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- 11 NCORP Town Hall
- 13 New Investigator Educational Session
- 15 NRG General Session
- 17 PSC Intro to Clinical Trials *(Agenda on page 72)*
- 18 PSC CTN/CRA Edu Sessions *(Agendas on page 74)*
- 19 Scientific Session - NRG Research Review
- 22 Social Media Workshop
- 23 Symposium - "Cancer Survival Disparities"
- 25 Symposium - "Endocrine Therapy for GYN and other Cancers; Many Target, Many Indications"
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- 30 Brain Tumor Cmte
  - Breast Cancer Committees
- 31 Breast Cancer Committee
- 32 Cancer Prevention & Control Cmte
- 34 Cancer Care Delivery Research Cmte (CCDR)
  - Developmental Therapeutics Cmte
- 35 Developmental Therapeutics Cmte
  - Dev. Therapeutics Radiation Therapy *(see pg 75)*
    - Gynecologic Cancer Committees
- 39 Cervix Vulvar Cancer Subcommittee
- 43 Ovarian Cancer Subcommittee
- 48 Rare Tumor Subcommittee
- 50 Uterine Corpus Subcommittee
- 56 Head and Neck Cancer Committee
- 58 Head and Neck Surgical Subcommittee
- 59 Lung Cancer Committee
  
- 60 Patient Centered Outcomes Research (PCOR)
  - Translational Science Committees
- 61 Translational Science Committee
- 62 Translational Science GU Cancer Workshop
- 63 Translational Science GYN Workshop
- 64 Translational Science Head & Neck Cancer Subcommittee
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### SCIENTIFIC CORE COMMITTEES

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- 68 Imaging Committee
  - Medical Oncology Committees
- 69 Medical Oncology Committee
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  - Protocol Support Committees
- 72 PSC Introduction to Clinical Trials
- 74 PSC CTN/CRA Edu Sessions
  - Radiation Oncology Committees
- 75 Developmental Therapeutics Radiation Therapy
- 76 Radiation Oncology Committee
- 78 Medical Physics Workshop
- 79 Particle Therapy Working Group
- 81 Surgical Oncology Committee

### ADMINISTRATIVE COMMITTEES

- 83 Canadian Members Subcommittee

### INSTITUTIONAL ACCRUAL

- 85 Member Accrual

### ACKNOWLEDGEMENTS

- 90 Commercial Supporters Acknowledgement
- 91 Sponsor/Exhibitor Acknowledgements
Our planning for our in-person/hybrid meeting for this winter reflected our dearest wish - to once again be in-person. But as the meeting days grew nearer, so many planned in-person meetings had to convert to virtual to accommodate the travel bans and health concerns that it became impossible to imagine we could meet the goals of our meeting through offering an in-person option.

But one thing is clear; a return to in-person meetings is a milestone we are all looking forward to. While virtual options have allowed more people to engage and to engage differently, nothing replaces a handshake or a friendship blossoming from a hallway conversation.

Even so, the NRG Winter 2022 meeting is a time to share updates and gather our committees to continue the important work of NRG Oncology in making a difference in the lives of cancer patients. We have been so impressed with the work that has continued, despite so many obstacles!

We hope you'll attend many of the various offered sessions over the week and say "Hello" to friends and colleagues, and reaching out to make connections with others while you are in the meeting platform.

Wishing you a healthy and safe new year, looking forward to seeing you during our Winter 2022 Meeting!
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.
CONTINUING EDUCATION

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 Education for physicians.

AMA PRA Category 1 Credits™
The GOG Foundation, Inc. designates this live activity for a maximum of 28 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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

Disclosure Declaration
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 included with this program.

How do I collect CME/CEU Certificates?
When you attend a CME/CEU session, you will be able to print your certificate right from the platform on the last day of the NRG Meeting (February 15th). We will not be emailing certificates so please be sure to access them from the portal. To find your certificate, please enter any of the rooms from the Lobby. They will all bring you to a page with the left-side menu. Select the “My Meeting” person icon and then select “My Profile”. You will be taken to your profile page. The top menu has a button that says, “CE Credits”. Click to enter the certificates page.

Certificates are generated based on attendance times and whether or not you’ve completed the required surveys, when applicable. Attendees must complete and submit the NRG Oncology 2022 Virtual Meeting Overall Evaluation for CME credits to be validated. Overall Meeting Evaluations must be submitted by March 1, 2022.

Important: Please be sure to print all certificates within 30 days of the meeting. NRG Oncology cannot generate or store individual copies of certificates. You can collect certificates at the end of each day when the meeting concludes.

If you have issues accessing your certificate or questions about CME/CEUs, please reach out to cmeinfo@gog.org.

For questions or comments about this CE activity, please contact:
Michelle N. Small, MHA, Dir, Education Programs/CME Compliance at smallm@nrgoncology.org
The NRG Oncology virtual meeting provides the opportunity to earn up to **28 AMA PRA Category 1 Credits™**.

<table>
<thead>
<tr>
<th>SESSION TITLE</th>
<th>MON 2/7</th>
<th>Tues 2/8</th>
<th>WED 2/9</th>
<th>THURS 2/10</th>
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<th>SAT 2/12</th>
<th>MON 2/14</th>
<th>TUE 2/15</th>
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<tbody>
<tr>
<td>Winter Symposium, “Cancer Survival Disparities”</td>
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<tr>
<td>Winter Symposium “Endocrine Therapy for Gynecologic and Other Cancers”</td>
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<td>Breast Cancer Committee</td>
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<td>Cancer Care Delivery Research CCDR</td>
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<td>Cervix Vulvar Cancer Subcmte</td>
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<td>Developmental Therapeutics</td>
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<td>Uterine Corpus Subcommittee</td>
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<td>PSC CTR/CRA “Intro to Clinical Trials”</td>
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NRG Oncology Meeting Agenda

all times listed in Eastern Time (US)

Monday, February 7, 2022
11:00 am - 1:00 pm    Medical Oncology Committee
12:00 pm - 1:00 pm    Social Media Workshop
1:00 pm - 3:00 pm     Translational Science Lung Workshop
1:30 pm - 3:00 pm     Imaging Committee
3:00 pm - 3:30 pm     Joint Seminar Presentation "What is Biology-Guided Radiotherapy?"
3:30 pm - 5:00 pm     Medical Physics Subcommittee Meeting
4:00 pm - 5:30 pm     Canadian Members Subcommittee

Tuesday, February 8, 2022
12:30 pm - 2:00 pm    Pharmacy Subcommittee

Wednesday, February 9, 2022
5:00 pm - 8:00 pm     Winter Symposium "Cancer Survival Disparities - Interventions are Possible"

Thursday, February 10, 2022
9:30 am - 2:00 pm     Introduction to Clinical Trials "Principles of Clinical Trial Management"
10:00 am - 2:00 pm    Winter Symposium
"Endocrine Therapy for Gynecologic and Other Cancer: Many Targets, Many Indications"
2:00 pm - 3:45 pm     Cancer Prevention and Control Committee
2:30 pm - 4:30 pm     Developmental Therapeutics Committee
3:15 pm - 6:30 pm     Introduction to Clinical Trials - Discussion Sessions
4:00 pm - 5:30 pm     Patient Centered Outcomes Research Committee
4:00 pm - 5:30 pm     Rare Tumor Subcommittee
4:30 pm - 6:00 pm     FORTE
6:00 pm - 7:30 pm     New Investigator Educational Session
6:30 pm - 8:00 pm     Translational Science Workshop
6:30 pm - 8:00 pm     Radiation-Developmental Therapeutics
NRG Oncology Meeting Agenda

all times listed in Eastern Time (US)

Friday, February 11, 2022
8:00 am - 10:00 am Sarcoma Working Group
9:00 am - 11:00 am Radiation Oncology Committee
9:30 am - 12:00 pm Cervix/Vulva Cancer Subcommittee
10:00 am - 11:30 am NCORP Townhall
11:30 am - 2:00 pm PSC Education Session Part 1
12:00 pm - 1:30 pm Scientific Session
12:00 pm - 1:30 pm Neurosurgical Subcommittee
12:00 pm - 1:45 pm Cancer Care Delivery Research Committee
12:00 pm - 2:00 pm Uterine Corpus Cancer Subcommittee
2:00 pm - 3:00 pm General Session
3:15 pm - 4:15 pm Translational Head & Neck Subcommittee
3:15 pm - 4:45 pm PSC Educational Session Part 2
3:15 pm - 5:15 pm Ovarian Cancer Subcommittee
3:15 pm - 5:45 pm Breast Cancer Workshop
3:30 pm - 5:00 pm Brain Tumor Committee General Session
4:30 pm - 6:30 pm Head & Neck Surgical Subcommittee
5:30 pm - 7:00 pm Translational GYN Workshop
6:30 pm - 8:00 pm Translational Science GU Workshop
6:45 pm - 8:15 pm Head & Neck General Committee

Saturday, February 12, 2022
9:00 am - 10:00 am Surgical Oncology Committee
9:30 am - 11:00 am Lung Cancer General Committee
9:45 am - 11:30 am Gynecologic Cancer Committee
11:30 am - 1:00 pm Genitourinary Cancer Committee
12:00 pm - 1:30 pm Gastrointestinal Colorectal Cancer Committee
1:45 pm - 3:15 pm Gastrointestinal Non-Colorectal Cancer Committee

Monday, February 14, 2022
2:00 pm - 4:00 pm Health Disparities Committee
4:30 pm - 6:00 pm Patient Advocate Committee

Tuesday, February 15, 2022
1:00 pm - 3:00 pm Pathology Committee
5:00 pm - 6:30 pm Particle Working Group
# FORTE Protocol Workshop Agenda

**Date:** Thursday, February 10, 2022  
**Time:** 4:30 p.m. – 6:00 p.m. ET  
**Location:** Virtual NRG Winter Meeting

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
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<tbody>
<tr>
<td>4:30 p.m.-4:35 p.m.</td>
<td>Welcome</td>
<td>Lisa Kachnic, MD, NRG NCORP Associate Chair</td>
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</tbody>
</table>
| 4:35 p.m.-4:50 p.m. | Part I: The FORTE trial: Nuts and Bolts     | Robert Schoen, MD, MPH  
Principal Investigator/Study Chair—University of Pittsburgh  
Jeffrey Dueker, MD  
Protocol Co-chair—University of Pittsburgh  
Robert Schoen, MD, MPH  
Principal Investigator/Study Chair—University of Pittsburgh |
| 4:50 p.m.-5:20 p.m. | Part II: How will NRG Oncology help with FORTE? | Martha Duncan, RN, MSN  
Protocol Nurse Specialist-Clinical Coordinating Dept. (CCD)  
Kristen Kotsko, RN BSN  
Director- NRG Oncology Clinical Coordinating Depart. (CCD)  
Michelle Shepard  
NRG Oncology Communications Team  
Robert Schoen, MD, MPH  
Principal Investigator/Study Chair—University of Pittsburgh |
<p>| Questions and Answers |                                              |                                                                            |</p>
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<tr>
<th>5:20 p.m.- 5:50 p.m.</th>
<th>Part III: Site Participation</th>
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<tr>
<td>8. Site Perspectives on FORTE: Why are we all in?</td>
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<tr>
<td>a. Columbia University Medical Center-Why is Columbia participating? How are we making it happen?</td>
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<tr>
<td>Anna Krigel, MD</td>
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<td>Columbia University Medical Center</td>
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<td>b. University of North Carolina</td>
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<td>Seth Crockett, MD, MPH</td>
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<td>University of North Carolina</td>
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<td>Questions and Answers</td>
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<th>5:50 p.m.-6:00 p.m.</th>
<th>Part IV: Call to Action</th>
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<tr>
<td>9. Call to Action</td>
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<tr>
<td>Robert Schoen, MD, MPH</td>
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<tr>
<td>Principal Investigator/Study Chair—University of Pittsburgh</td>
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<td>Questions and Answers</td>
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NRG NCORP TOWN HALL
Friday, February 11, 2022
11:00 am - 11:30 am ET

SPEAKERS

Welcome & NRG NCORP Updates
Deborah Bruner, PhD, RN
NRG NCORP PI

NRG-CC005 (FORTE) Implementation: A Site Perspective
Douglas Corley, MD
Kaiser Permanente

NRG-CC008 (SOROCK) Implementation: A Site Perspective
Carolyn Muller, MD
University of New Mexico Cancer Center

Q&A - Open Discussion

NCI NCORP Update
Sandra Russo, MD
Community Oncology & Prevention Trials Research Group, DCP

NCI CCDR Update
Kathleen Castro, RN, MS
Nurse Consultant, Office of the Associate Director of the Healthcare Delivery Research Program

Q&A - Open Discussion - Chat Moderators

Closing Remarks
Deborah Bruner, PhD, RN & Joan Walker, MD
NRG NCORP PIs

Register now at: www.nrgoncology.org/NRG2022-Winter-Meeting
NRG NCORP Town Hall

Date: Friday, February 11, 2022
Start and End Time: 10:00am – 11:30am EST
Chairs: Deborah Bruner, PhD, RN; Joan Walker, MD; Lisa Kachnic, MD

Learning Objectives
Following this activity, participants will be better able to:
1. Discuss proposed and ongoing NRG NCORP research trials.
2. Apply procedures required to implement a protocol
3. Learn about opportunities in CCDR and CPC clinical trials

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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>8:00 – 8:20am</td>
<td>Welcome NRG NCORP Updates</td>
<td>Deborah Bruner, PhD, RN, NRG NCORP PI</td>
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<tr>
<td>8:20 – 8:30am</td>
<td>NRG-CC005 (FORTE) Implementation: A Site Perspective</td>
<td>Douglas Corley, MD, Kaiser Permanente</td>
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<tr>
<td>8:350 – 8:40am</td>
<td>NRG-CC008 (SOCROCK) Implementation: A Site Perspective</td>
<td>Carolyn Muller, MD, University of New Mexico Cancer Center</td>
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<tr>
<td>8:40 – 8:50am</td>
<td>Q&amp;A – Open Discussion</td>
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<td>8:50 – 8:55am</td>
<td>Introduction of NCI speakers</td>
<td>Deborah Bruner, PhD, RN, NRG NCORP PI</td>
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<td>8:55 – 9:05am</td>
<td>NCI NCORP Update</td>
<td>Sandra Russo, MD, Community Oncology and Prevention Trials Research Group, DCP</td>
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<tr>
<td>9:05 – 9:15am</td>
<td>NCI CCDR Update</td>
<td>Kathleen Castro, RN, MS, Nurse Consultant, Office of the Associate Director of the Healthcare Delivery Research Program</td>
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<tr>
<td>9:15 – 9:25am</td>
<td>Q&amp;A – Open Discussion – chat moderators</td>
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<tr>
<td>9:25 – 9:30am</td>
<td>Closing Remarks</td>
<td>Deborah Bruner/Joan Walker</td>
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NEW INVESTIGATOR EDUCATIONAL SESSION
HOSTED BY THE NRG EARLY CAREER NEW INVESTIGATOR COMMITTEE

Thursday, February 10, 2022
6:00 pm - 7:30 pm ET

Welcome Remarks
Beth Gore, MD; Angeles Secord, MD; Priya Rastogi, MD
NRG Early Career New Investigator Committee Co-Chairs

Overview of NRG Oncology
Quynh-Thu Le, MD, FACR, FASTRO
An NRG Group Chair

NRG Uterine Corpus Cancer Committee
Matthew Powell, MD
NRG Uterine Corpus Cancer Committee Chair

NRG Breast Cancer Committee
Julia White, MD
NRG Breast Cancer Committee Vice Chair

NRG Central Nervous System/Brain Tumor Committee
Minesh Mehta, MD
NRG Brain Tumor Committee Chair

NRG Medical Oncology Committee
Corey Langer, MD
NRG Medical Oncology Committee Chair

NRG Developmental Therapeutics RT Subcommittee
Steven Lin, MD, PhD
NRG DT RT Subcommittee Chair

NRG Surgical Oncology Committee
Thomas Julian, MD
NRG Surgical Oncology Committee Chair
# New Investigators Educational Session Agenda

**Date:** Thursday, February 10, 2022  
**Start and End Time:** 6:00 pm – 7:30 pm EST  
**Chairs:** Angeles Alvarez Secord, MD; Elizabeth Gore, MD; Priya Rastogi, MD

<table>
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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>6:00 pm – 6:05 pm</td>
<td>Welcome Remarks</td>
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<td>An NRG Oncology Session Chair</td>
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<tr>
<td>6:05 pm – 6:15 pm</td>
<td>Overview of NRG Oncology</td>
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<tr>
<td></td>
<td>Quynh-Thu Le, MD, FACP, FASTRO</td>
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<td>NRG Oncology Group Chair</td>
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<td>6:15 pm – 6:25 pm</td>
<td>NRG Gynecologic Cancer – Uterine Corpus Cancer Committee Overview</td>
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<td></td>
<td>Matthew Powell, MD</td>
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<td>NRG Oncology Uterine Corpus Cancer Committee Chair</td>
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<td>6:25 pm – 6:35 pm</td>
<td>NRG Breast Cancer Committee Overview</td>
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<td>Julia White, MD</td>
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<td>NRG Oncology Breast Cancer Committee Vice Chair</td>
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<td>6:35 pm – 6:45 pm</td>
<td>NRG CNS Overview</td>
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<td>Minesh Mehta, MD</td>
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<td>NRG Oncology Brain Tumor Committee Chair</td>
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<td>6:45 pm – 6:55 pm</td>
<td>NRG Medical Oncology Committee Overview</td>
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<td>Corey Langer, MD</td>
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<td>NRG Oncology Medical Oncology Committee Chair</td>
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<td>6:55 pm – 7:05 pm</td>
<td>NRG Developmental Therapeutics RT Subcommittee Overview</td>
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<td>Steven Lin, MD, PhD</td>
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<td>NRG Oncology DT RT Subcommittee Chair</td>
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<td>7:05 pm – 7:15 pm</td>
<td>NRG Surgical Oncology Committee Overview</td>
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<td>Thomas Julian, MD</td>
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<td>7:15 pm – 7:28 pm</td>
<td>Questions &amp; Answers</td>
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<tr>
<td>7:28 pm – 7:30 pm</td>
<td>Closing Remarks</td>
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<td>An NRG Oncology Session Chair</td>
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NRG ONCOLOGY
GENERAL SESSION

Friday, February 11, 2022
2:00 - 3:00 pm ET

Group Updates & Highlights

Norman Wolmark, MD
NRG Oncology, Contact PI

Quynh-Thu Le, MD
NRG Oncology Board Chair

Robert Mannel, MD
NRG Oncology Presiding Group Chair

NRG Research Center

Mitchell Machtay, MD
Deputy Group Chair
Research

Membership

David Miller, MD
Deputy Group Chair
Membership

Communications

Thomas Julian, MD
Chair
Communications Committee

Publications

Krishnansu S. Tewari, MD
Chair
Publications Committee

NRG Biospecimen Bank

Richard Jordan, DDS, PhD
Biospecimen Bank
Grant Co-PI

NRG Statistical & Data Management Center

James Dignam, PhD
Group Statistician

NRG NCORP Research Base

Deborah W. Bruner, RN, PhD
NCORP Research Base
Contact PI

Register now:
www.nrgoncology.org/
NRG2022-Winter-Meeting
NRG Oncology General Session

Friday, Feb 11, 2022
2-3pm ET

| Group Updates & Highlights | Norman Wolmark, MD  
NRG Oncology, Contact PI |
|-----------------------------|------------------------|
|                             | Quynh-Thu Le, MD       
NRG Oncology Board Chair    |
|                             | Robert Mannel, MD      
NRG Oncology Presiding Group Chair |

| NRG Research Center Update | Mitchell Machtay, M.D.  
Deputy Group Chair, Research |

| NRG Membership Update      | David Miller, M.D.      
Deputy Group Chair for Membership |

| NRG Communications         | Thomas Julian, M.D.     
Chair, Communications Committee |

| NRG Publications           | Krishnansu S. Tewari, M.D.  
Chair, NRG Publications Committee |

| NRG Biospecimen Bank Update | Richard Jordan, DDS, Ph.D.  
Biospecimen Bank Grant Co-PI |

| NRG Statistical and Data Management Center Update | James Dignam, Ph.D.  
Group Statistician |

| NRG NCORP Research Base Update | Deborah Watkins Bruner, RN, Ph.D.  
NCORP Research Base Contact PI |

| Closing Remarks | Robert Mannel, MD  
NRG Oncology Presiding Group Chair |
PROTOCOL SUPPORT COMMITTEE

INTRODUCTION TO CLINICAL TRIALS:
PRINCIPLES OF NRG ONCOLOGY
CLINICAL TRIAL MANAGEMENT
FOR NURSES & CRAS

SPEAKERS

Cindy Licavoli, RN, MA & Karen Holeva, BS, CCRP
Welcome Remarks / Closing Remarks

Kati Stoermer, MSBA
NRG Oncology Overview

Judy Langer, BS
Regulatory Affairs

Karan Boparai, BS, RT(R)(M)
NRG Membership

Sara McCartney, MS, RN
Expedited Adverse Event Reporting

Brian Miller, Pharm D
Investigational Drug Management

Joseph Mroziak
Medidata Rave

Mary Jo Antonelli, MBA, MHA
Quality Assurance Audits

Lisa Beaverson, BA, CCRP,
Sandy DeVries, MA & Melanie Finnigan, BS
Pathology/Biospecimen Collections

Shannon Puhalla, MD
RECIST Criteria

Nancy Fusco, RN, BSN
Mentorship Program

Register now at:
www.nrgoncology.org/
NRG2022-Winter-Meeting

Thursday, February 10, 2022
9:30 am ET - 6:00 pm ET

AFTERNOON DISCUSSION SESSION TOPICS:

Patient Screening & Enrollment
Treatment Modalities in Clinical Trial Management
Data Management
Adverse Event Reporting
PROTOCOL SUPPORT COMMITTEE

CLINICAL TRIAL NURSE / CLINICAL RESEARCH ASSOCIATE
CONTINUING EDUCATIONAL SESSIONS

Friday, February 11, 2022
PART 1:  11:30 am ET - 1:45 pm ET
PART 2:  3:15 pm ET - 4:45 pm ET

PART ONE:
Karen Holeva, BS, CCRP
Introduction / Welcome Remarks

Kati Stoermer, MSBA
Welcome Remarks

Robert Schoen, MD, MPH
FORTE

Michelle Shepard
NRG Oncology Social Media Activities

Mary Jo Antonelli, MBA, MHA
NRG Oncology Quality Assurance Program Updates

Jenny Hopkins, BA, BSN
CTSU Updates

PART TWO:
Angela A Rice-Warren, M.Ed.
Turnover, Retirements, Burnout - OHMY!
The Story of Leadership Development at an NCI-Designated Cancer Center During a Pandemic

Kristine Lipowski, MA, CCRP
Quality Assurance Program from a Site Perspective

Register now at:
www.nrgoncology.org/
NRG2022-Winter-Meeting
NRG Oncology Virtual Meeting - Feb 2022
**SCIENTIFIC SESSION**
**NRG ONCOLOGY RESEARCH REVIEW**

Friday, February 11, 2022
12:00 pm - 1:30 pm ET

**SPEAKERS**

**Patricia A. Ganz, MD**
Quality of life results from OlympiA: A phase III, multicenter, randomized, placebo-controlled trial of adjuvant olaparib after (neo)-adjuvant chemotherapy in patients with germline BRCA1/2 mutations and high-risk HER-2 negative early breast cancer (NSABP B-55)

**Spring Kong, MD**
NRG-RTOG 1106/ACRIN 6697: A phase IIR trial of standard versus adaptive (mid-treatment PET-based) chemoradiotherapy for stage III NSCLC — Results and comparison to NRG-RTOG 0617 (non-personalized RT dose escalation)

**Benjamin Movsas, MD**
Dose Escalated Radiotherapy (RT) Alone or in Combination with Short-Term Total Androgen Suppression (TAS) for Intermediate Risk Prostate Cancer: Patient Reported Outcomes (PROs) from the NRG Oncology/RTOG 0815 Randomized Trial

**Daniel Krauss, MD**
Dose escalated radiotherapy alone or in combination with short-term androgen suppression for intermediate risk prostate cancer: outcomes from the NRG Oncology/RTOG 0815 randomized trial

**Jeanne Carter, PhD**
The Lymphedema and Gynecologic cancer (LeG) study: The impact of lower-extremity lymphedema on quality of life, psychological adjustment, physical disability, and function.

**Linda Mileshkin, MD**
Adjuvant chemotherapy following chemo-radiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: The randomised phase 3 OUTBACK Trial (ANZGOG 0902, RTOG 1174, NRG 0274)
Date: Friday, February 11, 2022  
Start and End Time: 12:00 pm - 1:30 pm Eastern Time  
Publications Deputy Chair-Moderator: Harry D Bear, MD, PhD  
Publications Chair: Krishnansu S Tewari, MD  
Publications Vice Chairs: Elizabeth M. Gore, MD and Thomas B Julian, MD

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

1. (Ganz) Understand how the quality-of-life of patients, with germline BRCA1/2 mutations and high-risk HER-2 negative early breast cancer, were affected.
2. (Kong) Describe primary results for stage III NSCLC patients comparing the use of standard versus adaptive (mid-treatment PET-based) chemoradiotherapy.
3. (Movsas) Understand the differences in patient-reported outcomes between dose escalated radiotherapy (RT) alone or in combination with short-term total androgen suppression (TAS) for intermediate risk prostate cancer patients.
4. (Krauss) Investigate whether dose escalated radiotherapy alone or in combination with short-term androgen suppression can improve outcomes for intermediate risk prostate cancer.
5. (Carter) Examine how this publication led to the design of the current lymphedema study, highlighting whether there was an impact on quality of life for the patients.
6. (Mileshkin) Describe the effects of giving adjuvant chemotherapy after chemoradiation on survival for patients with locally advanced cervical cancer.

**WORKSHOP AGENDA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Presenter</th>
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</thead>
<tbody>
<tr>
<td>12:00 – 12:05 pm</td>
<td>Welcome</td>
<td>Harry D Bear, MD, PhD</td>
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<tr>
<td>12:05 – 12:15 pm</td>
<td>Quality of life results from OlympiA: A phase III, multicenter, randomized, placebo-controlled trial of adjuvant olaparib after (neo)-adjuvant chemotherapy in patients with germline BRCA1/2 mutations and high-risk HER-2 negative early breast cancer (NSABP B-55)</td>
<td>Patricia A Ganz, MD</td>
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<tr>
<td>12:15 – 12:20 pm</td>
<td>Discussant</td>
<td>Alexandra Thomas, MD</td>
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<tr>
<td>12:20 – 12:30 pm</td>
<td>NRG-RTOG 1106/ACRIN 6697: A phase IIIR trial of standard versus adaptive (mid-treatment PET-based) chemoradiotherapy for stage III NSCLC — Results and comparison to NRG-RTOG 0617 (non-personalized RT dose escalation)</td>
<td>Spring Kong, MD</td>
</tr>
<tr>
<td>12:30 – 12:35 pm</td>
<td>Discussant</td>
<td>Pamela Samson, MD</td>
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<tr>
<td>12:35 – 12:41 pm</td>
<td>Dose Escalated Radiotherapy (RT) Alone or in Combination with Short-Term Total Androgen Suppression (TAS) for Intermediate Risk Prostate Cancer: Patient Reported Outcomes (PROs) from the NRG Oncology/RTOG 0815 Randomized Trial</td>
<td>Benjamin Movsas, MD</td>
</tr>
<tr>
<td>12:41 – 12:47 pm</td>
<td>Dose escalated radiotherapy alone or in combination with short-term androgen suppression for intermediate risk prostate cancer: outcomes from the NRG Oncology/RTOG 0815 randomized trial</td>
<td>Daniel Krauss, MD</td>
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<tr>
<td>12:47 – 12:52 pm</td>
<td>Discussant</td>
<td>Bridget Koontz, MD</td>
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<tr>
<td>12:52 – 1:02 pm</td>
<td>The Lymphedema and Gynecologic cancer (LeG) study: The impact of lower-extremity lymphedema on quality of life, psychological adjustment, physical disability, and function.</td>
<td>Jeanne Carter, PhD</td>
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<tr>
<td>1:02 – 1:05 pm</td>
<td>Discussant</td>
<td>Allan Covens, MD</td>
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<tr>
<td>1:05–1:15 pm</td>
<td>Adjuvant chemotherapy following chemo-radiation as primary treatment for locally advanced cervical cancer compared to chemo-radiation alone: The randomised phase 3 OUTBACK Trial (ANZGOG 0902, RTOG 1174, NRG 0274)</td>
<td>Linda Mileshkin, MD</td>
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<tr>
<td>1:15–1:20 pm</td>
<td>Discussant</td>
<td>Scott Glaser, MD</td>
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SOCIAL MEDIA WORKSHOP

- **Miriam Knoll, MD, DABR**
  - @MKnoll_MD
  - Montefiore Nyack Hospital
  - "Paradigm Shifts in Oncology: Social Media and Advocacy"

- **Kristin A. Higgins, MD**
  - @KHigginsMD
  - Winship Cancer Institute of Emory University
  - "Advocacy for Clinical Trial Participation"

- **Jennifer Campisano**
  - @JCampisano
  - Patient Advocate
  - "Patient Based Advocacy"

- **Amanda Rivera, MD**
  - @AmandaRiveraMD
  - Montefiore Radiation Oncology
  - "Advocacy Regarding Social Determinants of Health"

- **Fumiko Ladd Chino, MD**
  - @fumikochino
  - Memorial Sloan Kettering Cancer Center
  - "Advocacy Regarding Financial Toxicity"

The Winter 2022 Virtual Educational Symposium is titled “Cancer Survival Disparities - Interventions are Possible” with noted Oncologists and Scientists serving as speakers and moderators. The targeted audiences are members and non-members of the NRG research teams to include: Gynecologic Oncologists, Medical Oncologists, Radiation Oncologists, Pathologists, Patient Advocates, and others engaged in oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, and other interested Allied Health professionals.

The speakers will focus their presentations addressing health disparities utilizing the NRG Oncology NCORP clinical trial networks. They will concentrate on primary studies on changing mortality for underserved minorities as well as secondary outcome measures on CTEP randomized trials.

**LEARNING OBJECTIVES:**
Following this activity, participants will be better able to:

- Discuss NRG/NCORP goals for overcoming poor survival of Black women with endometrial cancer.
- Standardize molecular testing (somatic and genomic) for early-stage endometrial cancer to improve survival with enrollment in clinical trial therapy.
- Mentoring a new generation of oncologists with cancer health disparity focus to create clinical trials specifically for under-represented minority cancer patients.
- What can we learn from secondary objectives added to CTEP trials?
## Presentation Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic/Title</th>
<th>Speaker/Moderator</th>
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<tbody>
<tr>
<td>5:00 pm</td>
<td>Welcome/Opening Remarks</td>
<td>Joan Walker, MD</td>
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<tr>
<td>5:10 pm</td>
<td><strong>Session 1 – Can We Improve Cancer Mortality?</strong></td>
<td><strong>Moderator: Sonya Reid, MD, MPH</strong></td>
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<tr>
<td>5:10 – 5:30</td>
<td>Molecular Studies of Black Women with Endometrial Cancer</td>
<td>Vickie Bae-Jump, MD, PhD</td>
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<tr>
<td>5:30 – 5:50</td>
<td>Actionable Targets and On-going Clinical Trials</td>
<td>Katherine Fuh, MD, PhD</td>
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<tr>
<td>5:50 – 6:10</td>
<td>NGS as a Tool to Close the Gap for Black Endometrial Cancer Patients: A Mentored Concept in Development</td>
<td>Tara Castellano, MD</td>
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<tr>
<td>6:10 – 6:20</td>
<td>Q/A</td>
<td>Session 1 Speakers</td>
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<tr>
<td>6:20 pm</td>
<td><strong>Session 2 – Modifiable Social Factors in Cancer Patients</strong></td>
<td><strong>Moderator: Sonya Reid, MD, MPH</strong></td>
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<tr>
<td>6:20 – 6:40</td>
<td>Food Insecurity and Relationship to Cancer Related Outcomes</td>
<td>Christina Washington, MD</td>
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<tr>
<td>6:40 – 7:00</td>
<td>Cancer Survival and Patient-Reported Outcomes in Cancer Clinical Trials: Patient Zip Code Matters</td>
<td>Jinbing Bai, PhD, RN</td>
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<tr>
<td>7:00 – 7:10</td>
<td>Q/A</td>
<td>Session 2 Speakers</td>
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<tr>
<td>7:10 – 8:00 pm</td>
<td>Panel Discussion</td>
<td>Panelists/Speakers</td>
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<tr>
<td></td>
<td>Vicki Bae Jump, MD, PhD</td>
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<td>Jinbing Bai, PhD, RN</td>
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<td>Tara Castellano, MD</td>
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<td>Katherine Fuh, MD, PhD</td>
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<td>Chanita Hughes Halbert, PhD</td>
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<td>Sonya Reid, MD, MPH</td>
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<td>Joan Walker, MD</td>
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<td>Christina Washington, MD</td>
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<td>Jennifer Wenzel, PhD</td>
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Winter Virtual Symposium
Endocrine Therapy for Gynecologic and Other Cancers: Many Targets, Many Indications

Thursday, Feb 10, 2022 - 10:00 am - 2 pm (EST)
NRG Oncology Winter 2022 Meeting #NRG2022

Program Co-Chairs

Gini Fleming, MD
University Of Chicago

Stéphanie Gaillard, MD, PhD
Johns Hopkins School of Medicine

Shannon Westin, MD, MPH
UT MD Anderson Cancer Center

Speakers/Moderators

Aditya Bhardwaj, MD, MPH
Mass General Hospital

Suzanne Conzen, MD
UT Southwestern Med Ctr

David Gershenson, MD
UT MD Anderson Can Ctr

Gregory Gressel, MD
Spectrum Health Can Ctr

Katherine Kurnit, MD, MPH
Univ of Chicago Medicine

David Gershenson, MD
UT MD Anderson Can Ctr

Suzanne Conzen, MD
UT Southwestern Med Ctr

Bradley Corr, MD
Univ of Colorado Sch of Med

Linda Duska, MD, MPH
UVA School of Med

Amanda Nickles Fader, MD
Johns Hopkins Medicine

Marilyn Huang, MD, MS
Univ of Miami Sch of Med

Joyce Liu, MD, MPH
DFCI Harvard Med Sch
Winter Symposium Agenda (Virtual Session)

Endocrine Therapy for Gynecologic and Other Cancers: Many Targets, Many Indications

Thursday, February 10, 2022 – 10 am – 2 pm EST
NRG Oncology Winter 2022 Meeting

Program Co-Chairs: Gini Fleming, MD, Stephanie Gaillard, MD, PHD, Shannon N. Westin, MD, MPH

PROGRAM DESCRIPTION:

The Winter 2022 Virtual Educational Symposium is titled Endocrine Therapy for Gynecologic and Other Cancers: Many Targets, Many Indications with noted Oncologists and Scientists serving as speakers and moderators. The targeted audiences are members and non-members of the NRG research teams to include Gynecologic Oncologists, Medical Oncologists, Radiation Oncologists, Pathologists, Patient Advocates and others engaged in oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, Physician Assistants, and other interested Allied Health professionals.

The speakers will focus their presentations on 1) appropriate settings to utilize currently available endocrine therapies, 2) current clinical trials of novel endocrine therapies, and 3) promising future approaches in endocrine therapy.

LEARNING OBJECTIVES:

Following this activity, participants will be better able to:

- Recognize appropriate settings to utilize currently available endocrine therapies
- Identify appropriate clinical trial opportunities for patients
- Distinguish promising future approaches

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<tr>
<th>Time (EST)</th>
<th>Topic</th>
<th>Speaker/Moderator</th>
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<tbody>
<tr>
<td>10:00 am</td>
<td>Welcome/Opening Remarks</td>
<td>Gini Fleming, MD</td>
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<tr>
<td>10:10 am</td>
<td>Session 1 – Current Approaches</td>
<td>Moderator: Bradley Corr, MD (GOG New Investigator)</td>
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<tr>
<td>10:10-10:20</td>
<td>Basics of Endocrine Therapy</td>
<td>Stéphanie Gaillard, MD, PhD</td>
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<tr>
<td>10:20-10:40</td>
<td>Overview of Endocrine Therapy in GYN Cancers</td>
<td>Helen MacKay, MD</td>
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<tr>
<td>10:40-11:00</td>
<td>Debate: AI vs Chemo/AI for LGSOC</td>
<td>Amanda Nickles Fader, MD &amp; David Gershenson, MD</td>
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<tr>
<td>11:00-11:10</td>
<td>Panel Q &amp; A</td>
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<tr>
<td>11:10-11:20</td>
<td>Break</td>
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<tr>
<td>11:20</td>
<td>Session 2 – Overcoming Resistance to Endocrine Therapy</td>
<td>Moderator: Rebecca Previs, MD (GOG New Investigator)</td>
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<tr>
<td>11:20-11:40</td>
<td>Lessons from Breast Cancer Therapy</td>
<td>Aditya Bardia, MD, MPH</td>
</tr>
<tr>
<td>11:40-11:55</td>
<td>CDK4/6 Inhibitors</td>
<td>Marilyn Huang, MD, MS (GOG New Investigator)</td>
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<tr>
<td>Time</td>
<td>Session Title</td>
<td>Speaker/Attendee(s)</td>
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<tr>
<td>11:55-12:10</td>
<td>PI3K Inhibitors</td>
<td>Michaela Onstad Grinsfelder, MD, MPH</td>
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<tr>
<td>12:10-12:25</td>
<td>Epigenetic Therapies</td>
<td>Linda Duska, MD</td>
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<tr>
<td>12:25-12:35</td>
<td>Panel Q &amp; A</td>
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<td>12:35-12:45</td>
<td>Break</td>
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<tr>
<td>12:45-1:05</td>
<td>Session 3 – New Directions</td>
<td>Moderator: Gregory Gessel, MD (GOG New Investigator)</td>
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<tr>
<td>12:45-1:05</td>
<td>Androgen Approaches in Prostate Cancer</td>
<td>Russell Szmulewitz, MD</td>
</tr>
<tr>
<td>1:05-1:15</td>
<td>Androgen Receptors Therapy for Gynecologic Cancers</td>
<td>Katherine Kurnit, MD (GOG New Investigator)</td>
</tr>
<tr>
<td>1:15-1:35</td>
<td>Glucocorticoid Receptors</td>
<td>Suzanne Conzen, MD</td>
</tr>
<tr>
<td>1:35-1:50</td>
<td>Organoids as Model Systems</td>
<td>Joyce Liu, MD, MPH</td>
</tr>
<tr>
<td>1:50-2:00</td>
<td>Panel Q &amp; A</td>
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<tr>
<td>2:00-2:05</td>
<td>Closing Remarks</td>
<td>Shannon Westin, MD</td>
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TRANSLATIONAL SCIENCE WORKSHOP

☑ Thursday, February 10, 2022
🕒 6:30 PM - 8:00 PM ET

VIRTUAL SESSION

SPEAKERS

James Gulley, MD, PhD, FACP
National Cancer Institute
"The Quest for Effective IO in Non-Inflamed Tumors"

Samir Khleif, MD
Georgetown University
"Overcoming Immune Resistance, New Mechanisms, and Strategies"

Andrew Nixon, PhD
Duke University School of Medicine
"Use of the Plasma Angiome in NRG Trials"

CHAIRS

Michael Birrer, MD, PhD
Adam Dicker, MD, PhD
Matthew Ellis, MB, BChir, PhD, FRCP

Register now at: www.nrgoncology.org/NRG2022-Winter-Meeting
Brain Tumor Committee Agenda

Date:  Friday, February 11, 2022
Time:  3:30pm – 5:00 pm

Chair: Minesh Mehta, MD
Co-Chairs: Mark Gilbert, MD; Michael Vogelbaum, MD; Arnab Chakravarti, MD; Mei Polley, PhD

WORKSHOP AGENDA

NRG GBM PORTFOLIO: 15 MIN
A. NRG-BN001: Mehta/Gondi
B. NRG-BN007: Lassman
C. EAF 151: Tsien
D. NRG-BN010: Bagley
E. NRG-BN011: Iwamoto
F. A701702: Jing Wu

NRG BRAIN METASTASES PORTFOLIO: 15 MIN
A. NCCTG CE 7: Roberge
B. Alliance A071801: Wang
C. NRG-BN009: Gondi/Chan
D. NRG-BN012: Burri
E. NRG-CC003: Gondi
F. NRG-CC009: Gondi
G. S2000: Kotecha

NRG LOWER GRADE GLIOMA PORTFOLIO: 5 MIN
A. NRG-BN005: Grosshans
B. 1071 (Alliance CODEL): Vogelbaum

NRG OTHER TUMORS PORTFOLIO: 4 MIN
A. NRG-BN003: Rogers
B. ACNS 2021: NGGCT: Hall

NRG DEVELOPING TRIALS/NEW CONCEPTS: 85 MIN
A. Rimas Lukas: Unmethylated GBM, NRG-BN2048 IDO
B. Jiayi Huang: elderly nGBM
C. Yazmin Odia: Midline Glioma
D. Yazmin Odia: PCNSL
E. John Kalapurakal: High Grade Meningioma
F. Jonathan Yang: LMD - P3 Proton CSI vs IFRT
G. Melanoma/Lung/TN Breast Mets: ICI + SRS vs SRT
Breast Cancer Committee Agenda (Virtual by Zoom)

Date: Friday, February 11, 2022
Start and End Time: 3:15 pm – 5:45 pm
Chair: Eleftherios Mamounas, MD
Co-Chairs: Julia White, MD; Charles Geyer, 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

3:15 – 3:45 Report from the Breast Working Group Meeting
   Eleftherios Mamounas, MD
   Julia White, MD

3:45 – 4:00 SABCS Talk (Management of special subtypes of TNBC)
   Alexandra Thomas, MD

4:00 – 4:15 NRG BR007: A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Breast Cancer with a Low Oncotype Recurrence Score
   Julia White, MD

4:15 – 4:30 BR004: A Randomized Phase III Trial of Taxane/Trastuzumab/Pertuzumab/Placebo Compared to Taxane/Trastuzumab/Pertuzumab/Atezolizumab in First Line HER2-Positive Metastatic Breast Cancer
   Charles Geyer, Jr., MD

4:30 – 4:45 BR008: A phase III randomized trial evaluating omission of breast radiotherapy for low-risk HER2-positive breast cancer
   Lior Braunstein, MD

4:45 – 4:55 BR009: Chemotherapy plus ET vs. Ovarian Ablation plus ET in Early Stage Hormone-Positive Premenopausal Women with Oncotype ≤ 25 (OFSET CHEMO)
   Eleftherios Mamounas, MD

4:55 – 5:05 ALLIANCE A011801: COMPASS HER2 Trials Examining Escalating and De-Escalating Therapy in HER2-Positive Breast Cancer: Optimizing Treatment in Residual Disease (COMPASS HER2 RD): A Double-Blinded, Phase III Randomized Trial
   Virginia Borges, MD

5:05 – 5:15 DESTINY BREAST-05 (NSABP B-60): DS-8201a vs. T-DM-1 for high risk patients with HER2-positive residual invasive cancer following preoperative therapy
   Jame Abraham, MD

5:15 – 5:30 LidERA/NSABP-B-61: Giredestrant vs. Physician’s Choice ET in Medium/High-Risk ER+/HER2- Early-Stage Breast Cancer
   Mothaffar Rimawi, MD

5:30 – 5:45 Discussion
Cancer Prevention and Control Committee Agenda

Date: Thursday, February 10, 2022
Start and End time: 2:00 pm – 3:45 pm EST
Chairs: Lisa Kachnic, MD; Warner Huh, MD
Vice Chairs: Debra Barton, PhD; Julie Bauman, MD

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. Identify and discuss the results and publication status of CPC clinical trials recently completed by NRG Oncology.
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. CPC Announcements – Lisa Kachnic, MD

B. NRG NCORP publication, NRG-CC004: Phase II Double Blind Dose Finding Trial of Bupropion Versus Placebo for Sexual Desire in Women with Breast or Gynecologic Cancer - Debra Barton, PhD, RN, NRG-CC004 PI

C. Review of open CPC studies
   - NRG-CC003: A Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer
   - NRG-CC005: (FORTE) Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps
   - NRG-CC008: A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-Oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers (SOROCK)
   - NRG-CC009: Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for 10 or Fewer Brain Metastases from Small Cell Lung Cancer – CPC Chairs


E. Developing Concepts
   - *Rand, blinded, placebo controlled ph II trial of concurrent chemoRT w/ and w/out BMX-001 for H&N squamous cancer* – David Brizel, MD; Sue Yom, MD
• *Neoadjuvant partial breast radiotherapy in early-stage breast cancer: A randomized phase III trial to improve cosmetic outcomes* – Simona Shaitelman, MD

• *Endometrial cancer prevention in obese women utilizing levonorgestrel-releasing IUD* – Laurence Bernard, MD

• *Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus* – Eric Leung, MD

• Intergroup developing concept: *Cryocompression therapy vs. control for prevention of CIPN* – Kathryn Pennington, MD

F. Questions and Discussion
Cancer Care Delivery Research (CCDR) Committee Agenda

Date: Friday, February 11, 2022
Start and End Time: 12:00pm – 1:45pmEST
Co-Chair: Mary E. Cooley, PhD, RN
Co-Chair: Matthew F. Hudson, PhD, MPH

Learning Objectives

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

| SPEAKERS |
|-----------------|------------------|
| Welcome and Committee Updates | Mary Cooley, PhD, RN, CCDR Chair |
| NRG-CC007CD: Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy | Matthew Hudson, PhD, CCDR Vice-Chair |
| • Study update | Ron Chen, MD, NRG-CC007CD Study Chair, |
| • Top accruing sites | |
| CCDR developing concept: Implementation of A Toolkit to Address Persistent Chronic Cancer Pain Syndromes (ATACC) | Jeannine Brant PhD, RN |
| | Mary E. Cooley, PhD |
| CCDR developing concept: Sexual orientation and gender identity (SOGI) measurement for patient centered cancer care in sexual and gender minority (SGM) populations | Megan Mullins, PhD |
| NRG CCDR pilot project results: Physical Activity Monitoring to Predict Hospitalization in Advanced Cancer Patients | Nitin Ohri, MD |
| NRG CCDR pilot project results: Exploring the implementation context in community oncology practices for evidence-based lifestyle interventions | Prajakta Adsul, PhD |
| Institutional pilot project: Implementation of guideline-based molecular profiling of early-stage endometrial cancer | Andrea Hagemann, MD |
| QUESTIONS / DISCUSSION | ALL |
Developmental Therapeutics Committee Agenda

Date: Thursday, February 10, 2022
Start and End Time: 2:30-4:30 PM
Chairs: Roisin O’Cearbhaill, MD (Dev. Therapeutics)
Translational Research Chair: Panagiotis Konstantinopoulos, MD, PhD (Dev. Therapeutics)
Co-Chairs: Floor Backes, MD (Phase II),
Russell Schilder, MD (Phase I)
Stephanie Gaillard, MD, PhD (Phase I)

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

1. Participants will become familiar with current status of translational research projects involving phase I and II studies that are under development or activated for accrual.
2. New concepts will be reviewed for approval or disapproval, including a discussion of trial design including multi-arm studies as well as preclinical and early clinical data related to investigational agents.
3. Participants will become familiar ComboMATCH Trial
4. Recommendations for action by the GYN Developmental Therapeutics committee will be summarized.

2:30 PM – 2:40 PM  Introduction, Dr. O’Cearbhaill and Dr Backes. Welcome. Review of opportunities for new investigators and discuss committee rotation and welcome new members

   Members rotating off: Richard Carvajal, David O’Malley, Jung-Min Lee, Rob Coleman.
   New Core: Christina Annunziata, Erin Crane, June Hou
   New General: Jain Dharamvir, Elizabeth Lee, Mihae Song
   New Phase I: Sarah Lynam

2:40 PM – 3:10 PM  Update on concepts from last meetings and studies under development:

   See below for list

3:10 PM - 4:00 PM  Review of new and resubmitted concepts

4:00 PM – 4:10 PM  Phase 1 committee updates (Gaillard/Schilder)

4:10 PM – 4:30 PM  ComboMATCH update (O’Cearbhaill, NRG representative for the ComboMATCH study)
List of Studies

Active studies:

- **NRG-GY014**, A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid or clear cell carcinoma of the ovary, and recurrent or persistent endometrioid endometrial adenocarcinoma (Ramez Eskander)
  - Second stage amendment for ovarian clear cell cancer ARID1A mutant cohort has been submitted to CTEP (awaiting approval)
  - 21 more patients to be accrued to study (for ARID1A subset)
- **NRG-GY022**, Assessment of carboplatin clearance predictors: a companion PK study to NCI sponsored clinical trials or standard of care treatments using carboplatin (Sarah Taylor/Jan Beumer)
  - 205/250 enrolled, currently only open to males

Under development:

- **PI1915/PI2136**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent recurrent squamous or non-squamous carcinoma of the cervix (Moxley) RSC approved Oct 2020
  - Changing to new ATR inhibitor BAY185344 ceralasertib through CTEP.
  - Resubmission under PI2136 (Oct 2021)
  - Company not supporting drug → no further development
- **PI1966**, A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Simpkins) on hold
  - Discussion about plan for drug acquisition/supply
- **DT2013** CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer. (Corinne Doll)
  - Submitted to CTEP (Oct 2021)
  - Lack of company support → no further development
- **PI2014** Phase IB of AVB500 in combination with carboplatin and paclitaxel or carboplatin and pegylated liposomal doxorubicin (Katherine Fuh)
  - Company not pursuing NExT program
- **DT2059**: Phase 1/2 M3814 plus hypofractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (Henson/Moore)
  - Preclinical data now complete
  - RSC 2/2022
- **GY027/PI2054** Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Fuh/Moore)
  - PTMA #100805
  - Submitted to CTEP 10/20, CRF build NACT/IDS ongoing
  - Feb activation (drop dead 02/11)
- **GY028/UC2055 (UC2055/PTMA #100828)** Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Onstad/Westin)
• **PTMA #100828**  
  • Call with CTEP on 1/14/22 – response due 1/27  
  • Awaiting final LOI approval by CTEP

• **DT2106** A Phase IB study of combination BET protein inhibition and ATR kinase for the treatment of recurrent *ARID1A* mutated clear cell and endometrioid ovarian and endometrial carcinomas (Fiona Simpkins).  
  • Updated with new BET and ATR inhibitors  
  • Call with CTEP IDB 9/20/21, RSC approved Oct 2021  
  • Call on 1/18/2022 w/ NCI – responses due 2/1/22

• **PI2132** A Phase Ib/II Study of adavosertib combined with carboplatin in women with primary platinum-resistant TP53-mutated ovarian, fallopian tube, or primary peritoneal carcinoma with and without CCNE1 amplifications. (Washington/Moore)  
  • RSC 2/16/22

• **PI2134** A Multi-Arm, Non-Comparative Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel in Combination with ZEN003694, or Birinapant in Epithelial Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer (Haggerty/Martin/ Arend/Moore/ Zhang/Annunziata)  
  • RSC approved 11.3.21  
  • No drug supply for pevo  
  • Haider Madhi bringing arm (CD47) to meeting in Feb - had call on 12/16/2021  
  • N=78  
  • Plan for final LOI to CTEP

### Safety lead-in under development

• **NRG-GY025** A randomized phase II trial of immunotherapy with dual immune checkpoint inhibitors compared to antiPD1 monotherapy in patients with deficient mismatch repair system recurrent endometrial carcinoma (Mahdi)

• **NRG-GY026** A randomized phase II/III trial of paclitaxel/carboplatin alone or combined with either trastuzumab or trastuzumab/pertuzumab in HER2 Positive Stage I-IV uterine serous carcinoma and carcinomasarcoma after primary surgery (Erikson, Fader)

• **NRG-GY029:** A Randomized Phase II trial comparing the combination of PI3K inhibitor Copanlisib and PARP inhibitor Olaparib to standard chemotherapy in patients with recurrent platinum resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have progressed through prior PARP inhibitor therapy (Konstantinopoulos)  
  • TBD

• **OV2135:** Randomized Phase II of Paclitaxel /Carboplatin +/- Selinexor in Ovarian, Tubal, Peritoneal Carcinoma characterized as homologous recombination proficient (HRp) (Arend, Moore)  
  • To RSC 2/16/22

### Active Phase I Studies (including safety lead-ins):

• **NRG-GY022** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Taylor/ Beumer)
Accrual for female participants completed, only open to males currently (45 needed)

Active Phase II Studies (including safety lead-ins):

Ovarian Cancer and Endometrial cancer studies:

- NRG-GY014 A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid-clear cell carcinoma of the ovary, and recurrent endometrioid endometrial adenocarcinoma (R Eskander) CTEP CRDL LOI. First stage completed accrual August 2019
  - Under review by CTEP to open to second stage (anticipated in late February)

Ovarian Cancer Studies (prior safety lead-in):

Closed

- 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 (O’Cearbhaill)
  - Phase II completed accrual May 2019. Phase III completed accrual October 2021

- 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. (Mackay) Prior DT safety review

- NRG-GY021 A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Adams)
  - Safety lead-in closed March 2021, study permanently closed

Closed DT/Phase I studies:

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. (Mayadev/ Schilder/Zamarin)
  - Safety lead-in – completed. Study closed. Plenary at SGO 2022

Endometrial Cancer Studies:

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 (Landen)
  - Completed accrual
Cervix Vulvar Cancer Subcommittee Agenda

Date: Friday, February 11, 2022
Start and End Time: 9:30 am – 12:00 pm EST (via zoom)
Chair: Charles A. (Trey) Leath, III, MD, MSPH
Co-Chair: Jyoti Mayadev, MD
Translational Co-Chair: Dmitriy Zamarin, MD, PhD

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

WORKSHOP AGENDA

Scientific Developmental Focus

A. Introduction / Announcements (8:30-9:00AM)
   a. Welcome, committee membership and rotation plan and review of Jul 2021 minutes
   b. Cervix updates from the task forces
      i. Cervical Cancer Task Force – Dana Chase (2nd Term), Katherine Moxley (1st Term)
      ii. Cervical Cancer Task Force (Junior Investigator) – Naresh Jegadeesh

B. New Concepts (9:00-9:30AM)

   PRIMARY
   NONE

   SECONDARY
   RT2212 Randomized phase II trial to assess efficacy of IV topotecan with or without ATR inhibitor, M6220 in patients with high grade neuroendocrine (small cell and large cell) carcinoma of cervix and other gynecologic origin. (Mahdi) RT, CV, TS, GY

C. Questions/Future Directions for Cervical Cancer Management (9:30-10:30)
   a. Populations with Unmet needs
      i. Patients with recurrent cervical cancer – PDL1 Negative Tumors
      ii. Early Stage Cervical Cancer
      iii. LACC with PA positive nodes
   b. Other Populations?

D. Previously committee approved/reviewed concepts – current updates and future directions (10:30AM-10:45AM)
i. CV1963 (Neil Taunk/Junzo Chino): A Randomized Phase II trial of ablative radiation therapy for women with oligometastatic gynecologic cancers
   1. GCSC Review January 20, 2022
ii. CV2040, Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARATACUS) II (Eric Leung)
iii. DT2059: Phase 1/2 M3814 plus hypofractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (Christina Henson; Mentor – K. Moore)

**DISAPPROVED**

i. PI1915 (Katherine Moxley): A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix
   1. Not supported by CTEP
ii. PI2136 (Katherine Moxley): A Phase I Study of the Combination of the Poly-ADP ribose polymerase inhibitor, olaparib, and DNA damaging ATR kinase inhibitor elimusertib (BAY1895344) in the Second-line Treatment of Persistent or Recurrent Squamous or Non-squamous Carcinoma of the Cervix.
   1. Not supported by CTEP / Drug sponsor
iii. DT2013 (Corrine Doll): CB-839 before and concurrent with chemoradiotherapy in patients with locally advanced, node positive cervical cancer
   1. Not supported by Drug Sponsor
iv. GY0025 (CV1922) (Ritu Salani): PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer
   1. Not supported by Drug Sponsor
v. CV2133 (Mayadev, Zamarin, Mell): Prospective phase II trial of radiation and durvalumab in patients with locally advanced cervical cancer with contraindications to cisplatin concurrent chemotherapy
   1. Not supported
vi. CV2143 (Salani, Randall, Monk): Frontline platinum, tisotumab vedotin plus pemrolizumab with or without bevacizumab in women with advanced, persistent, or recurrent cervical cancer
   1. Tisotumab vedotin is not on the CTEP CRADA
   2. Company not interested in pursuing

Operational management on-going NRG trials (10:45-10:55AM)

E. Closed Studies

Protocols: 101, 120, 205, 222, 141, 173, 179, 204, 206, 240, 233, 9806
F. Active / Recently Completed Trials

a. **GOG-0724/RTOG0724**: Phase III trial randomized study of concurrent chemotherapy and pelvic RT with or without adjuvant chemotherapy in high-risk patients with early stage cervical carcinoma following radical hysterectomy. (Heidi Gray, Anuja Jhingran)
   i. Opened April 2009
   ii. Awaiting number of events to close
   iii. Planned Discussion – Does Outback impact decision to enroll?
   iv. Accrual 236/285 (82.8%)

b. **GOG-0263**: Randomized clinical trial for adjuvant chemoradiation in post-operative cervical cancer patients with intermediate risk factors (Sang Young Ryu, Kevin A)
   i. Opened April 2010
   ii. Amended Nov 2017 to decrease accrual from 534 to 360
   iii. Pending closure
   iv. Accrual 339/360 (94.2%)

c. **GOG-0270**: Groningen International Study on Sentinel nodes in vulvar cancer (GROINSS-VII) – An observational study (Brian Slomovitz)
   i. NRG Opened January 2012; NRG target accrual 140 (Actual 148)
   ii. Amendment for treatment of SLN macro-metastatic disease
   iii. Amendment for IMRT approved July 2015 by GROINSS, NOT by CTEP
   iv. JCO Publication

d. **GOG-0274**: A phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: GOG collaboration with the OUTBACK trial (ANZGOG 0902/GOG 0274 / RTOG 1174). (Kathleen Moore)
   i. Opened January 2012; NRG target accrual 500
   ii. Expanded target accrual to 900 patients
   iii. Accrual completed May 2017
   iv. Study closed 6/1/2017 – 924/900 accrued – NRG accrual 627
   v. ASCO Oral Presentation

e. **GOG-0278**: Evaluation of physical function and quality of life (QOL) before and after non-radical surgical therapy for stage IA1-IB1 (≤2cm) cervical cancer. (Al Covens)
   i. Opened October 1, 2012
   ii. PET imaging amendment approved July 2015
   iii. Accrual 220/220 (100%)

f. **GOG-0279**: A phase II trial evaluating cisplatin and gemcitabine concurrently with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva. (Neil S. Horowitz)
   i. Opened July 2, 2012
   ii. Temporarily Closed June 15,2015 after enrolling 28 in 1st stage
   iii. 2nd stage re-opened July 2016
   iv. Accrual completed

g. **NRG-GY006**: A randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, stage II, IIIB, or IVA Cancer of the uterine cervix or Stage II-IVA vaginal cancer. (Trey Leath, Loren Mell)
   i. Opened January 15, 2016
ii. Amendment to CTEP re: increase in accrual size and transition to Randomized phase 3
iii. Temporarily closed secondary to drug shortage May 28, 2021
iv. Accrual 396/450 (88.0%)
h. **NRG-GY017**: Phase I trial using anti PD-L1 (atezolizumab) as immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer. (Jyoti Mayadev)
   i. Opened October 26, 2018
   ii. Accrual: 40/40
   iii. Presentation SGO 2022
i. **NRG-GY0024**: GROINSS V3 (Brian Slomovitz/Lillian Gien)
   i. Opened
   ii. Accrual: 0/157
   iii. Amendment for US sites and increased sample size to 15 annually x 3 years submitted

Reports from Other Committees and Groups

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

G. Concluding Remarks and Wrap-up

Next Semi-Annual Meeting – Chicago, IL July 21-23, 2022

**QUESTIONS / DISCUSSION**
Ovarian Cancer Subcommittee Agenda

Date: Friday, February 11, 2022
Start and End Time: 3:15-5:15 pm ET
Chair: Kathleen Moore, MD
Co-Chair: Joyce Liu, MD
Translational Chair: Elizabeth Swisher, MD
Translational Co-Chair: Rebecca Arend, MD

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

1. Review the status of completed and ongoing NRG-GOG clinical trials on the treatment of ovarian cancer
2. Review the status of approved NRG-GOG concepts that are under development
3. Apply standards and review procedures required to design, submit, and conduct a research protocol within NRG, including ancillary data proposals
4. 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. NRG Winter Meeting Education: Rachel Grisham, MD Memorial Sloan Kettering – Updates and Best Practices in Low Grade Serous Ovarian Cancer
C. Review of Closed Studies (not-terminated)
   • GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
   • GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman)
   • GOG0262 A randomized phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III or IV epithelial ovarian, peritoneal or fallopian tube cancer (John K Chan)
   • GOG0273 Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen) Modified dose dense cohort manuscript in draft form.
   • 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 (Zamarin) J Clin Oncology Jun 2020
• **GOG0281** RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson). Presented at IGCS 2019

• **GOG0264** RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naive sex cord stromal tumors of the ovary (Jubilee Brown)
  o Activated 08FEB2010
  o Futility limits met, Study closed to accrual 6/12/2020
  o Presented at IGCS 2020

• **NRG-GY004** Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Joyce Liu and Ursula Matulonis). Expanded overall accrual to 550 patients, closed to accrual 10-NOV-2017
  o Presented ASCO 2020
  o Accepted JCO (congratulations team!!!)

D. Review of Active Studies (all metrics are as of 3/2021)

• **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)
  o Closed 10/2/2020 – total accrual 562

• **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. (Chip Landen)
  o Closed to accrual

• **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).
  o Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
  o Second-stage safety lead-in (all three arms) opened 14NOV2017
  o Group-wide activation 6/18/2018
  o Suspended at the end of phase 2 (May 2019) –
  o Re-activated to Phase III portion 8/25/2020. Bevacizumab supplied by CTEP for Phase III.
    o A9 (to detail PD-L1 endpt) posted 11/23/20.
  o Closed to accrual 10/2021

• **NRG-GY14 (DT1718)** A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. (Ramez Eskander and David Hyman)
  o Activated 4/2019
  o Suspended 8/2019

• Plan to reopen for ovarian clear cell with ARID1A mut, Awaiting activation in CTSU
• **NRG-GY019 (RT1753)** 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).
  - Activated 8/26/19
  - 130/450

• **NRG-GY021** Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams)
  - Activated Oct, 12 2019
  - Safety calls coordinated through DT committee
  - Closed to accrual 10/19/2020 –

• **NRG-GY022 (DT1833)**: Assessment of carboplatin clearance predictors: PK protocol to allow for extra sample collection and collection of demographic data, laboratory values, and outcome data. (Liz Villaruz/Jan Beumer) GYN Cancer Committee: 7/14/18. Open to male pts only.
  - Activated 11/2019
  - 205/250

• **NRG GY023**: A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) vs doublet therapy (durvalumab and cediranib) vs physician choice chemotherapy in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung Min Lee)
  - Activated 4/28/21
  - 32/164

• **NRG-CC008 (CC1923) (NC1427) (CPC1206)** A non-randomized prospective clinical trial comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers (SOROC) (Doug Levine).
  - Activated 6/2020
  - 111/2262

• **AGCT1531 (RT1205)** Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, Al Covens NRG)
  - Activated group-wide 30MAY2017
  - 600/2059

E. Review of Approved Concepts under Development

• **NRG-GY027**: A Phase IB Trial of Ipatasertib plus paclitaxel and carboplatin in women undergoing neoadjuvant chemotherapy for treatment naïve, epithelial ovarian cancer (Katherine Fuh/Kathleen Moore)
  - CTEP approved 5/13/21
  - CTEP comments returned 1/20/2022 (OEWG 2/11/2022- extension requested)

• **NRG-GY029 (OV2113)** PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib vs Standard Chemotherapy in Patients with Recurrent, Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos) LOI submitted 10/2018
Submitted to OTF 11/20 for Dec review
Approved by GCSC 6/2/2020; Drug supply declined. Company reconsidered early 2021
Submitted to CTEP on 12/21/2021 (OEWG 5/21/2022)
Comment review 1/24/2022

- **NRG-GY030** A Randomized Phase III Study of the ATR inhibitor Berzosertib in Combination with Gemcitabine versus Gemcitabine alone in Platinum Resistant/Refractory High Grade Serous Ovarian Cancer (HGSOC) (Panagiotis A. Konstantinopoulos MD, PhD)
  - 4/16/21 OTF review; GCSC 06/17/21
  - RSC May 2021, approved
  - GCSC approved 09/01/2021
  - Protocol UD with PROs

- **PI1966**: Wee1 + ATRi in CCNE1 amplified ovarian and endometrial (Simpkins)
  - For RSC 10/29/19
  - Phase I UD

- **DT2106** A Phase IB study of combination BET protein inhibition (ZEN3694) and ATR kinase (M6620) for the treatment of recurrent ARID1A mutated clear cell and endometrioid ovarian carcinomas (Yasuto Kinose/Fiona Simpkins)
  - Trial design under development
  - RSC July 2021

- **OV2135** Randomized Phase II of Paclitaxel /Carboplatin/Bevacizumab +/- Selinexor in Ovarian, Tubal, Peritoneal Carcinoma characterized as homologous recombination proficient (HRp). (Arend/Rubinstein/Moore)
  - Submitted for OTF 10/2021
  - RSC 2/16/2022

- **PI2132** A Phase Ib/II Study of adavosertib combined with carboplatin in women with primary platinum-resistant TP53-mutated ovarian, fallopian tube, or primary peritoneal carcinoma with and without CCNE1 amplifications. (Washington/Naqash/Moore) –
  - RSC 2/16/2022

- **PI2134** A Multi-Arm, Non-Comparative Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel in Combination with ZEN003694, or Birinapant in Epithelial Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer. (Arend/Moore/Martin)
  - Under development in DT/Phase 1
  - RSC 7/2021

**F. Review of New Concepts**

1. **OV2206** Randomized Phase 2/3 Trial of Weekly Paclitaxel with or without Birinapant for Platinum Resistant, Recurrent Epithelial Ovarian Cancer (Moore, Annunziata). OV, TS, GY

**Reviewers: R. Coleman, D. Khabele, S. Wethington**

2. **OV2209** Phase II Combination ATR and PARP Inhibitor following PARP inhibition in recurrent ovarian cancer: a comparison of PARPi and ATRi combination (olaparib and ceralasertib) and standard of care platinum doublet. (OV2109R) (Simpkins, Wethington) OV, PCOR, TS, GY
Reviewers: A. Alvarez-Secord, D. Richardson, K. Kurnit

3. **P12207** Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel in Combination with Magrolimab in Epithelial Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer (Arm 1 in planned multi-arm trial P12134) (Mahdi) **DT, PI, OV, GY**

F. DISCUSSION: Phase I RFP:

QUESTIONS / DISCUSSION
Rare Tumor Subcommittee Agenda

Date: Thursday, February 10, 2022
Start and End Time: 4:00 pm - 5:30 pm
Chair: Allan Covens
Co-Chair: Jubilee Brown

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

1. Discuss past, ongoing, and emerging NRG clinical trials in rare gynecologic cancers
2. Discuss priorities and promising preclinical and translational objectives for future clinical trials
3. Discuss strategies to increase the portfolio of clinical trials in rare gynecologic cancers, including strategies to increase knowledge and access to preclinical data.
4. Discuss potential new approaches and collaborations with ovarian spores for development of preclinical data
5. Discuss new amendments to AGCT 1531 and strategies to disseminate and increase accrual

WORKSHOP AGENDA

A. Active Studies

1. 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 COG lead group. To date, this trial has accrued 607/2059 patients.

2. Gy019: A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum recently opened. Accrued 131/450.

3. GOG3026: Phase II trial of letrozole + Ribociclib for women with recurrent low-grade serous carcinoma. accrued 36/50, second stage of accrual open.

4. GOG3051: A Phase II, Open Label, Multicenter, Platform Study Evaluating the Efficacy and Safety of Biomarker-Driven Therapies in Patients with Persistent or Recurrent Rare Epithelial Ovarian Tumours. 27 patients accrued

5. GOG3052: A Study of VS-6766 v. VS-6766 + Defactinib in Recurrent Low-Grade Serous Ovarian Cancer With and Without a KRAS Mutation. Accrued 72/100.

B. Previously proposed Studies
A091903: A Randomized Phase II Trial Of Adjuvant Nivolumab With Or Without Cabozantinib In Patients With Mucosal Melanoma. (Vicus). At IRB submission. CCTG participating.

RT2141: Phase II Study of Combination of Androgen Receptor (AR) Inhibition by Bicalutamide in combination with Leuprolide Acetate and Exemestane in Recurrent AR Positive Adult-Type Ovarian Granulosa Cell Tumor (Hopp) – approved by IDB 1/19/22. To go to RSC

C. New Concepts
1. RT2212 Randomized phase II trial to assess efficacy of IV topotecan with or without ATR inhibitor, M6220 in patients with high grade neuroendocrine (small cell and large cell) carcinoma of cervix and other gynecologic origin. (Mahdi) Vicus, Aldredge

D. Closed Studies

0187, 0239, 0241, 0251, 0254, 0268, 0283, GY-001, 0281, 0264, Gy016

E. Other Business

1. Planning in person strategy session at July meeting to improve concept development for rare tumours including procurement of pre clinical data

2. Amendments to AGCT1531

QUESTIONS / DISCUSSION

ATTACH List of Concepts
1. RT2212 Randomized phase II trial to assess efficacy of IV topotecan with or without ATR inhibitor, M6220 in patients with high grade neuroendocrine (small cell and large cell) carcinoma of cervix and other gynecologic origin. (Mahdi)
# Uterine Corpus Cancer Subcommittee Agenda

Please refer to calendar invite if you need to dial in using your phone.

**AGENDA:** If your name is highlighted in yellow please be prepared to update:

**Chair:** Matthew Powell, MD

**Rad Onc Co-Chair:** Ann Klopp, MD

**Med Onc Co-Chair:** Martee Hensley, MD

**TR Co-Chairs:** Katherine Fuh, MD, PhD, Victoria Bae-Jump, MD, PhD

**GTN subcommittee:** Neil Horowitz, MD

**GOG 210 Subcommittee:** David Mutch, MD

***NOTE*** if your name is listed as PRESENTER or Discussant below please be prepared to discuss/review

## Learning Objectives:

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

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

| Uterine Corpus Cancer Subcommittee | Notes | Status
<table>
<thead>
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<tbody>
<tr>
<td><strong>ACTIVE/TEMPORARILY CLOSED</strong></td>
<td></td>
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<tr>
<td><strong>Matthew Powell and Ann Klopp</strong></td>
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<td><strong>NRG-GY012</strong></td>
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| A Randomized Phase II Study       | Open to accrual 9/4/18 | 138
| Comparing Single-Agent Olaparib,  | (Closed 2/4/19-4/8/19 - | Mackay to
| Single Agent Cediranib, and the   | noncompliance)          | UPDATE |
| Combinations of Cediranib/Olaparib| Temporarily closed to accrual | |
| (MED14736), Cediranib/Durvalumab  | 6/17/19 | |
| (MED14736), Olaparib/AZD5363     | Reactivated 8/16/21 | |
| (Capivasertib) in Women with Recurrent, Persistent or | New RAVE build for data collection | |
| Metastatic Endometrial Cancer.: A Platform | | |
Trial for Women with Recurrent or Persistent Endometrial Cancer (Mackay, Bender, Westin, Rimel)  
**CTEP IND**  
N=120 (through 6/17/19)  
N=168 (beginning 8/16/21)  
Total=288  
Stat: Enserro  
Uterine Corpus Cancer Subcommittee  
Amendment 5 (RRA) pending 12/15/21.

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Current Status</th>
<th>Notes</th>
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</table>
| **NRG-GY018** | A Phase III Randomized Placebo-Controlled Study of Pembrolizumab in addition to Paclitaxel and Carboplatin for Measurable Stage III Or IVA, Stage IVB or Recurrent Endometrial Cancer (Eskander) | Open to accrual 7/16/19  
Temporarily closed to accrual 4/6/20  
Reactivated 11/30/20 | Canada active  
Japan and Korea to begin participation in near future  
Saline vial shortage will require change from 2 to 1 saline vials being provided by PMB; also preparing for the possibility of no saline vials being provided. PMB to include info about this in shipment boxes. Amendment in development.  
SDMC to look at EOT forms to determine causes for so many patients not proceeding from Step 1 to Step 2. |
| **NRG-GY020** | Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Backes/Cohn) | Open to accrual 2/7/20 |  
Backes to update |

Closed Studies, primary manuscript NOT published (Corpus): 238,  
Closed Studies, primary manuscript NOT published (DT): 286B analyses in progress (SGO 2020)  
Closed Studies, primary manuscript published: 188*, 258 OS data Q1 22  
*patient on active treatment  
Terminations:  

**REPORTS:** GOG 0210: Dr. Mutch to provide report from sub-committee
| **Uterine Corpus Cancer Subcommittee**  
**Developing Studies**  
Matthew Powell and Ann Klopp |
|---|
| **NRG-GY025** Efficacy of immunotherapy with dual immune checkpoint inhibitors compared to anti-PD1 monotherapy in patients with deficient mismatch repair system recurrent endometrial carcinoma: A randomized phase II trial (Mahdi)  
**Stat:** Sill  
**N:**  
**Uterine Corpus Cancer Subcommittee** |
| **NRG-GY026** A randomized phase II/III trial of paclitaxel/carboplatin alone or combined with either trastuzumab or trastuzumab/pertuzumab in HER2 Positive Stage I-IV uterine serous carcinoma and carcinosarcoma after primary surgery (Erikson, Fader, Santin, Havrilesky QOL)  
**Stat:** Miller  
**N:** 525  
**Uterine Corpus Cancer Subcommittee** |

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<th><strong>Notes</strong></th>
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| UC1844 (UC1843)  
GCSC Disapproved 6/28/19  
GYN Cancer Committee 1/11/20  
UTF 5/15/20, 7/24/20  
RSC 10/21/20, Exec 11/16/20  
GCSC 12/17/20 (Pending)  
GCSC 2/18/21 (AOH)  
GCSC Approval 3/18/21  
Formal SLI Phase I sites CTEP follow-up review rec’d 10/5/21. Rec’d AOH; CIRB approved 12.7.21. CTEP approval pending DTL approval. SDMC will be ready to activate mid-February ’22. |
| GYN Cancer Committee 7/20/19  
UTF 6/19/20  
RSC 7/18/20, RSC Exec 8/19/20  
GNE will supply trastuz/pertuz under umbrella agreement w PMB (emails 6/4/20)  
Miller, CA, Powell spoke w L Rubenstein. Trial can continue accrual while Ph II matures. Central testing mechanism should not be needed. QOL-yes. Meeting 9/14/20 w Australian collaborators  
GCSC 9/17/20 (Pending)  
GCSC 11/19/20 (AOH)  
GCSC approval 2/23/21  
2nd circulation to entire study team for full modality input well under development. *(Not registration trial)*  

<table>
<thead>
<tr>
<th><strong>OEWG dates</strong></th>
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</table>
| **Start:** S  
**Target:** T  
**Absolute:** A |
| 12/17/2020 S  
07/15/2021 T  
03/12/2022 A |
| **Powell to Update**  
**Erickson to Update** |
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Title</th>
<th>Status</th>
<th>Notes</th>
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<tbody>
<tr>
<td>NRG-GY028 (PI2129)</td>
<td>Phase IB and Randomized Phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer. (Weston, Onstad)</td>
<td></td>
<td>PTMA#100828 GYN Cancer Committee 10/11/20 RSC 2/3/21 GCSC 1/21/21, 4/15/21 AOH 4/29/21 GNE declined to support as written 6/17/21. Team plan: revise to Ph1B/2 and resubmitted CrDL 11.22.21. LOI AOH await GNE 01/21/2021 S 11/21/2021 T 07/15/2022 A Weston / Onstad to provide update</td>
</tr>
<tr>
<td>UC2043</td>
<td>A Pilot Study of Dactinomycin plus Avelumab as First line Treatment for Selected Patients with Gestational Trophoblastic Neoplasia (Eriksson)</td>
<td></td>
<td>GYN Cancer Committee 7/17/20 Tabled. Team continues to work to harmonize with international trial. Horowitz to provide update</td>
</tr>
<tr>
<td>UC2108</td>
<td>Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Women with Advanced or Recurrent AR Positive ER Low Endometrial Cancer (Kurnit)</td>
<td></td>
<td>GYN Cancer Committee 1/30/21 Weston to provide update</td>
</tr>
<tr>
<td>UC2110</td>
<td>Molecularly Driven Salvage Therapy for Recurrent Endometrial cancer GOG-0238R (Harkenrider)</td>
<td></td>
<td>GYN Cancer Committee 1/30/21 Harkenrider to update: See below under new concepts.</td>
</tr>
<tr>
<td>UC2120</td>
<td>A Phase III Randomized Trial of PD1/PDL1 inhibitor +/- radiation or chemotherapy inhibitor for Newly Diagnosed Completely Resected Stage III-IVA or recurrent chemo naive Mismatch Repair Deficient (dMMR) Endometrial Cancer (Backes)</td>
<td></td>
<td>GYN Cancer Committee 4/9/21 UTF 9/17/21. Comments received 9/29/21. RSC? Backes to Update</td>
</tr>
<tr>
<td>UC2142</td>
<td>Neoadjuvant chemotherapy versus primary debulking surgery using molecularly</td>
<td></td>
<td>GYN Cancer Committee 10/8/21 Rossi and Bae-Jump to update</td>
</tr>
<tr>
<td>Project Code</td>
<td>Title</td>
<td>Sponsor</td>
<td>Details</td>
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| PI2140      | A Phase IB study of the combination SM08502 CLK inhibitor and weekly paclitaxel in recurrent endometrial carcinoma (B Corr, R Arend) | Uterine Corpus Subcommittee | GYN Cancer Committee 10/8/21  
On hold pending NExT application  
Corr to update |
| UC2208      | Tailored adjuvant therapy in POLE-mutated and p53-wildtype/NSMP early-stage endometrial cancer (TAPER)/Refining Adjuvant treatment IN endometrial cancer  
Based On molecular features (RAINBO POLEmut BLUE) A CCTG trial (McAlpine, Han) | Uterine Corpus Concepts NEW | Collaboration with NCIC  
McAlpine to present  
Discussants:  
Cosgrove,  
Viswanathan  
TS Winterhoff |
| UC2210      | Prospective Phase II Trial of Volume-Directed Salvage Radiation Therapy and Pembrolizumab for Mismatch Repair Deficient Recurrent Endometrial Cancer. GOG-0238R (Harkenrider) | UC2210  
Prospective Phase II Trial of Volume-Directed Salvage Radiation Therapy and Chemotherapy for p53 Abnormal and No Specific Molecular Profile Recurrent Endometrial Cancer. GOG-0238R (Harkenrider) | Harkenrider to present  
Discussants:  
Russo, Makker,  
Kurnit  
TS Darcy |
| UC2214      | Prospective Phase II Trial of Volume-Directed Salvage Radiation Therapy and Chemotherapy for p53 Abnormal and No Specific Molecular Profile Recurrent Endometrial Cancer. GOG-0238R (Harkenrider) | UC2214  
Prospective Phase II Trial of Volume-Directed Salvage Radiation Therapy and Chemotherapy for p53 Abnormal and No Specific Molecular Profile Recurrent Endometrial Cancer. GOG-0238R (Harkenrider) | Harkenrider to present  
Discussants:  
Russo, Makker,  
Kurnit  
TS Leslie |
| UC2211      | Efficacy of combined LAG3 inhibitor, relatlimab combined with nivolumab in recurrent endometrial cancer with deficient mismatch repair system. (Mahdi): Will have to be proposed as stand alone. | UC2211  
Efficacy of combined LAG3 inhibitor, relatlimab combined with nivolumab in recurrent endometrial cancer with deficient mismatch repair system. (Mahdi): Will have to be proposed as stand alone. | Mahdi to present  
Discussants:  
Nickles-Fader,  
Duska,  
Eskander, |
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<tr>
<td>1.</td>
<td><strong>PI2213</strong> Phase I/II study of ATR inhibition with M6220 combined with mTOR inhibition with Temsirolimus in recurrent endometrial cancer with emphasis on uterine serous cancer in dose expansion (Mahdi).</td>
<td><strong>Discussants:</strong> MacKay, Bae-Jump, TS Darcy</td>
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<td><strong>RT2212</strong> Randomized phase II trial to assess efficacy of IV topotecan with or without ATR inhibitor, M6220 in patients with high grade neuroendocrine (small cell and large cell) carcinoma of cervix and other gynecologic origin. (Mahdi)</td>
<td><strong>Discussants:</strong> Khanna, Erickson, TS Fuh</td>
</tr>
</tbody>
</table>
Head and Neck Committee Agenda

Date: Friday, February 11, 2022
Start and End Time: 6:45 – 8:15 PM ET
Chair: Sue Yom, MD
Co-Chair: Erich Sturgis, MD, MPH; Stuart Wong, MD

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

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

WORKSHOP AGENDA

A. Head and Neck portfolio overview
   Sue Yom, MD

B. Actively developing studies

- **HN010 trial**: Randomized phase II trial of docetaxel and HER2 targeted therapies in HER2 positive recurrent/metastatic salivary duct/salivary gland cancers
  Alan Ho, MD, PhD

- **NRG-HN2138 concept**: Biomarker-guided phase III trial of PD-1 inhibition with LAG3 inhibition as maintenance therapy after first-line platinum-gemcitabine -PD1 inhibition for recurrent/metastatic nasopharyngeal carcinoma
  Brigette Ma, MD

- **NRG-HN2139 concept**: Randomized phase II trial of chemo-immunotherapy vs. immunotherapy vs SOC in patients with recurrent/persistent PD-L1 enriched SCCHN undergoing salvage surgery
  Nabil Saba, MD

- **NRG-HN2201 concept**: Randomized phase II/III trial of RT and SMAC mimetic vs. cetuximab in LA HNSCC patients with cisplatin contraindication
  Loren Mell, MD

C. Review of active studies

   Actively accruing trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Description</th>
<th>PI(s)</th>
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<tbody>
<tr>
<td>NRG-HN008</td>
<td>Phase I RT + DNA-PK inhibitor in cisplatin-ineligible patients with high risk LA HNSCC</td>
<td>Maura Gillison, Michael Samuels</td>
</tr>
<tr>
<td>NRG-HN009</td>
<td>Phase II-IIIR RT with high-dose cisplatin (100 mg/m² x 3) vs weekly cisplatin (40 mg/m² x 7) for locoregionally advanced HNSCC</td>
<td>Paul Harari</td>
</tr>
<tr>
<td>RTOG 3507</td>
<td>Phase IIIR ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC</td>
<td>Stuart Wong</td>
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<tr>
<td>NRG-HN001</td>
<td>Individualized NPC treatment based on post-RT EBV DNA (Phase III)</td>
<td>Nancy Lee</td>
</tr>
<tr>
<td>NRG-HN005</td>
<td>Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer</td>
<td>Sue Yom</td>
</tr>
<tr>
<td>NRG-HN006</td>
<td>Phase II-III SLN Biopsy vs. END in T1-2N0 oral cavity cancer</td>
<td>Stephen Lai</td>
</tr>
</tbody>
</table>
**RTOG 1216**  
RT+cisplatin vs. RT+docetaxel+cetuximab vs. RT+cisplatin+atezolizumab for “high risk” resected HNSCC (Phase IIIR)  
Julie Bauman  
Paul Harari  
David Rosenthal

### D. Report on publications and protocols closed to active accrual

**Temporary Closure**

<table>
<thead>
<tr>
<th>Protocol Code</th>
<th>Description</th>
<th>Investigator(s)</th>
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<tbody>
<tr>
<td>NRG-HN004</td>
<td>Phase II-III RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC</td>
<td>Loren Mell</td>
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### Recently completed

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<thead>
<tr>
<th>Protocol Code</th>
<th>Description</th>
<th>Investigator(s)</th>
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<tbody>
<tr>
<td>NRG-HN007</td>
<td>Phase III Gem/Cis vs. Gem/Cis/Nivo in 1st line rec/met NPC</td>
<td>Brigette Ma</td>
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### E. NRG Core and General Membership

Sue Yom, MD

### F. NRG Championed Trials updates

Sue Yom, MD

<table>
<thead>
<tr>
<th>Protocol Code</th>
<th>Description</th>
<th>Investigator(s)</th>
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<tbody>
<tr>
<td>ECOG-ACRIN EA3132</td>
<td>Phase II Randomized Trial of Radiotherapy with or without Cisplatin for Surgically Resected Squamous Cell Carcinoma of the Head and Neck (SCCHN) with TP53 Sequencing</td>
<td>Trisha Wise-Draper, MD, Phd</td>
</tr>
<tr>
<td>ECOG-ACRIN EA3161</td>
<td>Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation in Patients with Locally Advanced, Intermediate Risk HPV Positive OPSCC</td>
<td>Christina Henson, MD</td>
</tr>
<tr>
<td>ECOG-ACRIN EA3163</td>
<td>A Phase II Randomized Trial of Neo-Adjuvant Chemotherapy Followed by Surgery and Post-Operative Radiation Versus Surgery and Post-Operative Radiation for T3 and T4a Nasal and Paranasal Sinus Squamous Cell Carcinoma</td>
<td>Michael Samuels, MD, FACP</td>
</tr>
<tr>
<td>ECOG-ACRIN EA6174</td>
<td>STAMP: Surgically Treated Adjuvant Merkel cell carcinoma with Pembrozilumab, a Phase III Trial</td>
<td>Evan J. Wuthrick, MD</td>
</tr>
<tr>
<td>ECOG-ACRIN EA3191</td>
<td>A Phase II Randomized Trial of Adjuvant Therapy with Pemrolizumab After Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma with High Risk Features</td>
<td>Jennifer Choe, MD, PhD</td>
</tr>
<tr>
<td>ECOG-ACRIN EA3202</td>
<td>Atezolizumab and/or Bevacizumab Beyond Progression on Immune Checkpoint Inhibition in Recurrent/Metastatic Head and Neck Cancers</td>
<td>Vidhya Karivedu, MD</td>
</tr>
<tr>
<td>CCTG HN11</td>
<td>SPECT-CT Guided ELEctive Contralateral Neck Treatment in Lateralized Oropharyngeal Cancer (SELECT): The Phase III Randomized Controlled Trial</td>
<td>Steve Chinn, MD, James Bates, MD</td>
</tr>
</tbody>
</table>

### G. New Investigator Committee update

Shlomo Koyfman, MD

### H. HNC Translational activities

Neil Hayes, MD, MPH

### I. NCI Head and Neck Steering Committee update

Loren Mell, MD

**QUESTIONS / DISCUSSION**
I. Welcome

Presenter: **Erich Sturgis, MD, MPH**

II. Brief Updates

Presenter: **Erich Sturgis, MD, MPH**

III. New Trial Concepts and Trials in Development (4:40 p.m.)

A. Neoadjuvant Carbo / Docetaxel / Nvo +/- Post Op XRT Followed by Consolidation Nivo; An XRT De-Escalation Trial

Presenter: **Ralph Zinner, MD**

B. NRG HN2139 – Phase II Randomized Trial of Chemo Immunotherapy or Immunotherapy in Patients with Recurrent / Persistent PDL1 Enriched HNSCC Undergoing Salvage Surgery

Presenters: **Nabil Saba, MD**

**Steve Chinn, MD**

C. Reduced Volume Post-Operative Radiation in Intermediate Risk Patients

Presenter: **Wade Thorstad, MD**

IV. Updates of Open Trials (5:20 p.m.)

A. NRG HN006 – Sentinel Lymph Node Biopsy Versus Elective Neck Dissection for Early-Stage Oral Cavity Cancer, Update Session for Surgeons at the American Head & Neck Society Meeting in late April in Dallas

Presenters: **Stephen Lai, MD, PhD** and **Steve Chang, MD**

B. SELECT Lymphatic Mapping Trial

Presenter: **John De Almeida, MD, MSc**

C. Multi-Institution Phase II/III Randomized IMPT vs IMRT Trial

Presenter: **Steven Frank, MD**

V. Adjourn
LUNG CANCER GENERAL MEETING
Held during scheduled NRG Oncology Semi-annual Virtual Meeting

Saturday, Feb. 12th | 9:30am to 11:00am (EDT)
Chair: Jeffrey Bradley, MD | Co-Chairs: Jessica Donington, MD PhD and Martin Edelman, MD

1. Learning Objectives

Following this activity, participants will be better able to:
   a) Learn about ongoing clinical trials within the lung cancer committee.
   b) Participate in feedback about ongoing and prospective trials.
   c) Develop strategies to participate in these trials at your home institution.

2. Active Studies:

   a) RTOG 1308: Protons vs photons for St III NSCLC
      Xing Liao
   b) NRG-LU002: Phase II/III chemo +/- SBRT for Stage IV
      Puneeth Iyengar
   c) NRG-LU004: Phase I anti-PD1 concurrent with RT
      Steven Lin
   d) NRG/Alliance-LU005: LPhase III Limited-stage SCLC
      Andreas Higgins
   e) NRG-LU006: Phase III; Dose-painting IMRT for mesothelioma
      Cliff Robinson
   f) RTOG 3515 / PAC 4: SBRT +/- durva for medically-inoperable Stage I
      Quynh-Nhu Nguyen
   g) NRG-LU007: Phase II/III ES-SCLC; chemo+atezo +/- RT
      Charles Simone
   h) SWOG S1914: Phase III SBRT +/- neoadjuvant atezo for Stage I and also
      Charles Simone
   i) NRG-LU008: Phase III; SBRT+chemoRT for locally-advanced NSCLC
      Vinai Gondi
   j) NRG-CC003: Hippocampal avoidance brain
      Gondi / Rusthoven
   k) NRG-CC009: SRS vs HA-WBRT for SCLC brain mets
      Saiama Waqar
   l) Lung-MAP SWOG S-1400
      Saiama Waqar
   m) ALCHEMIST Trial

QUESTIONS / DISCUSSION
Patient Centered Outcomes Research (PCOR) Committee Agenda

Date: Thursday, February 10, 2022
Start and End Time: 2:00 pm – 3:30 pm (MST) or 4:00 pm - 5:30 pm (EST)
Co-Chairs: Benjamin Movsas, MD; Patricia Ganz, MD; Lari Wenzel, PhD

Learning Objectives:
Following this activity, participants will be better able to:
1. Understand the importance of QOL compliance and data completeness
2. Analyze appropriate PRO and CER endpoints and instruments for use in NCTN Phase II and III clinical trials
3. Apply criteria for inclusion of PROs, CER, and PRO-CTCAE in NCTN Phase II and III clinical trials

Educational Needs: Identified through current PRO topics of interest and PCOR Committee meeting evaluations from prior meetings.

4:00 – 4:05 Session Introduction and Welcome
Lari Wenzel, PhD

4:05 – 4:45 Assessing and Addressing Symptom Burden and Health-Related Quality of Life in Adolescents and Young Adults with Cancer in NCTN Trials
Susan Parsons, MD, MRP
Michael Roth, MD

4:45 – 5:00 PRO and QOL Data Compliance
Marcie Ritter, PhD
Kandi Dempsey, DBA, MS, RN, OCN

5:00 – 5:25 Developing Concepts/Protocols

5:25 – 5:30 Closing Remarks
Ben Movsas, MD
Lari Wenzel, PhD
Translational Science Committee Agenda

Date: Thursday, February 10, 2022
Start and End Time: 6:30 pm - 8:00 pm EST
Chair: Michael Birrer, MD, PhD
Co-Chairs: Adam Dicker, MD, PhD / Matthew Ellis, MB, BChir., PhD, FRCP

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

1. To understand the mechanistic ways of improving Immuno-Oncology drugs
2. To understand the mechanisms of immune resistance
3. To understand the state of the science of angiogenesis biomarkers
4. To understand the translational research in NRG trials

WORKSHOP AGENDA

“The Quest for Effective IO in Non-Inflamed Tumors”
James Gulley, MD, PhD, FACP (National Cancer Institute)

“Overcoming Immune Resistance, New Mechanisms, and Strategies”
Samir Khleif, MD (Georgetown University)

“Use of the Plasma Angiome in NRG Trials”
Andrew Nixon, PhD (Duke University School of Medicine)

QUESTIONS / DISCUSSION
Translational Science GU Cancer Subcommittee Agenda

**Date:**  
Friday, February 11, 2022

**Time:**  
6:30pm – 8:00pm EST

**Chairs:**  
Phuoc Tran, MD, PhD

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>6:30 – 6:35</td>
<td>Introduction and Welcome</td>
<td>Phuoc Tran, MD, PhD (University of Maryland)</td>
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<tr>
<td>6:35 – 7:05</td>
<td>“Update on NRG-GU-Navigator 141 (NRG/RTOG 0126)”</td>
<td>Daniel Spratt, MD (University Hospitals)</td>
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<tr>
<td>7:05 – 7:35</td>
<td>“Pathology AI using NRG Prostate Trials Overview”</td>
<td>Osama Mohamad, MD, PhD (University of California, San Francisco)</td>
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<tr>
<td>7:35 – 7:50</td>
<td>&quot;Validating a High-Risk Mutational Signature for Oligorecurrent Castration-Sensitive Prostate Cancer&quot;</td>
<td>Matthew Deek, MD (Rutgers) / Phuoc Tran, MD, PhD</td>
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<tr>
<td>7:50 – 7:55</td>
<td>General TS Project Updates</td>
<td>Phuoc Tran, MD, PhD</td>
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<tr>
<td>7:55 – 8:00</td>
<td>Closing Remarks and Discussion</td>
<td>Phuoc Tran, MD, PhD</td>
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</table>
Translational Science GYN Workshop Agenda

Date: Friday, February 11, 2022
Start and End Time: 3:30 am – 5:00 pm (MST) or 5:30 pm – 7:00 pm (EST)
Chair: Michael Birrer, MD, PhD
Co-Chair: Heather Lankes, PhD, MPH

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

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

WORKSHOP AGENDA

3:30-3:40   Opening Remarks
            Michael Birrer, MD, PhD
            Heather Lankes, PhD, MPH

GYN Subcommittee Translational Science Updates

3:40-3:50   Cervix/Vulva Cancer Subcommittee
            Dmitriy Zamarin, MD, PhD

3:50-4:05   Ovarian Cancer Subcommittee
            Rebecca Arend, MD
            Elizabeth Swisher, MD
            Gloria Huang, MD

3:50-4:05   Rare Tumor Subcommittee

4:05-4:15   Uterine Corpus Cancer Subcommittee
            Vickie Bae-Jump, MD, PhD
            Katherine Fuh, MD, PhD

4:15-4:25   GYN Developmental Therapeutics
            Panagiotis Konstantinopoulos, MD, PhD

MP2PRT Moonshot Updates

4:25-4:40   Genomic and molecular characterization of biomarkers associated with self-reported race/ethnicity in high-risk endometrial cancers from NRG Oncology/GOG Protocol 210, Molecular Staging of Endometrial Cancer
            Casey Cosgrove, MD

4:40-4:55   Genomic and molecular characterization of biomarkers associated with tumor angiogenesis, DNA repair, and immunologic tolerance among exceptional responders and long-term survivors in NRG Oncology/Gynecologic Oncology Group protocol 240, a phase 3, randomized, controlled, open-label, multi-institutional, international trial of chemotherapy doublets with and without bevacizumab for primary treatment of women with recurrent, persistent, and/or metastatic cervical cancer (NCT00803062)
            Krish Tewari, MD

4:55-5:00   Closing Remarks
            Michael Birrer, MD, PhD
            Heather Lankes, PhD, MPH
Date: Friday, February 11, 2022
Time: 3:15pm-4:15pm EST
Chairs: Hayes, MD, MS, MPH

3:15 – 3:20 Introduction and Welcome
Neil Hayes, MD, MS, MPH (University of Tennessee)

3:20 – 3:45 “Interpreter of Maladies: AI and Computational Imaging for Risk Stratification and Treatment Response Assessment for Head and Neck Cancers”
Anant Madabhushi, PhD (Case Western Reserve University)

3:45 – 4:10 “Radiomic Signatures in Head and Neck Cancer”
Ruijiang Li, (Stanford University)

4:10 – 4:15 Closing Remarks and Discussion
Neil Hayes, MD, MS, MPH (University of Tennessee)
Translational Science LU Cancer Subcommittee Agenda

Date: Monday, February 7
Time: 2:00pm-3:00pm EST
Chair: Bo Lu, MD, PhD

1:00 – 1:05
Introduction and Welcome
Bo Lu, MD, PhD (Thomas Jefferson University)

1:05 – 1:20
“Clinical Translation of an Integrated Clinomic Framework for Individualizing Lung SBRT Dose”
Mohamed Abazeed, MD, PhD (Northwestern University)

1:20 – 1:35
“Metabolomic Predictors of Radiation Late Effects”
Cheema Amrita, PhD (Georgetown University)

1:35 – 1:50
“Applications of Artificial Intelligence to Quantify Cardiac Injury Risk from Radiation Therapy for Lung Cancer”
Raymond Mak, MD (Brigham & Women’s Hospital/Dana-Farber Cancer Institute)

2:05 – 2:20
“Prognostic Gene Signatures Derived from Combined Primary Tumor – PDX Small Cell Lung Cancer Profiling”
Phuoc Tran, MD (University of Maryland) ~ Luigi Marchionni, MD, PhD (Weill Cornell Medical College) ~ Christine Hann, MD, PhD (Johns Hopkins University)

2:20 – 2:35
Heath Skinner, MD (University of Pittsburgh)

2:35 – 2:50
“Cardiac Toxicity after CRT in Lung Cancer”
Zhongxing Liao, MD (MD Anderson)

2:50 – 3:00
Closing Remarks and Discussion
Bo Lu, MD, PhD (Thomas Jefferson University)
# Health Disparities Committee

**Monday, February 14, 2022 (Virtual Meeting) 2:00 pm-4:00 pm ET**

## Agenda

### Chairs:

*Chanita Hughes Halbert, PhD*
*Jennifer Wenzel, PhD, RN, CCM, FAAN*

### 2:00 - 2:05 pm

**Welcome/Announcements** – Jennifer Wenzel, PhD, RN, CCM, FAAN / Chanita Hughes Halbert, PhD

### 2:05 – 2:30 pm

**Research Spotlight** - NRG Oncology Health Equity New Investigator Mentor Program for Underrepresented Minority (URM) Scholars - Victoria Bae-Jump, MD, PhD / Jennifer Wenzel, PhD, RN, CCM, FAAN

- Tara Castellano, MD - Next Generation Sequencing as a Tool to Reduce Barriers to Targeted Therapy and Clinical Trial Enrollment for US Black Women with Endometrial Cancer
- Sonya Reid, MD MPH - Integrating gene signatures to guide management of HR+ MBC in a diverse cohort (INSIGHT)

### 2:30 – 2:40 pm

**Research Implementation (Education/Training/Mentorship) SIG update** – Victoria Bae-Jump, MD, PhD: Introduction of Mylin Torres, MD

- Clinical Trial Enrollment Updates - Statistics/Metrics - SDMC Reports - Victoria Bae-Jump, MD, PhD / Reena Cecchini, PhD, MS

### 2:40 – 2:50 pm

**Older Adult Research SIG update** – William Tew, MD

### 2:50 – 3:00 pm

**Rural Health Research SIG Update** – Na Tosha Gatson, MD, PhD, FAAN

### 3:00 – 3:45 pm

**HDC Research Concept Development SIG update** - Chanita Hughes Halbert, PhD: Introduction of Evan Graboyes, MD, MPH, FACS

- Simona Shaitelman, MD, Ed.M. - Neoadjuvant partial breast radiotherapy in early-stage breast cancer: a randomized phase III trial to improve cosmetic outcomes

- Concepts Under Development – Chanita Hughes Halbert, PhD
  - Co-morbidities and Clinical Trial Accrual
  - Multimorbidity Management in Cancer Survivors

### 3:45 – 3:55 pm

**Protocol Operations Management Liaison:** Lauren Henke, MD, MSCI

Introduction and plans

### 3:55 – 4:00 pm

**Closing remarks/Summary/Adjournment**

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*Please note all times listed are EASTERN TIME ZONE*
Imaging Committee Agenda

Date: Monday, February 7, 2022
Start and End Time: 1:30 PM-3:30 PM Eastern/12:30 PM Central/10:30 AM-12:30 PM Pacific
Chair Daniel Pryma, MD
Vice Chair Amy Fowler, MD, PhD
Members James Fink, MD, Rathan Subramaniam, MD, PhD
Mark Rosen, MD, Ying Xiao, PhD, Feng-Ming (Spring) Kong, PhD, MD
NRG Staff Support Denise Manfredi

(Eastern Times - PM)
MEETING AGENDA

1:30-1:35 Greetings Amy Fowler, MD
1:35-1:55 Disease Site Reports
   • H&N: Cynthia Wu, MD/ Min Yao, MD
   • Brain: Tammy Benzinger, MD / Ashok Srinivasan, MD
   • Breast: Heidi Umphrey, MD/ Mohammad Eghtedari, MD
   • Gyn: Karthik Sundaram, MD
   • GI: Aoife Kilcoyne, MD
   • GU: Ashesh Jani MD / Bill Hall, MD
   • Lung: Michelle Ginsberg, MD
   • Sarcoma: Dan Pryma, MD

1:55-2:25 Long Axial Field of View PET Austin Pantel, MD
2:25-2:35 Open Discussion

2:35-2:45 Recruitment Effort- How to get more imagers involved Dan Pryma, MD

2:45-2:55 Update from IROC PHL for NRG Oncology Trials Michael Boss, PhD

2:55-3:00 Update on RPT Trials Ying Xiao, PhD/ Michael Boss, PhD

3:00-3:30 Imaging and Medical Physics Symposium

   What is Biology-Guided Radiotherapy (BgRT)?
   • Whole Body PET –
     Lucas Kas Vitzthum, MD
     Clinical Assistant Professor, Radiation Oncology
     Radiation Therapy, Stanford University
   • Reflexion RT
     Nataliya Kovalchuk, PhD
     Clinical Associate Professor, Radiation Oncology
     Radiation Physics, Stanford University
   • Spectroscopic MRI to guide radiation dose escalation in GBM patients
     Hyunsuk Shim, MD, PhD
     Professor, Department of Radiation Oncology
     Emory University School of Medicine
Medical Oncology Committee Meeting Agenda

Date: Monday, February 7, 2022
Start and End Time: 11:00 am – 1:00 pm EST
Chairs: Corey Langer, MD; Deborah Armstrong, MD

LEARNING OBJECTIVES
Following this activity, participants will be better able to:
1. Update recent clinical trial outcomes in major disease entities from ASCO and ESMO 2021
2. Identify unique studies involving systemic therapy in the Medical Oncology sphere
3. Define and Update the criteria for arms of the Combo-Match study
4. Itemize the accomplishments of the Pharmacy Subcommittee

WORKSHOP AGENDA

I. Introductions
   Corey Langer, MD

II. Pharmacy Subcommittee Update
    Judith Smith, PharmD

III. Combo-Match Update
     Roisin O’Cearbhaill, MD

IV. GOG Partners and its Therapeutic Implications
    Kathleen Moore, MD

V. NCI Steering Committees: Structure and Function
    Elise Kohn, MD

VI. Emerging Studies and Critical post-ASCO and post ESMO updates: (10 min each)
   a. Breast
      TBN
   b. GYN
      Deborah Armstrong, MD
   c. HNC
      Stu Wong, MD (tentative)
   d. Thoracic
      Corey Langer, MD
   e. GU
      Oliver Sartor, MD (tentative)
   f. GI
      TBN
   g. CNS
      TBN

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

DISCUSSION
Pharmacy Subcommittee Meeting Agenda

Date: Tuesday, February 8, 2022
Start and End Time: 12:30-2 PM (EST)
Chair: Judith Smith, B.S., Pharm.D., BCOP, CPHQ

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

1. Discuss the supportive care resources available to investigators for management of common toxicities associated with chemotherapy.
2. Recognize the benefits of pharmacy review on NRG Oncology research protocols.
3. Understand the rationale and benefits of standardizing drug information for research protocols.
4. Explain the primary aspects for tracking variables for use of biosimilars on research protocols.
5. Discuss the role of standardization of pre-medication components.

AGENDA

I. Introductions (5 minutes)

II. CME lecture: “Review of Updates in Pharmacy Resources for NRG Oncology Investigators” Judith Smith, Pharm.D. (30 min)

III. Protocol Drug Information Update – Judith Smith, Pharm.D. (5 min)

IV. Practice Recommendation Documents – ALL (25 min)
   a. Discussion on dose rounding statement proposal
   b. Other resources to be developed:
      i. Chemotherapy with Photosensitivity
      ii. Drugs with dose modifications
         1. Renal function
         2. Liver function
         3. Age
      iii. PPE prevention and management (include list of common chemo)

V. Biosimilars Update Judith Smith, Pharm.D. (5 min)

VI. PMB Updates – Tali Johnson, Pharm.D. (10 min)

VII. Other Discussion Items (10 min) - All
Pathology Committee Agenda

Date: Tuesday, February 15, 2022
Start and End Time: 1:00pm-3:00pm EST

Chair: Jeffry Simko, MD, PhD
Co-Chairs: Peter Lucas, MD, PhD / Tan Ince, MD, PhD

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

1. Gain a broader understanding of pathology contributions to current and future NRG Clinical Trials.
2. Identify new translational research opportunities using NRG Clinical Trial material as it relates to Pathology.
3. Gain new insights into how new image technologies can be leveraged to improve Pathologic diagnostics and interpretations.
4. Gain exposure to recent developments in image analysis and artificial intelligence as they apply to histologic interpretations.

WORKSHOP AGENDA

“Committee Updates”
Jeffry Simko, MD, PhD (University of California, San Francisco)
Peter Lucas, MD, PhD (University of Pittsburgh)
Tan Ince, MD, PhD (Weill Cornell Medicine)

“Disease Site Pathology Reports”
Disease Site Pathologists

“Developing Digital Pathology Resources for Creation of Artificial Intelligence Tools in NRG Oncology” Felix Feng, MD (University of California, San Francisco)

“Non-Destructive 3-Dimensional Rapid High Resolution Scanning of Clinical Biopsy Specimens”
Nicholas Reder, MD, MPH (Lightspeed Microscopy, Inc.)

QUESTIONS / DISCUSSION
Protocol Support Committee
Introduction to Clinical Trials: Principles of NRG Oncology Clinical Trial Management for Nurses and CRAs

Date: Thursday, February 10, 2022
Start and End Time: 9:30 am ET – 6:00 pm ET
PSC Chair: Terry Thomas MS, CCRC
PSC Vice-Chairs: Nancy Fusco RN, BSN & Cynthia Licavoli RN, BSN, MA
Facilitators: Cynthia Licavoli RN, BSN, MA & Karen Holeva BS, CCRP

Learning Objectives
Following this activity, participants will be better able to:
1. Discuss NRG Oncology membership requirements.
2. Identify and describe relevant regulations for federally funded clinical research involving human subjects.
3. Describe the processes to be followed by clinical research sites in adhering to IRB requirements.
4. Describe the key components of adverse event assessment for expedited reporting including seriousness criteria, term selection, grading and attribution.
5. Describe the standard drug accountability procedures for NCTN trials.
6. Identify and discuss resources regarding investigational drug management.
7. Discuss and navigate the Rave data management system.
8. Utilize basic commands to key data into the RAVE system.
9. Discuss the nature of and preparation for NCI-mandated Quality Assurance Audits.
10. Discuss the basics of pathology and translational research specimen requirements and submissions.
11. Describe the basic methodology of RECIST 1.1 and other response criteria used in NRG Oncology trials.
12. Discuss RECIST 1.1 criteria as well as other response criteria used and identify methods of source documentation.
13. Discuss NRG Oncology Mentorship Program.
14. Discuss patient screening and enrollment process and identify best practices.
15. Identify methods for screening patients for clinical trials.
16. Identify the informed consent process according to federal regulations and local practices.
17. Discuss protocol requirements for administration of chemotherapy, immunotherapy, radiation therapy and surgery.
18. Describe useful tools and methods to ensure timely and accurate data management in the clinical trial setting.
19. Identify proper forms of source documentation.
20. Describe procedures for completion and submission of case report forms.

AGENDA

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<th>Presentation</th>
<th>Speakers</th>
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<tr>
<td>9:30 am - 9:40 am</td>
<td>Welcome</td>
<td>Cindy Licavoli RN, MA &amp; Karen Holeva BS, CCRP</td>
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<tr>
<td>9:40 am-9:55 am</td>
<td>NRG Oncology Overview</td>
<td>Kati Stoermer, MSBA</td>
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<td>9:55 am- 10:15 am</td>
<td>NRG Membership</td>
<td>Karan Boparai, BS, RT(R)(M)</td>
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<td>10:15am- 10:40 am</td>
<td>Regulatory Affairs</td>
<td>Judy Langer, BS</td>
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<td>Time</td>
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<td>Facilitators</td>
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<td>10:40 am-11:10 am</td>
<td>Expedited Adverse Event Reporting</td>
<td>Sara McCartney, MS, RN</td>
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<td>11:10 am-11:40 am</td>
<td>Investigational Drug Management</td>
<td>Brian Miller, Pharm D</td>
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<td><strong>11:40 am-11:50 am</strong></td>
<td>Break</td>
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<td>11:50 am-12:15 pm</td>
<td>Medidata Rave</td>
<td>Joseph Mroziak</td>
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<td>12:15 pm-12:45 pm</td>
<td>Quality Assurance Audits</td>
<td>Mary Jo Antonelli, MBA, MHA</td>
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<td>12:45 pm-1:05 pm</td>
<td>Pathology/Biospecimen Collections</td>
<td>Lisa Beaverson, BA, CCRP, Sandy DeVries, MA, Melanie Finnigan, BS</td>
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<td>1:05 pm-1:40 pm</td>
<td>RECIST Criteria</td>
<td>Shannon Puhalla, MD</td>
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<td>1:40 pm–1:50 pm</td>
<td>Mentorship Program</td>
<td>Nancy Fusco, RN, BSN</td>
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<td>1:50 pm–2:00 pm</td>
<td>Morning Closing Remarks</td>
<td>Cindy Licavoli RN, MA &amp; Karen Holeva BS, CCRP</td>
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<td><strong>2:00 pm–3:15 pm</strong></td>
<td>Lunch Break</td>
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<td><strong>Afternoon Discussion Sessions:</strong></td>
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<tr>
<td>3:15 pm–3:55 pm</td>
<td>Patient Screening &amp; Enrollment</td>
<td><em>Lead Facilitator</em> Cindy Licavoli, RN, BSN, MA Joni Shortt, RN, BSN, CCRC Tiffany Elsea, BA, CCRP</td>
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<td>3:55 pm–4:35 pm</td>
<td>Treatment Modalities in Clinical Trial Management</td>
<td><em>Lead Facilitator</em> Terry Thomas, MS, CCRC Pamela Mason, RN, BSN, CCRP Alison Ivey, RN, MS, MBA, OCN, CCRP</td>
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<td>4:35 pm–5:15 pm</td>
<td>Data Management</td>
<td><em>Lead Facilitator</em> Alex Kudryashev, MS, CCRP Becky Kramer, RN, BSN, CCRC Whitney Jacobson, RN, BSN, OCN, CCRP</td>
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<td>5:15 pm–5:55 pm</td>
<td>Adverse Event Reporting</td>
<td><em>Lead Facilitator</em> Mary Smrekar, RN, MSN, CNP Donna White, RN, BSN, OCN Cortney Montgomery BSN, RN, CCRP, CBCN</td>
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<td>5:55 pm–6:00 pm</td>
<td>Evaluation</td>
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**Protocol Support Committee**  
**Clinical Trial Nurse/Clinical Research Associate Continuing Educational Sessions**

**Date:** Friday, February 11, 2022  
**Start and End Time:**  
- **Part 1:** 11:30 am ET – 1:45 pm ET  
- **Part 2:** 3:15 pm ET - 4:45 pm ET  
**PSC Chair:** Terry Thomas MS, CCRC  
**PSC Vice Chairs:** Nancy Fusco RN, BSN & Cynthia Licavoli RN, BSN, MA  
**Program Facilitator:** Karen Holeva, BS, CCRP

**Learning Objectives**  
**Following this activity, participants will be better able to:**
1. Discuss social media activities for NRG Oncology.  
2. Develop a strategy to incorporate social media activities for your cancer research program.  
4. Discuss, locate and describe current procedures and support services available with CTSU.  
5. Describe successful practices for developing leaders and increasing staff retention.  
6. Discuss the role of the Quality Assurance program from a site perspective, structure and responsibilities.

**AGENDA**

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<td><strong>PART 1:</strong></td>
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<tr>
<td>11:30 am- 11:40 am</td>
<td>Introduction/Welcome</td>
<td>Karen Holeva BS</td>
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<td>11:40 am - 11:50 am</td>
<td>Welcome</td>
<td>Kati Stoermer, MSBA</td>
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<tr>
<td>11:50 am - 12:20 pm</td>
<td>FORTE</td>
<td>Robert Schoen, MD, MPH</td>
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<tr>
<td>12:20 pm- 12:35 pm</td>
<td>NRG Oncology Social Media Activities</td>
<td>Michelle Shepard</td>
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<tr>
<td>12:35 pm– 1:10 pm</td>
<td>NRG Oncology Quality Assurance Program Updates</td>
<td>Mary Jo Antonelli, MBA, MHA</td>
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<tr>
<td>1:10 pm – 1:35 pm</td>
<td>CTSU Updates</td>
<td>Jenny Hopkins, BA, BSN</td>
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<tr>
<td>1:35 pm – 1:45 pm</td>
<td>Questions &amp; Evaluations</td>
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<tr>
<td><strong>PART 2:</strong></td>
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| 3:15 pm – 4:15 pm | Turnover, Retirements, Burnout- OH MY!  
*The Story of Leadership Development at an NCI-Designated Cancer Center During a Pandemic* | Angela A. Rice-Warren, M.Ed. |
| 4:15 pm- 4:45 pm | Quality Assurance Program from a Site Perspective | Kristine Lipowski, MA, CCRP |
Developmental Therapeutics Radiation Therapy Subcommittee Agenda

Date: Thursday February 10, 2022
Start and End Time: 6:30-8:00 pm ET
Chairs: Steven Lin, MD PhD and Sandip Patel, MD

I. Introduction
   A. General Business
      Steven Lin, M.D., PhD

II. DTRT White Paper update
    Zachary Zumsteg MD, Sid Sheth MD

III. Disease Site and Working Group Updates (ongoing and developing protocols)
   a. Brain/CNS (Committee Liaison: Vinay Puduvalli, MD)
      i. BN010: A Safety Run-In and Phase II Study Evaluating the Efficacy, Safety, and Impact on the Tumor Microenvironment of the Combination of Tocilizumab, Atezolizumab, and Fractionated Stereotactic Radiotherapy in Recurrent Glioblastoma. (PI: Stephen J. Bagley, MD, MSCE)
         1. Activated July 6, 2021
         2. 23 sites approved to enroll; no enrollments (as of 1.24.2022)
      ii. Concept BN2123: Phase 1/1b trial of combination high-dose methotrexate, rituximab, temozolomide, plus selinexor (MR-TS) followed by investigator’s choice consolidation for newly diagnosed primary CNS lymphoma (PCNSL) (PI: Yazmin Odia, MD)
         1. RSC approval October 2021; LOI in development
   b. Sarcoma Working Group (WG Liaison: Meng Welliver, MD)
      i. DT001: A Phase IB Trial of Neoadjuvant AMG-232 Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma (STS) (Meng Welliver, MD)
         1. Cohort A enrolled to all 3 DL, no DLT—next steps to be discussed; cohort B enrolling
   c. Genitourinary (Committee Liaison: Zachary Zumsteg, MD and Chad Tang, MD)
      i. GU007—Randomized Phase II Trial of Niraparib with Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (with INITIAL Phase I) (PI: Dror Michaelson, MD)
         1. Dose level 2 completed; Dose level 3 OPEN
   d. Head and Neck (Committee Liaison: Sid Sheth, MD)
      i. HN008: Ph I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC) (PI: Maura Gillison MD, Michael Samuels MD); Activated: 12/10/2020; Enrollment: 1/42 patients
   e. Breast (Committee Liaison: Steve Chmura, MD)
   f. Lung (Committee Liaison: Steven Lin, MD, PhD)
      i. LU004: Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined with MEDI4736 (Durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1) (PI: Steven Lin, MD, PhD)
         1. Closed to accrual 6/21/21; toxicity results to be reported November 2021
   g. GI-non colorectal (Committee Liaison: Terence Williams, MD)
      i. GI007: Phase I trial with Expansion Cohort of OBP-301 (telomelyn) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who Are Not Candidates for Surgery (PI: Geoffrey Ku, MD)
         1. Accrual=2 (as of 1.24.2022)
      ii. Concept GI2128: A Phase I Trial of Dose Escalated Radiation in 5 or 15 Fractions for Locally Advanced Pancreas Cancer (LAPC) Patients (PI: Nina Sanford, MD)
Radiation Oncology Meeting in conjunction with the 2022 NRG Winter Semiannual Meeting Agenda
CENTER FOR INNOVATION IN RADIATION ONCOLOGY (CIRO)

Meeting Link: Must register via NRG website register

Date: Friday, February 11, 2022
Start and End Time: 9:00 AM – 11:00 AM (Eastern)/ 7:00 AM - 9:00 AM (Mountain)/ 8:00 AM – 10:00 AM (Central)/ 6:00 AM – 8:00 AM (Pacific)
Chair: Jeff Michalski, MD
Vice Chair: Evan Wuthrick, MD / Ivy Petersen, MD
NRG Staff Support: Elizabeth O'Meara / Theresa Powell

9:00 – 9:30 2022 Winter RO Symposium Theme: Radio Protectors – Next Generation
Evan Wuthrick, MD (Moderator)

- **Title 1**: NCORP CC2145 - Rand, blinded, placebo controlled ph II trial of concurrent chemoRT w/ and w/out BMX-001 for H&N squamous Ca (7min)
  - David M. Brizel, MD

- **Title 2**: Nanogenistein as a Radioprotector: Findings from a Phase 1b/2a study in Combination w/ Chemoradiotherapy for Non-Small Cell Lung Ca (7min)
  - Charles B. Simone, II, MD, FACRO

- **Title 3**: Galera Ph. III ROMAN trial (7min)
  - Cullen M. Taniguchi, MD, PhD

- Discussion (5 to 9 min)

NRG RADIATION ONCOLOGY COMMITTEE REPORTS

9:30 – 9:32 Radiation Oncology (RO) Committee Introductions
Jeff Michalski, MD

9:32 – 9:40 NCI/NCTN Updates
Ceferino Obcemea, PhD

- NCI Communications
- NCTN Medical Physics

9:40 – 9:45 NRG RO Medical Physics Subcommittee Updates
Ying Xiao, PhD/ Stan Benedict, PhD

9:45 – 9:50 NRG RO Particle Therapy Workgroup Updates
Charles Simone, MD

9:50 – 10:00 Imaging Committee
Dan Pryma, MD

10:00 – 10:10 Imaging and Radiation Oncology Core (IROC)

- IROC Houston
  - Stephen Kry, PhD

- IROC Philadelphia RT (Contouring & Dosimetry)
  - Denise Manfredi / Ying Xiao, PhD

10:10 – 10:55 Disease Site Reports – (Updates on concepts near development)

- **H&N**
  - Jimmy Caudell, MD / Jason Chan

- **Brain**
  - Christina Tsien, MD / Tony Wang, MD

- **Breast**
  - Steven Chmura, MD / Simona Shaitelman, MD

- **Gyn**
  - Mark Bernard, MD / Eric Donnelly, MD

- **GI**
  - Evan Wuthrick, MD / Emma Holliday, MD

- **GU**
  - Dan Krauss, MD / Hiram Gay, MD

- **Lung**
  - Pamela Samson, MD / Charles Simone, MD

- **Sarcoma**
  - Philip Wong, MD / Dian Wang, MD

10:55 Other Business

- Questions / Discussions

11:00 Adjournment
h. GI-colorectal (Committee Liaison: Theodore Hong, MD)
   i. CR2103: Phase I trial: Combination of an ATR inhibitor in combination with capecitabine and radiation for rectal cancer (PI: Eric Miller, MD/Mentor: Terence Williams); Approved by Research Strategy. LOI under development for submission to CTEP.

i. GYN (Committee Liaison: Jyoti Mayadev, MD)
   i. Currently, the GYN phase I studies in development do not include RT

QUESTIONS / DISCUSSION
Medical Physics Subcommittee Virtual Meeting Agenda

CENTER FOR INNOVATION IN RADIATION ONCOLOGY (CIRO)

Zoom meeting Link: Must Register through the NRG Oncology Meeting Portal

Date: February 07, 2022
Start and End Time: 3:30 PM - 5:00 PM (Eastern) / 2:30 PM – 4:00 PM (Central) / 1:30 PM – 3:00 PM (Mountain)
12:30 PM – 2:00 PM (Pacific)

Chair: Ying Xiao, PhD
Vice Chair: Stanley Benedict, PhD
NRG Staff Support: Elizabeth O’Meara / Theresa Powell

3:00 – 3:30 Medical Physics/ Imaging Joint Symposium

Theme: What is Biology-Guided Radiotherapy (BgRT)?

Title 1: Whole Body PET
Nataliya Kovalchuk, PhD
Clinical Assistant Professor, Radiation Oncology
Radiation Therapy, Stanford University

Luca Kas Vitzthum, MD
Clinical Assistant Professor, Radiation Oncology
Radiation Physics, Stanford University

Title 2: MR SPECT
Hyunsuk Shim, MD, PhD
Professor, Department of Radiation Oncology
Emory University School of Medicine

3:30 – 3:32 Introductions
Ying Xiao, PhD

• Subcommittee Updates
Stanley Benedict, PhD

3:32 – 3:40 NCI/NCTN Updates
Ceferino Obcemea, PhD

• NCI Communications
• NCTN Medical Physics

3:40 – 3:50 NRG QA Report

• IROC Houston
Stephen Kry, PhD

• IROC Philadelphia RT (Contouring & Dosimetry)
Ying Xiao, PhD

• IROC Philadelphia Imaging (reporting at 2:45 pm)
Mark Rosen, MD / Michael Boss, PhD

3:50 – 4:15 Disease Site Reports

• Brain
Yunfeng Cui, PhD / Fang-Fang Yin, PhD

• Breast
Guang-Pei Chen, PhD / Jean Moran, PhD

• GI
William Parker, M.Sc. / Gemma Davies, PhD

• GU
Robert Wallace, PhD / Rajat Kudchadker, PhD / Mihaela Rosu, PhD

• GYN
Hayeon Kim, PhD / Cecilia Lee, PhD

• H&N
Nataliya Kovalchuk, PhD / Ping Xia, PhD

• Lung
Martha Matuszak, PhD / Timothy Ritter, PhD

• NCORP
Yimei Huang, PhD / Tian Liu, PhD

4:15 – 4:25 Modality Technology Reports

• Notable Technologies (Proton)
Chris Beltran, PhD

○ Proton SBRT
Liyong Lin, PhD

4:25 – 4:58 Working Group and Other Updates

• Xoft
Ceferino Obcemea, PhD/Ying Xiao, PhD

• Recommendations and Guidelines for Clinical Trials involving Artificial Intelligence Assisted Automated Segmentation in Radiotherapy
Sharon Qi, PhD / Yi Rong, PhD

• RPT Dosimetry
Jacek Capala, PhD

• FLASH
Jennifer Zou, PhD

• SFRT
Heng Li, PhD

• Radiomics Phantom
Jason Sohn, PhD

4:58 Other Business: Questions / Discussions

5:00 Adjournment
Particle Therapy Working Group
Virtual Meeting in conjunction with the NRG Oncology Semiannual Meeting
CENTER FOR INNOVATION IN RADIATION ONCOLOGY (CIRO)

Meeting Link: Must register using NRG Registration via Bravura

Date: Tuesday, February 15, 2022
Start and End Time: 5:00 PM – 6:30 PM (Eastern)/4:00 PM – 5:30 PM (Central) 3:00 PM – 4:30 PM (Mountain)/ 2:00 pm – 3:30 PM (Pacific)
Chair: Charles B. Simone II, MD
NRG Staff Support: Theresa Powell/ Elizabeth O’Meara

Introduction
5:00 pm Welcome C. Simone, MD

Symposium Agenda

Particle Therapy 2022 Winter Symposium Theme
5:00 – 5:30 pm
“Defining the Value of Proton Therapy in the Next Generation of NRG Oncology Proton Trials”
- Moderator: Charles Simone
- Talk 1 (10 min): Proton Therapy Trial Design from a Statistical Endpoint Perspective - Soren M. Bentzen
- Talk 2 (10 min): Clinical Outcomes for Proton Therapy: Toxicity, Quality of Life, Cost Effectiveness and Other Endpoints Beyond Survival – Justin Bekelman
- Panel Discussion (10 min): Xing Liao and Mineh Mehta

Work Group Updates Agenda

5:30 – 5:35 pm Update from NCI J. Buchsbaum, MD
5:35 – 5:40 pm Update on Proton Center Credentialing by IROC Houston P. Taylor, MS
5:40 – 5:45 pm Update on Medical Physics Proton C. Beltran / Y. Xiao

Protocol(s) / Concept(s) Update from Members

5:45– 5:55 pm GI Studies
- NRG-GI003 Ph III Protons vs. Photons for Hepatocellular Carcinoma T. Hong, MD
- NRG-GI006 Ph IIIR Proton Beam Therapy (PBT) vs IMRT for Treatment of Esophageal CA S. Lin, MD

5:55 – 6:05 pm Brain Studies M. Mehta, MD
- NRG-BN001 Ph IIR photon/proton for ND GBM
- NRG-BN003 Phase III trial of observation versus irradiation for a gross totally resected grade II meningioma
- NRG-BN005 Intensity modulated proton (IMPT) vs. photon (IMRT) for cognitive preservation in patients with low grade glioma

6:05 – 6:10 pm Lung Studies Z. Liao, MD
- NRG/RTOG 1308 Ph III Protons vs. photons for inoperable NSCLC
- LU006 PH III Mesothelioma Surgery/Chemo +/- hemithoracic RT

6:10 – 6:15 pm H & N Studies N. Lee, MD
• NRG-HN001 Nasopharynx: Ph IIIR and PhIII, 2 cohorts based on EBV DNA level, chemo/RT +/- adj. chemo

6:15 – 6:25 pm  GU Studies
• NRG-GU009 Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with Higher Genomic Risk  K. Hoffman, MD
• NRG-GU008 (Amendment 2 adding Protons in progress) Randomized Phase III Trial incorporating abiraterone/ apalutamide and advanced imaging into salvage treatment for patients with node-positive prostate cancer after radical prostatectomy  J. Efstathiou, MD
• NRG-GU010 (In Development) Parallel Phase III Randomized Trials of Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: Deintensification and Intensification Clinical Trial (GUIDANCE)  B. Baumann, MD
• COMPARE: COMparative Study of Outcomes of Proton and Photon Radiation in Prostate Ca  N. Mendenhall, MD

6:25 – 6:30 pm  Breast Studies  S. MacDonald, MD
• RTOG 3509/3510 RADCOMP: Pragmatic Randomized Trial of Proton vs. Photon Therapy for Non-Metastatic Breast

6:30 pm  Other Business / Questions
Surgical Oncology Committee Agenda

Date: Saturday, February 12, 2022
Start and End Time: 7:00 – 8:00 AM MT (or 9:00 – 10:00 am ET)
Chair: Thomas Julian, MD
Co-Chairs: Mark S. Shahin, MD

Learning Objectives:

Following this activity, participant will be better able to:

1. Describe technological advances in surgical and radiation oncology for multiple NRG clinical disease sites.
2. Describe new approaches in medical oncology for multiple NRG clinical disease sites

Workshop Agenda

1. Welcome and Introductions
2. Approval of prior meeting minutes
3. Presentations
   a. Medical Oncology
   b. Radiation Oncology
4. Disease Site Liaison Reports
   a. CNS/Brain
   b. Breast
   c. GI
   d. GYN
   e. GU
   f. Head and Neck
   g. Thoracic/Lung
5. New Concepts and Proposals
6. Open Discussion and Future plans
Canadian Members Subcommittee Meeting Agenda

Date: Monday, February 7, 2022
Start and End Time: 4:00 – 5:30 pm EST
Chair: Jean-Paul Bahary, MD
Vice-Chair: Al Covens, MD
NRG Oncology Operations: Erica Field (Back-up representatives: Judy Langer and Kate Wiser)

Learning Objectives:
Following this activity, participants will be better able to:
1. Discuss the status and significance of new and ongoing NRG Oncology clinical trials available in Canada
2. Discuss and subsequently apply standards and procedures required to participate in a research protocol supported by NRG Oncology
3. Learn about trials available in Canada

AGENDA

I. General
   a. Welcome, Introductions, Housekeeping – Committee chairs
   b. Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest

II. Status of NRG Oncology Trials in Canada
      Discussion lead - NRG Oncology Regulatory
   b. Audit trends and remote auditing – Mary Jo Antonelli

III. Optimizing Accrual in Canada
   a. Discuss best practices for and barriers to optimizing accrual among Canadian sites
      Discussion lead – NRG Regulatory and Canadian Subcommittee Co-Chairs

IV. New Protocols
   a. Promotion of recently activated trial, NRG-GU009: Parallel Phase III Randomized Trials For High Risk Prostate Cancer Evaluating De-Intensification For Lower Genomic Risk and Intensification of Concurrent Therapy for Higher Genomic Risk with Radiation (Predict-RT*) *Prostate RNA Expression/Decipher To Individualize Concurrent Therapy with Radiation – Scott Morgan, MD
   b. Developing trial, NRG-BN012: A Randomized Phase III Trial of Pre-Operative Compared to Post-Operative Stereotactic Radiosurgery (SRS) in Patients with Resected Brain Metastases – Stuart Burri, MD

V. New Business, General Questions, Discussion, Next Meeting
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NRG Oncology Virtual Meeting - Feb 2022

NRG Oncology
Winter 2022
Virtual Meeting

Genomic/Exact Sciences
Immunogen
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