a. Disease Sites of interest
   b. RT only protocols (overview)
   c. Study protocols with RT and systemic chemotherapy, targeted, immunotherapy: involvement of pharmaceutical sponsor upfront early during protocol development if trial opened for international members

IV. New concepts and protocols

V. Site PI responsibility to review developing NRG trials – Erica Field
   a. NCI draft policy on international participation

VI. New Business, General Questions, Discussion - discussion lead Ben Corn, MD; Stephan Bodis, MD
   a. Goals and milestones
   b. Input from international members

VII. Evaluation
Local Regional Breast Cancer Subcommittee

Date: Friday, January 26, 2018
Start and End Time: 7:00 AM – 8:00 AM
Chair: Thomas Julian, MD
Co-Chair: Doug Arthur, MD

Learning Objectives:

Following this activity, participant will be better able to:
1. Provide information on committee mission and format.
2. Discuss local regional questions related to breast cancer.
3. Acquire insight to evolve LR clinical trials.

Workshop Agenda:

7:00 – 7:05 Welcome/Introduction Thomas Julian, M.D & Doug Arthur, M.D.
7:05 – 7:20 NRG 1014 re-treatment Follow-up study Atif Kahn, MD
7:20 – 7:35 Pre-OP RT Update of institutional experience Simona Shaitelman, MD
7:35 – 7:55 Ideal monotherapy in the elderly, hormone sensitive, Stage 1 breast cancer Manjeet Chadra, MD
7:55 – 8:00 Call for new ideas Lead by Thomas Julian, M.D & Doug Arthur, M.D.
NRG Medical Physics Subcommittee Workshop Agenda
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Date: Friday, January 26, 2018
Start and End Time: 4:00 pm – 6:00 pm
Chair: Ying Xiao, PhD
Co-Chairs Jason Sohn, PhD and Stanley Benedict, PhD

Learning Objectives
Following this activity, participants will be better able to:
1. Determine the technical concerns arising from the protocol development
2. Develop strategies to address the technical concerns/issues identified from protocol development
3. Provide updates on developments related to technology from other NCTN groups
4. Provide a summary on latest developments in technology that impacts Patient Care to enhance knowledge, improve Systems-Based Practice, and to prepare for possible application in trials.

WORKSHOP AGENDA

4:00 – 4:05 Introductions (5 min)  Ying Xiao, PhD
4:05 – 4:15 NCI Communications (10 min)  Ceferino Obcemea
4:15 – 4:30 NRG QA Report (15 min)
  • IROC Houston  David Followill, PhD
  • IROC Philadelphia RT (Contouring & Dosimetry)  Ying Xiao, PhD
  • IROC Philadelphia Imaging  Mark Rosen, MD
4:30 – 5:00 Disease Site Reports (30 min)
  • GI  William Parker, PhD
  • GU  Ying Xiao, PhD
  • GYN  Stanley Benedict, PhD
  • H&N  Jason Sohn, PhD
  • Lung  Martha M. Matuszak, PhD
  • Other (NCORP)  Tian Liu, PhD
5:00 – 5:25 Modality Technology Reports (25 min)
  • SBRT  Yimei Huang, PhD
  • IMRT  Martha M. Matuszak, PhD
  • IGBT  Stanley Benedict, PhD
  • Emerging technologies  Jason Sohn, PhD
5:25 – 5:40 NCTN Collaborations (15 min)  Ken Ulin, PhD
5:40– 5:50 Other Business
5:50 – 6:00 Questions/Discussions
Ovarian Workshop Agenda

Date: Friday, January 26, 2018  Saturday, January 27, 2018
Start and End Time: 8:00 am to 10:00 am  10:00 am to 11:00 am
Chair: Michael A Bookman  Michael A Bookman
Co-Chair: Paul DiSilvestro  Paul DiSilvestro

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 promising translational research objectives and priorities for future clinical trials
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)
   • Update regarding international studies from GCIG NOV 2017 (Michael Bookman)
   • Commentary on ICON8 data from ESMO 2017 regarding weekly chemotherapy (Premal Thaker and Keiichi Fujiwara)
   • Improved tracking of QOL assessments on NRG-GY004 and NRG-GY005 Lari Wenzel
   • Updated design for RT1713 to evaluate an aromatase inhibitor in LGSC (Amanda Nickles-Fader)
   • Development plan for CC1720 Elderly Platinum-Resistant Ovarian Cancer Patients (Dana Chase)
   • Development plan for OV1719 Randomized Phase II Trial of olaparib + tremelimumab vs platinum based physicians’ choice chemotherapy platinum sensitive recurrent ovarian cancer, pending GCSC review
   • Concept development for assay-guided therapy in recurrent disease (David O’Malley et al.)
   • Discussion of key design elements for OV1741, a randomized evaluation of interval cytoreductive surgery in elderly patients receiving neoadjuvant chemotherapy, in collaboration with the Elderly Working Group (Amina Ahmed, Amy Breggar, Helen Huang, et al.)

C. Review of Closed Studies (non-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). Accrual to surgical component completed and study closed JUN2017, awaiting events for primary analysis
   • 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 Grunigen)
- 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)
- 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 Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Rob Coleman).
- 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)
  - Activated 29JUN2015, 49 patients on first stage, temporary closure 07OCT2015
  - Re-activated 22MAY2017, 51 accrued on second stage (total = 100), closed 28AUG2017
- 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
  - Reminder to sites regarding completion of scheduled QOL assessments

D. Review of Active Studies (Status as of NOV2017)
- GOG0264 RP2 trial paclitaxel‐carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Carol Brown)
  - Activated 08FEB2010 with 45/128 accrued (as of NOV2017)
- GOG0281 RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson)
  - Activated 27FEB2014, closed to US sites 01MAY2017 with 178 enrolled, ongoing accrual in UK (slow), amendment approved to re-open for 20 additional patients at US sites
- 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 (estimated mid-2018)
  - Reminder to sites regarding completion of scheduled QOL assessments
- 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)
  - Tentative dose established for randomized phase II, awaiting NCI-CTEP review
- 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
  - Estimated Group-wide activation mid-2018
- 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)
E. Review of Approved Concepts under Development (Status as of NOV2017)

- **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. Protocol consensus review in progress. (Ramez Eskander and David Hyman)

- **NRG-GY015 (OVM1629)** A randomized phase II study of metformin combined with and maintained following front-line neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Diane Yamada and U Chicago SPORE). Protocol finalization NOV2017, preparing for activation (n=76)

- **NRG-GY016 (RT1627)** Randomized phase II evaluation pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. LOI approved 02OCT02017, preparing protocol for submission (n = 58) (L Gien and Robert Coleman)

- **OVM1505** Randomized Phase II study of paclitaxel/carboplatin +/- OMP-54F28 (a receptor decoy of Wnt ligands) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer receiving front-line neoadjuvant chemotherapy (Kathleen N Moore). Awaiting phase I data.

- **RT1507** A phase II trial of Cediranib in recurrent ovarian sex-cord stromal tumors. LOI and protocol development in progress (Danielle Vicus)

- **RT1713** A Phase III Randomized Three Arm trial of paclitaxel/carboplatin compared to paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV primary low-grade serous carcinoma of the ovary or peritoneum. (Amanda Nickles-Fader). GCSC review 21SEP2017, anticipate revision of study design using 2 arms. International interest from GCIG (AGO, AGO-Austria, GINECO, MRC-UK, NSGO)
  - Discussion of revised two-arm design

- **TS1514** Immunoscore determination as predictive biomarkers for clinical outcomes in GOG-0262. Awaiting amendment of data sharing plan (Samir Khleif).

- **CC1720** Elderly Platinum-Resistant Ovarian Cancer Patients (Dana Chase). Not approved by NCI, undergoing revision in collaboration with DCPC and Elderly Working Group.
  - Discussion of revised design and development plans

- **OV1719** Randomized Phase II Trial of olaparib + tremelimumab vs platinum based physicians’ choice chemotherapy in three subgroups of platinum sensitive recurrent ovarian cancer: BRCAmut, BRCAwt with HRD+, and HRD- (n = 420). (Sarah Adams). Presented at OTF 20OCT2017, response prepared for GCSC.
  - Discussion of updated study design and GCSC comments (pending review)

- **OV1741** Randomized evaluation of interval cytoreductive surgery in elderly patients receiving neoadjuvant chemotherapy. Coordinated development with Elderly Working Group, plan for initial OTF GCSC submission after JAN2018 (Amina Ahmed, Amy Breggar, Helen Huang, et al.)
  - Discussion of randomized study design, hypothesis, primary endpoint, sample size justification, secondary endpoints. Current proposal to utilize time-to-progression or PFS as primary endpoint, incorporating QOL-PRO. Study hypothesis is that “no interval surgery” will be superior in this elderly high-risk patient population with good response to initial chemotherapy.
  - Opportunity to evaluate the accuracy of post-C3 CT imaging to assess residual disease prior to cytoreductive surgery
  - Guidelines for utilization of minimally-invasive surgery vs open surgery (non-randomized)
  - Opportunity for international participation through GCIG
  - Allowance to assess for primary or secondary cytoreductive surgery in the setting of recurrent disease

- **OV1812** Assay-guided therapy for recurrent ovarian cancer (David O’Malley, et al.)
  - Discussion of key design proposals

- **NC1427 (CPC1206)** Risk reducing salpingectomy in premenopausal BRCA1/2 carriers (Doug Levine). To be submitted for NCORP review JAN2018.

F. Review of New Concepts and Future Request for Proposals

- **OV1810** A Randomized Phase II trial of reducing chemotherapy cycles accompanied by PARPi in platinum-sensitive recurrent ovarian and fallopian tubal cancer. (Se Ik Kim)
• **OV1811** A Randomized Phase II/III trial of PARPi and bevacizumab combined treatment with PARPi maintenance versus conventional carboplatin and paclitaxel chemo with PARPi maintenance as front line setting in patients with primary ovarian, peritoneal and fallopian tubal cancer. (Jae-Weon Kim)

**QUESTIONS / DISCUSSION**
Pathology Workshop Agenda

Date: Friday, January 26, 2018
Start and End Time: 8:00 am – 5:00 pm
Chair: William H Rodgers PhD, MD

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

1. Apply standardized criteria for evaluation of neoplasms
2. Discuss current diagnostic criteria for neoplasms as cited in the Pathology Manual
3. Utilize staging criteria as cited in the Pathology Manual
4. Utilize current quality assurance methods to review cases submitted for protocols
5. Discuss active and proposed protocols for neoplasms

WORKSHOP AGENDA

Discussion Topics:
- Orientation for new members
- Review slides from cases for eligibility
- Concurrent discussion of eligibility criteria

Noon: luncheon – business meeting

- Pathology Committee member involvement in protocol development
- Continuing review of cases
- Grant Application Preparation

QUESTIONS / DISCUSSION
Patient Centered Outcomes Research (PCOR) Workshop

Date: Thursday, January 25, 2018
Start and End Time: 4:00 pm – 6:00 pm
Co-Chairs: Patricia Ganz, MD; Benjamin Movsas, 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

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| 4:00 – 4:50 | I. Developing Concepts: Comments on PRO, QOL, and CER endpoints   | Ben Movsas, MD
                             Lari Wenzel, PhD |

OV 1719: A Randomized Phase II Trial of Olaparib + Tremelimumab Vs Platinum-Based Physician Choice Chemotherapy In HRD+ and HDR- Platinum Sensitive Recurrent Ovarian Cancer

OV 1741: Assessing the Role of Minimally Invasive Surgery in Patients Undergoing Neo-Adjuvant Chemo for Ovarian Cancer

UC1710: Randomized Phase 2/3 Trial of Carboplatin and Paclitaxel with or Without Pembrolizumab as initial therapy in Patients with Measurable Stage 3 or 4A, Stage 4B or Recurrent Endometrial Cancer

NC1744: Randomized Phase II Conventional vs Hypofractionated Pelvic RT for Adjuvant Treatment of Endometrial Carcinoma with Toxicity as Endpoint

NRG-LU1704: Limited Stage Small Cell Lung Cancer: A Phase III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab

SWOG 1806/NRG: Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer

4:50 – 5:25 | II. PCOR Compliance Update Comments/Audience Q & A | Ronald Chen, MD |

5:25 – 5:35 | III. NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates | Ben Movsas, MD
                             Lari Wenzel, PhD |

5:35 – 6:00 | IV. NCORP Seed Grants V. Other Business | Ben Movsas, MD
                             Lari Wenzel, PhD |

Activated Studies with PCOR/CER Endpoints

NRG-BN001: Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma (activated 10/14)

NRG-BN003: Phase III Trial of Observation versus Irradiation for a Gross Totally Resected Grade II Meningioma (activated 6/17)

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 (activated 8/17)
NRG-CC001: Phase III Trial of Memantine and Whole-Brain Radiotherapy with or without Hippocampal Avoidance for Patients with Brain Metastases (activated 7/15)

NRG-CC002: Pre-operative assessment and post-operative outcomes of elderly women with gynecologic cancers (activated 2/15)

NRG-CC003: Phase IIR/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer (activated 12/15)

NRG-GI003: A Phase III Randomized Trial of Protons versus Photons For Hepatocellular Carcinoma (activated 6/17)

NRG-GU003: A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) versus Conventional Post-Prostatectomy Radiation Therapy (COPORT) (activated 7/17)

NRG-GY004: A 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 (activated 2/16)

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/Persistent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS) (activated 2/16)

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 (activated 5/17)

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) (activated 4/14)

NRG-HN002: A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer (activated 10/14)


RTOG 1112: Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma (activated 4/13)

RTOG 1308: Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Chemoradiotherapy for Inoperable Stage II-IIIIB NSCLC (activated 2/14)
Pharmacy Subcommittee Workshop

Date: Friday, January 26, 2017
Start and End Time: 12:00 pm – 1:00 pm
Chair: Judith Smith, Pharm.D.

Learning Objectives:
Following this activity, participants will be better able to:
1. Describe the “synthetic lethality” mechanism associated with the class of PARP inhibitors.
2. Compare and contrast the indications, ADRs, and cost to consider when selecting a PARP inhibitor for treatment of ovarian cancer.
3. Understand the rationale and benefits of standardizing drug information for research protocols.
4. Discuss the limitations and concerns with placebo control arms in immunotherapy clinical studies.
5. Elucidate the primary aspects for standardizing patient variables for dosing carboplatin.

WORKSHOP AGENDA

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

II. CE Presentation: “Integrating PARP inhibitors into Clinical Practice and Considerations for Research” (30 min)
   – presented by Judith Smith, Pharm.D., B.S., BCOP, CPHQ

III. Protocol Review Process for Pharmacy Subcommittee (3 min)

IV. Protocol Drug Information Update (15 min)
   a. To be reviewed/approved at this meeting:
      i. Ado-Trastuzumab
      ii. Cetuximab
      iii. Carboplatin
      iv. Docetaxel
      v. Ramucirumab
      vi. Trastuzumab
   b. Next set of agents to be prepared for review at NRG Oncology February meeting:
      vii. Liposomal doxorubicin
      viii. Etoposide
      ix. Oxaliplatin
      x. Paclitaxel Albumin Bound (Abraxane)
      xi. Temozolomide
      xii. Topotecan
   c. Approval of standardized language/position on use of herbal/nutritional supplements

V. Finalized Proposal to omit “Placebo Controls” in Future Immunotherapy Clinical Trials (3 min)

VI. Carboplatin Position Paper Update (5 min)

VII. Updates/Discussion of any Pharmacy Related Issues Identified in Other NRG Committee Meetings (2 min)
   a. Any issues that the Pharmacy Subcommittee should follow up on regarding new protocol proposals presented at the other committee meetings.

VIII. Evaluation
Protocol NRG-BR005 Workshop

Date: Saturday, January 27, 2018

Start and End Time: 8:00 am - 9:00 am

Learning Objectives
Following this activity, participants will be better able to:
1. Explain the rationale for the BR005 Trial.
2. Understand eligibility/biopsy factors for BR005 Trial.
3. Describe the potential for a future Phase III study.

A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Response After Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment Without Surgery

WORKSHOP AGENDA

8:00-8:15 am  Background and Trial Rationale  Mark Basik, MD
8:15-8:30 am  Eligibility and Ineligibility Criteria  Jennifer F. De Los Santos, MD
8:30-8:40 am  Stereotactic Biopsy of the Tumor Bed  Heidi Umphrey, MD
8:40 -8:55 am  Moderated Panel Discussion: Potential Phase III Study  Thomas Julian, MD
8:55 -9:00 am  Questions and Answers

Date: Friday, January 26, 2018
Start and End Time: 10:00 am – 11:00 am

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. Identify critical aspects of the correlative science of the clinical trials.
3. Discuss the clinical logistics of the clinical trials.

Educational need for the presentations is based on the discussion at the July 2017 NRG Oncology Meeting and the ongoing calls to the Clinical Coordinating Department (Pittsburgh Office) regarding the trials.

WORKSHOP AGENDA

10:00-10:25 Overview of NRG-BR004
Priya Rastogi, MD
A Randomized Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab/Placebo compared to Paclitaxel/Trastuzumab/Pertuzumab/Pembrolizumab in First Line HER2-positive Metastatic Breast Cancer

10:25-10:35 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

10:35-10:40 Clinical Logistics
Kristen Kotsco RN, BSN

10:40-10:50 Overview of NSABP B-55/BIG 6-13
Lynne Suhayda, RN, MSEd.
A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multicenter Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

10:50-10:55 Questions/Discussion

10:55-11:00 Evaluation
Protocol GI002 and Protocol GI004 Workshop

Date: Friday, January 26, 2018
Start and End Time: 11:30 am – 1:00 pm
Presenters: Thomas George, MD, FACP
James J. Lee, MD, PhD
Mary Pat Matisko, RN

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 common eligibility and treatment questions.

WORKSHOP AGENDA

GI002: A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer

and

GI004: Colorectal Cancer Metastatic MSI-High Immuno-Therapy (COMMIT) Study:
A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer

11:30 am - 11:50 am Overview of GI002 Thomas George, MD
11:50 am - 11:55 am Frequently Asked Questions Mary Pat Matisko, RN
11:55 am - 12:00 pm Questions & Answers Thomas George, MD
Mary Pat Matisko, RN
12:00 pm - 12:50 pm Overview of GI004 James Lee, MD, PhD
12:50 pm - 1:00 pm Questions & Answers James Lee, MD, PhD

Questions/Discussion
Protocol Support Committee
Introduction to Clinical Trials: Principles of Clinical Trial Management

Date: Thursday, January 25, 2018
Start and End Time: 7:30 am – 4:30 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.
9. Discuss RECIST 1.1 criteria and identify method of source documentation for tumor measurements.
10. Describe how to record the RECIST data 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 attributions.
20. Discuss the importance of QOL Components to our trials.
21. Discuss NRG Oncology Mentorship Program.
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.

AGENDA

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<td>Welcome</td>
<td>Sharon Stockman, BA, CCRP &amp; Cindy Licavoli RN, MA</td>
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<td>7:45am-8:00am</td>
<td>NRG Oncology History and Contributions</td>
<td>D. Lawrence Wickerham, MD</td>
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<tr>
<td>8:00am-8:20am</td>
<td>NRG Membership</td>
<td>Mimi Passarello, MBA</td>
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<tr>
<td>8:20am-8:50am</td>
<td>IRB’s: Who, What, Where, When and How</td>
<td>Lynne Lippmann, BA, CCRP</td>
</tr>
<tr>
<td>8:50am-9:20am</td>
<td>Serious Adverse Event Reporting</td>
<td>Sara McCartney, MS, RN</td>
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<tr>
<td>9:20am-9:40am</td>
<td>Break</td>
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<tr>
<td>9:40am-10:05am</td>
<td>Investigational Drug Management</td>
<td>Nancy Knudsen, RN, BSN</td>
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<tr>
<td>Time</td>
<td>Topic</td>
<td>Speaker</td>
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<tr>
<td>10:05am-10:40am</td>
<td>Quality Assurance Audits</td>
<td>Tamara McLaughlin, MHA, MPH</td>
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<tr>
<td>10:40am-11:10am</td>
<td>Medidata Rave</td>
<td>Edward Kopek, AAS, MLT (ASCP), HT</td>
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<tr>
<td>11:10am-11:30am</td>
<td>RECIST</td>
<td>Mark Shahin, MD</td>
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<tr>
<td>11:30am – 11:40am</td>
<td>QOL</td>
<td>Sharon Stockman, BA, CCRP</td>
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<tr>
<td>11:40am-11:50am</td>
<td>Mentorship Program</td>
<td>Nancy Fusco, RN, BSN</td>
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<tr>
<td>11:50 am – 12pm</td>
<td>Morning Closing Remarks</td>
<td>Cindy Licavoli, RN &amp; Sharon Stockman, BA, CCRP</td>
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<tr>
<td>12:00 pm – 1:15pm</td>
<td>Lunch (on your own)</td>
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<tr>
<td>1:15pm – 4:10pm</td>
<td>Afternoon Breakout Sessions- All sessions run concurrently (40 minutes/session)</td>
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<tr>
<th>Topic</th>
<th>Speaker</th>
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</table>
| Patient Screening and Enrollment | Lead Facilitator- Cindy Licavoli, RN, BSN, MA  
Joni Shortt, RN, BSN, CCRC  
Michele Lacy, RN, BSN, OCN |
| Treatment Modalities in Clinical Trial Management | Lead Facilitator- Joyce Neading, RHIT, CTR  
Chrisann Winslow, RN, MSN  
Stacey Lewis, RN, BSN |
| Data Management                | Lead Facilitator- Lynne Lippmann, BA, CCRP  
Mary Shields, RN, MSN, CCRP, OCN  
Sue Eaton, CCRP |
| Adverse Event Reporting       | Lead Facilitator- Mary Smrekar, RN, MSN, CNP  
Donna White, RN, BSN, OCN  
Alison Ivey, RN, BSN, OCN, CCRP |

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

Date: Thursday, January 25, 2018
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 Sally Brown RN, BSN, MGA, 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 July 2018 meeting

WORKSHOP AGENDA
1) Welcome
2) Announcements of open positions
3) Review taping for July 2017 meeting
4) Review evaluation of July 2017 meeting
5) Discuss plans for July 2018 meeting
   a. Lunch time session
   b. Sub group
   c. Round tables
   d. Format for morning
      i. 4 hours lecture
      ii. 2 hours lecture
      iii. 2 hours concurrent sessions
6) Suggestions for winter 2018 meeting
   a. Sub working group

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

Date: Thursday, January 25, 2018
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:
1. Identify potential new topics for the Mentorship Welcome Packet
2. Discuss plans to develop the Mentor Program

WORKSHOP AGENDA
1. Roll call of Mentorship Working Group members
2. Update from Quality Control Working Group Liaison
3. Announcements
4. Approval of minutes from most recent conference calls
5. Review committee member number of participants
6. Review current projects for the working group:
   a. Introductory Materials For NRG Oncology Clinical Trials Coordinators:
      i. Annual review of content for updates and new content
   b. Develop Mentor Program:
      i. Review temporary mentor plan and effectiveness
      ii. Development of Mentorship Program tools
7. Meeting Plan: Conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

QUESTIONS/DISCUSSION
EVALUATION
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 Medicare analysis/additional funding for NCTN studies, receive updates on other NCTN group and incorporate tools presented at this meeting by guest speakers
4. Discuss current method for updates and corrections of existing protocols
5. Discuss additional ways the working group can assist the protocol development teams.
6. Discuss the role the protocol review committee identifying issues and concerns for the other working groups like education and mentor to review/discuss

WORKSHOP AGENDA

1. Review current Protocol review process
2. Update from the Protocol Development team. Any upcoming studies – it has been a slow few months?
3. CIRB update if member can attend
4. Discuss studies reviewed since last meeting (Reviewed CC005, GY012, GY013)
5. Update on Funding sheets and Medicare analysis?
6. Replacement members – review current roster, introduce new members
7. Update from Quality Control representative
8. Other business

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

Date: Thursday, January 25, 2018
Start and End Time: 5:00pm – 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 13, 2017 meeting
2. Introductions
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 – TBD
5. Discussion with Dr. Chen about QOL and neurocognitive testing deficiencies
6. Old Business

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

Date: Friday, January 26, 2018
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: Sally Brown RN, BSN, MGA, Joyce Neading RHIT, CTR

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

1. Identify, describe and discuss aspects of roles and responsibilities for the PSC Working Groups
2. Identify, describe and discuss the purpose and expectations of individual appointments to committees/working groups
3. Identify and discuss educational needs of both new and experienced CRAs/Nurses
4. Discuss the current activities of NRG Committees by CTN/CRA representatives

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

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

Date: Friday, January 26, 2018
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: Sally Brown RN, BSN, MGA, Melinda Weiblen, BS

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

1) Describe the delinquency reports (DQP) accessed through CTSU
2) Explain the use of Delegation Logs (DTL) on the CTSU web site
3) Describe one new NCI auditing guideline
4) Discuss the importance of patient reported outcomes to the success of a clinical trial
5) Explain one modification to the NCI informed consent document template
6) Identify one benefit of the use of immunotherapy in neuro-oncology
7) Summarize the differences between RECIST, mRECIST and irRECIST

AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
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</table>
| 2:00-2:10 | Introduction/Welcome                           | Sally Brown, RN, BSN, MGA, CCRP
|         |                                                 | Walter Curran, MD                             |
| 2:10-2:25 | Update from Statistics and Data Management Ctr | Mary Jo Antonelli, MBA, MHA                    |
| 2:25-2:45 | Update on NRG Oncology QA                      | Mimi Passarello, MBA                          |
| 2:45-3:15 | Update on NIH Pharmaceutical Electronic Investigator Registration and Delegation Logs | Donna Shriner, PharmD, MPH                    |
| 3:15-3:40 | Patient Reported Outcomes (PRO) Compliance     | Sharon Stockman, BA, CCRP                     |
| 3:40-3:50 | Overview of changes to the NCI informed consent document template | Andrea Denicoff, MS, RN                      |
| 3:50-4:00 | BREAK                                         |                                                |
| 4:00-5:00 | Immunotherapy with emphasis on neuro-oncology  | Surasek Phuphanick, MD, FAAN                  |
| 5:00-6:00 | Response Assessment Training                    | Allison Ivey, RN, BSN, OCN, CCRP             |

QUESTIONS/DISCUSSION
EVALUATION
Protocol Support Committee Workshop (Closed)

Date: Saturday, January 27, 2018
Start and End Time: 9:00 – 12:00 am
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC

AGENDA

1. Meeting summary
2. Report from CTN and CRA Subcommittees- Sharon Stockman & Cindy Licavoli (includes reports from Working Groups)
3. NRG Oncology Newsletter  PSC column
4. NRG Oncology Committee reports
5. PSC representation on NRG Oncology committees
6. New Business

QUESTIONS/DISCUSSION
EVALUATION
Proton Working Group Workshop Agenda
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Date: Saturday, January 28, 2018
Start and End Time: 6:45 am – 8:30 am
Chair: Tom DeLaney, MD

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

1. Recognize critical aspects of developing and conducting a clinical trial in cancer therapy research using proton therapy in a cooperative group setting.
2. Identify and describe the design and status of new clinical trials using proton therapy being planned and launched by NRG Oncology, to enable potential contribution to protocol design vetting and/or effective patient enrollment in newly-launched studies.
3. Identify, describe, and discuss aspects of ongoing RTOG clinical trials using proton therapy which are in need of special support and improvement (including QA & credentialing problems), 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 and describe new forms and techniques of proton delivery and its use in NRG Oncology trials.

WORKSHOP AGENDA
6:45 – 6:50 Welcome/Introduction/ Moderator
Tom DeLaney, MD

6:50 – 7:00 Update on Proton Center Credentialing by IROC Houston Protocols/ Concepts
David Followill, PhD

7:00 – 7:20 Protons in liver studies
Laura Dawson MD
RTOG 1112 - Ph III Sorafenib +/- SBRT for hepatocellular ca (L. Dawson)
NRG-GI001 - Ph III Cis/Gem +/- RT for unresectable cholangioCa (Ted Hong, MD)
NRG-GI003 - Ph III Protons vs Photons for Hepatocellular Carcinoma (Ted Hong, MD)

7:20 – 7:30 NRG-BN001 Brain: Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant /Adjuvant Temozolomide in Glioblastoma (Minesh Mehta, MD)

7:30 – 7:40 NRG-BN005 Brain: Ph II Randomized Proton vs IMRT for Cognitive Preservation in Pts with IDH Mutant, Low to Intermediate Grade Gliomas (David Grosshans MD)

7:40 – 7:50 RTOG 1308 Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable Stage II-IIIB NSCLC (Jeffrey Bradley, MD)
ZhongXing Liao, MD

7:50 – 8:00 PCORI (Patient-Centered Outcomes Research Institute) RADCOMP Breast MD
Randomized Trail of Photons versus Protons (Shannon Macdonald, MD)

8:00 – 8:10 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 (Annie Chan, MD)

8:10 – 8:20 NRG 1738 Ph III Randomized Protons vs. IMRT for Esophageal CA (Steven Lin, MD)

8:20 – 8:25 Other Business
Tom DeLaney, M.D.

8:25 – 8:30 Questions
Radiation Oncology Workshop Agenda
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Date: Friday, January 26, 2018
Start and End Time: 2:00 pm – 4:00 pm
Chair: Jeff Michalski, MD
Co-Chairs: Ivy Petersen, MD
Co-Chair Elect: Evan Wuthrick, MD

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

1. Provide information on the latest developments related to the Imaging and Radiation Oncology Core (IROC) Group and NRG Oncology. Learn about mechanisms of quality assurance and protocol development as they relate to innovative technology in radiation oncology.
2. Describe different aspects of the field of medical physics such as credentialing for advanced technologies.
3. Discuss the most recent findings and technological advances in radiation oncology for multiple NRG clinical disease sites.

WORKSHOP AGENDA

2:00 – 2:05 Welcome / Introduction
   Jeff Michalski

2:05 – 2:20 Update on NCTN Cooperative Groups
   a. NRG Oncology Group Update
      Jeff Michalski
   b. Imaging and Radiation Oncology Core (IROC) RT Update
      David Followill
      Denise Manfredi
   c. Imaging and Radiation Oncology Core (IROC) Imaging Update
      Mark Rosen

2:20 – 2:30 NCI Imaging Research Priorities/Opportunities
   Ying Xiao

2:30 – 2:40 Overview of Medical Physics
   Ying Xiao

2:40 – 2:50 Review RTOG/NRG Studies with Imaging and Oncology Trial
   Jeff Michalski

2:50 – 3:40 Disease Site Liaisons Reports
   a. Brain
      Christina Tsien
   b. Breast
      Steven Chmura
   c. Gyn
      Ann Klopp
   d. GI
      Evan Wuthrick / Eugene Koay
   e. GU
      Daniel Krauss / Hiram Gay
   f. H&N
      Sue Yom
   g. Lung
      Charles Simone
   h. Sarcoma
      Philip Wong

3:40 – 3:50 Other Business

3:50 – 4:00 Questions / Discussion
Rare Tumor Workshop

Date: Friday, January 26, 2018
Start and End Time: 2:00 pm - 4:00 pm
Chair: David M. Gershenson, MD
Co-Chair: Al Covens, MD

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

1. Discuss emerging and ongoing 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
4. Develop a strategy to study mucosal melanoma in a group-wide 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-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)

GY-001: 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)

B. Proposed Studies

RT1531: A randomized phase II trial of Temozolomide and Cisplatin versus Nivolumab (BMS-936558) in patients with completely resected mucosal melanoma (Vicus)
RT1627: A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary (Gien)

RT1507: A phase II trial of Cediranib in recurrent ovarian sex-cord stromal tumours (Vicus)

RT 1713: A randomized phase III, 3-arm trial of paclitaxel/carboplatin compared to paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV primary low-grade serous carcinoma of the ovary or peritoneum (Fader/Gershenson)

C. Discussion Topics:
   a. “Follow-up discussion of potential concepts for endometrioid carcinoma of the ovary”
   b. MSK Program for Germ Cell Tumors: “Make an Impact”  Carol Aghajanian, MD

QUESTIONS / DISCUSSION
A. Active Studies ---

1. ARST1321 (COG-NRG study): Pazopanib Neoadjuvant Trial In non-rhabdomyosarcoma soft tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (Chen/Scharschmidt/Weiss)

2. MGH/NRG: Phase I/II Trial of Preoperative Intensity Modulated Radiation Therapy (IMRT) For Retroperitoneal Sarcoma using a Simultaneous Integrated Boost (DeLaney/Wang)

3. Phase Ib Study To evaluate Neoadjuvant p53/MDM2 inhibitor combined with IMRT for Soft Tissue Sarcomas (Welliver/Wang)

B. Developing Concepts: Oral Update only

1. Phase IIR Trial of Radiotherapy versus Surgery and Radiotherapy for Soft Tissue Sarcomas of the Extremities and Chestwall Following an Unplanned Excision (Wolfson)

2. Phase II trial to investigate the role of peri-operative RT in desmoid tumors harboring CTNNB1 S45 mutation (Pollock/Welliver)


4. Phase IIR Trial of Immunotherapy and SBRT for Metastatic Soft Tissue Sarcoma (Wong) : update only

C. Sarcoma TRP

1. Availability of NCI support to study on the combination of new target agents and radiotherapy (Dr. Charles Kunos)

2. Sensitizing soft tissue sarcoma to chemotherapy and radiation by repurposing disulfiram and endogenous copper (Xinhui Wang):

3. BMN673 effects on Radiation in vitro (George Iliakis): update

4. Increase in PD-L1 expression after Pre-operative radiotherapy for Soft Tissue sarcoma (Kirtesh Patel): update

D: New Business
Surgical Oncology Workshop Agenda

Date: Saturday, January 27, 2018
Start and End Time: 6:30 – 8:00 AM
Chair: Thomas Julian, M.D.
Co-Chairs: Drew Ridge, M.D., Nick Spirtos, M.D.

Learning Objectives:
Following this activity, participant will be better able to:
1. Provide information on the latest developments related to the NCTN and NRG Oncology
2. Describe different aspects of the field of surgical oncology such as QA/QC and integration into trials
3. Discuss the most recent findings and technological advances in surgical oncology for multiple NRG clinical disease sites.

Workshop Agenda

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>6:30</td>
<td>Welcome/Introduction</td>
<td>Nick Spirtos, M.D.</td>
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<td>-Minutes approval</td>
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<td>6:35</td>
<td>Medical Oncology Update</td>
<td>Corey Langer, M.D.</td>
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<td>6:45</td>
<td>Radiation Oncology Committee Update</td>
<td>Jeff Michalski, M.D.</td>
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<td>6:55</td>
<td>Update QA &amp; QC Committee</td>
<td>Charles Whitney, MD</td>
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<td>7:05</td>
<td>NRG Oncology Update</td>
<td>Nick Spirtos, M.D.</td>
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<td>7:10</td>
<td>Disease Site Liaisons Reports (very brief update on developments)*</td>
<td>Quynh Le, MD</td>
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<td></td>
<td>a. Head and Neck</td>
<td>Harry Bear, MD, PhD</td>
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<td>b. Breast</td>
<td>Nick Spirtos, M.D.</td>
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<td>c. Gynecology</td>
<td>Jeffrey Bradley, M.D.</td>
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<td>d. Lung</td>
<td>Lenny Gomella, M.D.</td>
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<td>e. GU</td>
<td>Minesh Mehta, M.D.</td>
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<td>g. Brain</td>
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<td>7:45</td>
<td>Questions/Discussion</td>
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*Liaison to provide a 5 minute update on latest surgical advancement
Translational Science Workshop

Date: Thursday, January 25, 2018  
Start/End Time: 6:30 pm - 8:00 pm  
Chair: Michael Birrer, MD, PhD  
Co-Chairs: Adam Dicker, MD, PhD  
Matthew Ellis, MB, BCHIR, PhD

Learning Objectives: To better understand the translational research efforts of NRG Oncology  
Following this activity, participants will be better able to:

1. To understand the role of immunotherapy biomarkers  
2. To understand the interaction of CPTAC efforts with NRG Oncology  
3. To understanding the present translational research being conducted by the NRG U10.  
4. To recognize critical aspects of developing translational endpoints for legacy GOG clinical trials.  
5. To identify and describe new technologies for genomics and protein quantification and their use in legacy RTOG clinical trials

WORKSHOP AGENDA

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<tr>
<td>6:30 – 6:45</td>
<td>Opening Remarks and Introduction</td>
<td>M. Birrer, MD, PhD</td>
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<td>A. Dicker, MD, PhD</td>
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<td>Svasti Haricharan</td>
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<td>6:45 – 7:00</td>
<td>NRG Translational Research U10 Update</td>
<td>D. Mutch MD</td>
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<td>7:00 – 7:30</td>
<td>High-Dimensional Immune Monitoring of Immunotherapy Trials</td>
<td>S. Gnjatic, PhD</td>
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<td>7:30 – 8:00</td>
<td>Proteomic Update: Neoadjuvant Treatment of Breast Cancer</td>
<td>M. Ellis, MB, BCHIR, PhD</td>
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<td>Determination of Protein Biomarkers of Ovarian Cancer</td>
<td>M. Birrer MD, PhD</td>
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<td>Refractory Disease</td>
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Translational Science Brain Cancer Subcommittee and Low Grade Glioma Working Group

Friday January 26th, 2018
Phoenix Convention Center
Phoenix, AZ
8:00-10:30am

8:00- 8:05am Introduction
(Dr. Arnab Chakravarti, MD.)

8:05 - 8:25am “Genomic Predictors in Lower Grade Gliomas: RTOG 9802, 9813, and 0424”
(Erica Bell, PhD.)

8:25 -8:45am “Update on mRNA Biomarkers for NRG/Oncology RTOG 9802 and 9813”
(Jessica Fleming, PhD)

8:45 - 9:05am “IkB in Lower Grade Gliomas”
(Markus Bredel, MD, PhD)

9:05- 9:25am “ATP Drivers of Resistance”
(Pierre Robe, MD., PhD.)

9:25- 9:45am “MGMT and CMET updates in Glioblastomas”
(Aline Becker, MD., PhD.)

9:45- 10:05am “Biomarker Discovery: Genome-Wide methylation profiling for low-grade glioma”
(Wei Meng, PhD.)

10:05 - 10:25am “EORTC Low Grade Glioma Updates”
(J.C. Reijneveld, MD., PhD)

10:25 – 10:30 am Round Table Discussion
Translational Science GI Cancer Subcommittee Agenda

Date: Saturday, January 27, 2018

Time: 7:00am-9:00am

Chair: Chandan Guha, MD, PhD

7:00 – 7:20 Introduction/Overview
Chandan Guha, MD, PhD / Christopher Crane, MD

7:20 – 7:30 “DNA Damage Response and Replication Stress Response”
David Yu, MD, PhD, Associate Professor Emory University

7:30 – 8:00 “Chemoradiation Therapy with PARP Inhibitors for GI Malignancies”
Richard Tuli, MD, PhD, Associate Professor, Cedars-Sinai

8:00 – 8:30 “Modulation of Radiation Immune Response by Gut Microbiota”
Edgar Ben-Josef, MD, Professor of Radiation Oncology, University of Pennsylvania

8:30 – 8:50 “Expanding genetic Indications for PARP inhibitors”
Nadeem Riaz, MD, MSc, Associate Director, Genomics Operations, Immunogenomics, and Precision Oncology Platform, Memorial Sloan Kettering

8:50 – 9:00 Closing Remarks and Discussion
Chandan Guha, MD, PhD / Christopher Crane, MD
Translational Science GU Cancer Subcommittee Agenda

Date: Friday, January 26, 2018
Time: 2:00 pm - 4:00 pm
Chairs: Felix Feng, MD / Alan Pollack, MD, PhD

2:00 – 2:05
Introduction and Welcome (Felix Feng/ Alan Pollack)

2:05 – 2:30
Invited talk:
“Examination of Epithelial Plasticity-Induced Treatment Resistance using RTOG 0521 Biopsy Samples” (Phuoc Tran)

2:30 – 3:30
Update on ongoing TRP proposals:
- Using Next Generation Sequencing Approaches to Identify Early Biomarkers of Anti-Androgen Treatment Resistance from the RTOG 96-01 Trial (Chris Maher)
- Genomic analysis of Predictors of Response to Short-Term vs Long-Term ADT in High Risk Prostate Cancer (Paul Nguyen)
- Genomic analysis of Predictors of Response to Short-Term vs No ADT in Intermediate Risk Prostate Cancer (Dan Spratt/Felix Feng)
- C-Reactive Protein and Cytokines in RTOG 0521 (William Hall)
- Genomic analysis of Chemoradiation Response in Muscle-Invasive Bladder Cancers (Kent Mouw, Jason Efstathiou, Bill Shipley)
- Proposed TRP studies for the SWOG 1806/NRG trial of chemoRT +/- immunotherapy (Jason Efstathiou, Felix Feng)

New TRP proposal:
“Soluble Endoglin (sol CD105) as a Marker of Radiation Sensitivity in Prostate Cancer” (Anisha Madhav, Ed Posadas)

3:30 – 3:55

3:55 – 4:00
Closing Remarks
Felix Feng, MD / Alan Pollack, MD, PhD
Translational Science GYN Workshop

Date: Friday, Jan 26, 2018
Start and End Time: 10:30 am – 12:00 pm
Chair: Michael Birrer, MD, PhD
Co-Chair: Heather Lankes, PhD, MPH

Learning Objectives: To better understand the GYN translational research efforts of NRG Oncology.
Following this activity, participants will be better able to:

1. Understand the translational research being conducted by NRG and discuss translational research projects.
2. Understand the design and status of the NCTN Biobanks reorganization and specimen access process.
3. Discuss the developing research priorities of NRG GYN studies.

WORKSHOP AGENDA

10:30-10:40 Opening Remarks TR/Biospecimen Bank Update
   Michael Birrer, MD, PhD
   Heather Lankes, PhD, MPH

10:40-10:50 210 Subcommittee Update
   NRG TR U10 Update // NRG GY015
   CPTAC Update // NRG G007 & GY015
   Michael Birrer, MD, PhD

BRC – Experience and Lessons (Being) Learned

10:50-11:05 GOG 0286B
   Vickie Bae-Jump, MD

11:05-11:20 NRG GY011
   Kim Leslie, MD

11:20-11:35 NRG GY013
   Sarah Temkin, MD

11:35-11:50 Plasma Angiome
   Andrew Nixon, PhD
   Angeles Secord, MD

11:50-12:00 Cell-Free/Circulating Tumor DNA
   Biospecimen Collection and Testing
   Doug Levine, MD

Concept Review:

1. **UC1805**: A Randomized Phase III Trial of Radiation +/- checkpoint inhibitor for high intermediate risk mismatch repair deficient (dMMR) endometrial cancer (Floor Backes) **NEW**

2. **UC1808**: Phase II Efficacy of primary immunotherapy alone or combined immunotherapy and chemotherapy vs. chemotherapy alone in patients with advanced stage or recurrent endometrial cancer (Haider Mahdi) **NEW**

3. **UC1809**: Randomized Phase III Trial of adjuvant doxorubicin plus olaratumab (DO) versus gemcitabine plus docetaxel followed by doxorubicin (GDD) in uterus-limited high-grade Leiomyosarcoma. (Loggers) **NEW**

4. **DT1806**: Gemcitabine and Wee1 Inhibitor in persistent or recurrent endometrial malignancy: a phase II study (Megan McDonald) **NEW**

5. **OV1810**: A Randomized Phase II trial of reducing chemotherapy cycles accompanied by PARPi in platinum-sensitive recurrent ovarian and fallopian tubal cancer. (Se Ik Kim) **NEW**
6. **OV1811**: A Randomized Phase II/III trial of PARPi and bevacizumab combined treatment with PARPi maintenance versus conventional carboplatin and paclitaxel chemo with PARPi maintenance as front line setting in patients with primary ovarian, peritoneal and fallopian tubal cancer. (Jae-Weon Kim) NEW

7. **OV1812**: Assay-guided therapy for recurrent ovarian cancer (David O’Malley, et al.) NEW

8. **CV1807**: Phase I/II trial of Efficacy of concurrent immunotherapy with weekly cisplatin and radiation then maintenance immunotherapy vs weekly cisplatin and radiation in locally advanced cervical cancer. (Haider Mahdi) NEW

Other Business
Questions/Discussion
Translational Science Head & Neck Cancer Subcommittee Agenda

Date:     Friday, January 26, 2018
Time:     2:00 pm - 3:00 pm
Chairs:   Neil Hayes, MD, MPH / Christine Chung, MD

2:00 – 2:05   Introduction/Overview
              Neil Hayes, MD, MPH / Christine Chung, MD

2:05 – 2:45   “KEAP1/NFE2L2: A Commonly Altered Pathway in Aerodigestive Cancer with Clear Therapeutic Potential”
              Youngtae Jeong, MD, PhD/Maximilian Diehn, MD, PhD (Stanford)

2:45 – 3:00   Closing Remarks and Discussion
              Neil Hayes, MD, MPH
Translational Science Lung Cancer Workshop Agenda

Date: Friday, January 26, 2018
Start and End Time: 4:00 pm – 6:00 pm
Chair: Bo Lu, MD, PhD

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

1. Novel biomarkers for cancer immunotherapies and radiotherapy.
2. Optimal combination of immunotherapy with radiotherapy.
3. Toxicity concern from concurrent thoracic radiotherapy and anti-PD1 agents.

WORKSHOP AGENDA

Intro/Overview: Bo Lu, MD, PhD

Speaker: Joanne Weidhaas, MD, PhD, MSM (UCLA)
Presentation Title: “The KRAS-Variant and MicroRNA Binding Site Mutations in 0617”

Speaker: Jianda Yuan, MD, PhD (Merck)
Presentation Title: “TMB/GEP Dual Biomarker Strategy for the Era of Combination Cancer Immunotherapies”

Speaker: Robert Ferris, MD, PhD (UPMC Hillman Cancer Center)
Presentation Title: “Combining Immunotherapy and Radiation Therapy for Head and Neck Cancer”

Speaker: Bo Lu, MD, PhD (Thomas Jefferson University)
Presentation Title: “Toxicity concern from concurrent thoracic radiotherapy and anti-PD1 agents”

Speaker: Feng-Ming Kong, MD (Indiana University)
Presentation Title: “Correlative Blood Marker Study for SBRT Trials”

QUESTIONS / DISCUSSION
Uterine Corpus Committee

Date: Friday, January 26, 2018
Start and End time: 2:30 pm – 4:30 pm (Session I)

Date: Saturday, January 27, 2018
Start and End time: 10:00 am – 11:00 am (Session II)

Chair: David Scott Miller, MD
Co-Chair: Marcus Randall, 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.

Workshop Agenda

A. Introduction (Miller)

B. Review of Closed Studies

1. **GOG0086P**: A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab (NSC #704865, IND #7921), paclitaxel/carboplatin/temsirolimus (NSC #683864, IND #61010), and ixabepilone (NSC #710428/IND #59699)/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (Carol Aghajanian)

2. **GOG0184**: Tumor Volume-Directed Pelvic Plus or Minus Para-Aortic Irradiation followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for advanced Endometrial Carcinoma (Spirtos) (Gynecol Oncol 112: 543-52, 2009; Gynecol Oncol 119: 538-42, 2010):

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

4. **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) [Gynecol Oncol 125: 771-3, 2012]

5. **GOG0210**: A Molecular Staging study of Endometrial Carcinoma (William T Creasman)


7. **GOG0229O** A randomized phase II study with a phase I 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 (Shannon N Westin)

8. **GOG0233**: Utility Of Pre-Op Fdg-Pet/Ct Scanning Prior To Primary Chemoradiation Therapy To Detect Retroperitoneal Lymph Node Metastasis In Patients W/Locoregionally Advanced Ca Of The Cervix ( Ib2, Ila iY4 Cm, IIb-Iva) Or Endometrium (Gr 3 Endometrioid Endometrial Ca; Serous Papillary Ca, Clear Cell Ca, Or Ca (Any Grade); And Grade 1 Or 2 Endometrioid Endometrial Ca

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

10. **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)

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

12. **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)

13. **GOG0277** A Phase III Randomized Trial of Gemcitabine (NSC# 613327) plus Docetaxel (NSC# 628503) followed by Doxorubicin (NSC# 123127) v. observation for uterus-limited, High Grade Uterine Leiomyosarcoma (Martee L Hensley)

14. **GOG0283** A Phase II Trial of DCTD-Sponsored Dasatinib (NSC #732517 IND #73969) In Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, Endometrial, or Endometriosiis-Associated Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression. (David M Hyman)

15. **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)

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 (Jonathan Feddock)
   b. **GOG0286B** 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)
   c. **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)

D. Review of Approved Concepts/Protocols

1. **GOG-8038**: Epidemiologic Risk Factors and Endometrial Cancer Survival (Louise A Brinton)

2. **UC0905**: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (Mutch)
3. **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)

4. **GOG-8040 (UC1107):** An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino)

5. **UC1506** Translational Science for Uterine Carcinosarcoma Trials [Amendment to GOG0261] (Douglas Levine)

6. **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)

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

8. **GY013 (DT1620):** A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Temkin)

9. **DT1737:** Phase I/II study of megestrol acetate, entinostat, and SGI-110 in advanced, persistent, or recurrent endometrial carcinoma (McCourt)

10. **UC1630:** Randomized Two Arm Phase II Cross Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma (USC) Patients who Have Been Treated With One or Two Prior Regimens (Maxwell)

11. **UC1631:** Phase II Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)

12. **GY012 (UC1633):** A Four Arm Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, the Combination of Cediranib/Olaparib and the Combination of Olaparib/wee1 inhibitor AZD 1775 in Women with Recurrent or Persistent Endometrioid Endometrial Cancer (Mackay/Bender/Rimmel)

13. **PI1716:** A Phase I study of preoperative immunotherapy and brachytherapy in clinical early stage endometrial cancer with microsatellite unstable tumors (Harkenrider)

14. **PI1749:** Surgical Window of Opportunity Study of Abemaciclib and Letrozole versus Letrozole for Estrogen+, Progesterone + Endometrial Cancer. (Emma Barber/Daniela Matei)

15. **UC1644:** A Randomized Phase II Study of Letrozole Versus Observation in Patients with newly diagnosed Uterine LMS (Slomovitz)

16. **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)

17. **GY014 (DT1718):** A phase II study of tazemetostat (EPZ-64438) an EZH2 inhibitor in select gynecologic cancers (Eskander)
E. Proposed studies

1. **UC1715**: Durvalumab during Hypofractionated Pelvic Radiation Therapy for Intermediate to High Risk Endometrial Cancer (Gunderson) **Tabled 2/17**.

2. **UC1731**: Exemestane and Entinostat in low grade gynecologic malignancy: a phase II study (Mackay)

3. **UC1733**: A Phase II, prospective randomized open blinded end-point (PROBE) study of the use of combination pegylated liposomal doxorubicin with atezolizumab in women with recurrent endometrial cancer and MMR deficiency (Corr)

4. **UC1740**: Phase II Single Agent PD1 inhibitor in Chemo-refractory Gestational Trophoblastic Disease (Marilyn Huang) **Tabled 7/17 DART trial ongoing**

5. **UC1805**: A Randomized Phase III Trial of Radiation +/- checkpoint inhibitor for high intermediate risk mismatch repair deficient (dMMR) endometrial cancer (Floor Backes) **NEW**

6. **UC1808**: Phase II Efficacy of primary immunotherapy alone or combined immunotherapy and chemotherapy vs. chemotherapy alone in patients with advanced stage or recurrent endometrial cancer (Haider Mahdi) **NEW**

7. **UC1809**: Randomized Phase III Trial of adjuvant doxorubicin plus olaratumab (DO) versus gemcitabine plus docetaxel followed by doxorubicin (GDD) in uterus-limited high-grade Leiomyosarcoma. (Loggers) **NEW**

8. **DT1806**: Gemcitabine and Wee1 Inhibitor in persistent or recurrent endometrial malignancy: a phase II study (Megan McDonald) **NEW**

F. Studies from Other Committees for Review:


G. New Business

1. Report from GOG Foundation
   a. **GOG3007**: A RANDOMIZED PHASE II TRIAL OF EVEROLIMUS AND LETROZOLE OR HORMONAL THERAPY (TAMOXIFEN/MEDROXYPROGESTERONE ACETATE) IN WOMEN WITH ADVANCED, PERSISTENT, OR RECURRENT ENDOMETRIAL CARCINOMA (Brian M Slomovitz)

   b. **UCP1701**: A phase II trial of doxorubicin + olaratumab in the treatment of recurrent or persistent carcinosarcoma of the uterus or ovary

2. Report from Subcommittee on Gestational Trophoblastic Disease (Schink)

3. Report from GOG0210 Scientific Advisory Board (Mutch)

4. Report from RTOG (Klopp)
NRG Oncology wishes to acknowledge the following exhibitors:

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

Exhibit hours are:

Friday, Jan 25, 2018 - 7:00 am - 5:00 pm
Saturday, Jan 26, 2018 - 7:00 am - 4:00 pm
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IROC’s charge is to provide: Scientific expertise in advanced medical imaging, radiotherapy, and information technology to support establishment of appropriate QA procedures. Consultation to the NCTN groups in the development of research protocols early on in the process to assist with hypothesis generation and trial design that can be supported by effective QA programs. Resources for the efficient collection, qualification, analysis, archive and transfer of images, radiotherapy plans and associated clinical data. Qualification and credentialing policies and to help ensure the delivery of appropriate protocol-specified radiotherapy and advanced imaging. In addition to supporting NCTN research activities, IROC may be called upon to carry out quality assurance activities for other NCI-sponsored research.

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Janssen Products, LP harnesses innovations in large- and small-molecule research to create important new therapeutic options for oncology and nephrology. The company is at the forefront of developing initiatives to ensure patients, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services, and quality care.

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Mitra Biotech is a global leader in advancing truly personalized oncology treatment. Mitra’s CANscript™ platform recreates a patient’s own tumor microenvironment in vitro, measures multiple parameters to determine whether a tumor is responding to customer selected treatments, and then converts these parameters into a single score that predicts clinical response to each of the customer selected therapies.

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Novocure is an oncology company developing a profoundly different cancer treatment utilizing a proprietary therapy called TTFields, the use of electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division.

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TESARO is a biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. We see new possibilities to responsibly develop and commercialize innovative treatments where others may not. Relationships are vital to the success of our business, and we are committed to being a trusted partner to the cancer community.

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