NRG Oncology™ Virtual Summer Meeting

July 19 - 28, 2021

Meeting Program
## Table of Contents

**Welcome Message** .................................................................2  
**NRG Mission Statement/Educational Objectives** ......................3  
**Accreditation/CME Credit Information** .................................4  
**Final Listing of Approved CME Credits** ................................5  
**Meeting Agenda** ...................................................................6

### SESSIONS/SPECIAL EVENTS

**NRG PSC CTN/CRA Workshop Educational Sessions**  
*Agendas on page 67-68*

**NRG-CC005/FORE Trial Virtual Workshop** ..........................8  
*Agenda on page 9*

**NRG Oncology Plenary Session** ...........................................11  
**NCORP Town Hall** .................................................................12  
**NRG General Session** .............................................................13  
**CCDR Breakout Sessions** ......................................................14  
**NRG Social Media Workshop** .................................................15  
**NRG Digital Health Workshop** .............................................16  
**Health Disparities Cmte Virtual Symposium** ..........................17  
*Agenda on page 18*

**WORKSHOP AGENDAS (CME/Non-CME)**

### NRG SCIENTIFIC COMMITTEES

- **Brain Tumor Committee** ..................................................20  
- **Breast Cancer Committees**
  - **Breast Cancer Committee** ..............................................21  
  - **Rare and Genticly Linked Breast Cancer** .......................22  
  - **Cancer Prevention & Control Committee** .....................23  
  - **Cancer Care Delivery Research Committee (CCDR)** ....24  
- **Developmental Therapeutics Committees**
  - **Dev. Therapeutics/Phase I/Translational Science** .........25  
  - **Dev. Therapeutics Radiation Therapy** (see pg 69)  
- **Genitourinary Cancer Committee** ....................................28  
- **Gynecologic Cancer Committees**
  - **Cervix Vulvar Cancer Subcommittee** ..........................30  
  - **Gynecologic Cancer Committee** .................................34  
  - **GYN Dev. Ther/Phase I/Translational Science** (see pg 25)  
  - **Ovarian Cancer Subcommittee** ....................................40

- **Rare Tumor Subcommittee** .................................................45  
- **Uterine Corpus Subcommittee** ..........................................47  
- **Head and Neck Cancer Committee** ..................................51  
- **Lung Cancer Committee** ..................................................53  
- **Patient Centered Outcomes Research (PCOR)** ..................54  
- **Translational Science Committees**
  - **Translational Science Workshop** ..................................55  
  - **Translational Science Brain Cancer Subcmte/Low Grade Glioma Working Group** ...........................................56  
  - **Translational Science GYN Workshop** ..........................57  
  - **Translational Science GU Cancer Workshop** ................58  
  - **Translational Science Head & Neck Cancer Workshop** ....59  
  - **Translational Science Lung Cancer Workshop** ...............60

### SCIENTIFIC CORE COMMITTEES

- **Health Disparities Committee Meeting** ............................62  
- **Imaging Committee** ..........................................................63

### Medical Oncology Committees

- **Medical Oncology Committee** ........................................64  
- **Pharmacy Subcommittee** ..................................................65  
- **Pathology Committee** ......................................................66  
- **Protocol Support Committees(PSC)CTN/CRA Educational-Sessions** .................................................................67

### Radiation Oncology Committees

- **Developopemental Therapeutics Radiation Therapy** .........69  
- **Radiation Oncology Committee** ........................................71  
- **Medical Physics Workshop** ..............................................72  
- **Particle Therapy Working Group (formerly Proton WG)** ....73

### ADMINISTRATIVE COMMITTEES

- **Canadian Members Subcommittee** ..................................76

### INSTITUTIONAL ACCRUAL

- **Member Accrual** ...........................................................78  
- **Sponsors Acknowledgement** ............................................83  
- **Exhibitors Acknowledgement** ........................................84  
- **Commercial Supporters Acknowledgement** .....................85
Welcome to #NRG2021, the NRG Oncology Summer Virtual Meeting!

Even as we are meeting virtually, we are also planning and looking forward to our future in-person meetings in 2022. But for now, as so many of us have yet to return to traveling, we are pleased to offer this opportunity to gather virtually. Our meeting includes over 50 sessions over 10 days and offers new capabilities including a social lounge for informal networking and one ad hoc meetings. We look forward to connecting with you!

We have enjoyed the ability to have greater participation in meeting virtually, and as we look ahead to our return to in-person meetings we are figuring out what a hybrid meeting will mean for NRG Oncology. Having opportunities for more of our members to participate is a boon we intend to continue.

Enjoy what we hope is the final fully virtual meeting of NRG Oncology. Plan to join us in the social lounge for informal networking, and be sure to join our plenary sessions on Thursday and Friday, and don't forget to find us on social media at #NRG2021!
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.
Accreditation Statement

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

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

AMA PRA Category 1 Credits™

The GOG Foundation, Inc. designates this live activity for a maximum of 25 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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

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

How to Claim CME/CEU Credit

- Access the NRG Meeting Attendee Hub and attend your sessions
  - NRG Meeting/CME: After you attend your sessions, click the button for the Overall Evaluation located on the home page of the Attendee Hub. Once selected, you can complete and submit your Overall Evaluation*.
  - Summer Symposium/CME: Select evaluation and complete immediately following the session.*
  - PSC/CEU: After you attend your sessions, select and complete evaluation then submit.*

  *Certificates: After you submit your evaluations, you should receive an email with instructions to download, save and print your certificate. (Certificates will be sent to the email you used to register.)

For CME questions, please contact cmeinfo@gog.org

Disclosure Information

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

For questions or comments about this CME activity, please contact: Michelle N. Small, MHA, Dir, Education Programs/CME Compliance at msmall@gog.org
The NRG Oncology virtual meeting provides the opportunity to earn up to 25 AMA PRA Category 1 Credits™.

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NRG Oncology Summer 2021 Virtual Meeting

MONDAY, JULY 19, 2021
10:00 - 11:00  Canadian Members Subcommittee
1:00 - 3:00  Imaging Committee
2:30 - 3:00  Imaging & Medical Physics Subcommittee
2:30 - 4:30  Medical Physics Subcommittee

TUESDAY, JULY 20, 2021
10:00 - 11:00  Translational Science Head & Neck Cancer Subcommittee
11:00 - 12:30  Surgical Oncology Committee
12:00 - 2:00  Translational Science Lung Cancer Subcommittee
2:00 - 4:00  Translational Science Brain Cancer Subcommittee

WEDNESDAY, JULY 21, 2021
8:00 - 9:00  International Members Subcommittee
1:00 - 3:00  Radiation Oncology Committee
1:00 - 5:00  Summer Symposium “Cancer Immunotherapy: Successes, Challenges and New Frontiers”
3:00 - 4:30  FORTE
5:00 - 6:30  Particle (Proton) Working Group

THURSDAY, JULY 22, 2021
10:00 - 12:00  Developmental Therapeutics Committee
10:00 - 12:00  Health Disparities Committee
10:00 - 12:00  CTN/CRA Workshop – Workshop-Education Morning Session
12:00 - 2:30  Cancer Prevention & Control Committee
12:30 - 2:30  CTN/CRA Workshop – Workshop-Breakout Afternoon Session
12:30 - 2:30  Rare Tumor Subcommittee
2:45 - 3:45  NRG Plenary Session
4:00 - 6:00  Patient Centered Outcomes Research Committee
4:00 - 6:00  Translational Science Committee

FRIDAY, JULY 23, 2021
10:00 - 11:30  NCORP Townhall
10:00 - 12:00  Brain Tumor Committee
10:00 - 12:00  Breast Cancer Committee
10:00 - 12:00  Cervix/Vulvar Cancer Subcommitte
12:30 - 1:45  NRG General Session
1:45 - 3:45  Cancer Care Delivery Research Committee
1:45 - 3:45  Genitourinary Cancer Committee
1:45 - 3:45  Head & Neck Cancer Committee
1:45 - 3:45  Uterine Oncology Subcommittee
4:00 - 6:00  Medical Oncology Committee
4:00 - 6:00  Ovarian Cancer Subcommittee
4:00 - 6:00  Sarcoma Working Group

SATURDAY, JULY 24, 2021
10:00 - 11:30  Gastrointestinal Colorectal Cancer Committee
10:00 - 12:00  Gynecologic Cancer Committee
10:30 - 12:30  Lung Cancer Committee
11:45 - 1:15  Gastrointestinal Non-Colorectal Cancer Committee

MONDAY, JULY 26, 2021
11:00 - 12:00  Social Media Workshop
12:00 - 1:30  NRG Digital Health Working Group
2:00 - 3:00  Developmental Therapeutics-Radiation Therapy
3:00 - 4:30  Patient Advocate Committee
3:00 - 5:00  NRG-VA/MTF Special Session

TUESDAY, JULY 27, 2021
11:00 - 12:30  Translational Science Gyn Subcommittee
12:00 - 1:30  Pharmacy Subcommittee
1:00 - 3:00  Translational Science Genitourinary Subcommittee

WEDNESDAY, JULY 28, 2021
1:00 - 2:30  Health Disparities Symposium
3:00 - 5:00  Pathology Committee
Save the Date!

**NRG-CC005/ FORTE Trial Virtual Workshop**

**Wednesday, July 21, 2021**

**3:00-4:30 pm ET**

FORTE is a randomized trial of surveillance colonoscopy for participants with first time diagnosis of 1 or 2 non-advanced adenomas that will be opening soon. Subjects will be randomized to having their next colonoscopy exam at 5 years *and* at 10 years or their next colonoscopy exam at 10 years.

Plan to attend the important Forte kick off session during the virtual NRG Oncology semiannual meeting to learn about the trial and eligibility, approaches to retrospective enrollment/patient selection and recruitment, specimen collections, and data collection.

Register now at:
[https://www.nrgoncology.org/Meetings-Resources/Meetings/July-2021-Semiannual-Meeting-Resources](https://www.nrgoncology.org/Meetings-Resources/Meetings/July-2021-Semiannual-Meeting-Resources)

*Forte is part of the NCI NCORP structure. The trial will be led by NRG Oncology with the participation of the National Clinical Trials Network (NCTN) organizations: Alliance for Clinical Trials in Oncology, ECOG-ACRIN Cancer Research Group, and SWOG.*
FORTE Protocol Workshop

Date: July 21, 2021
Start and End time: 3:00 p.m. – 4:30 p.m. EST

Learning Objectives:
1. Review NRG/FORTE-CC005 Trail eligibility criteria
2. Outline examples of Retrospective Enrollment as part of Patient Selection

3:00 p.m.-3:05 p.m. Welcome
Lisa Kachnic, MD, NRG NCORP Associate Chair

3:05 p.m.-3:25 p.m. Part I: The FORTE trial: Nuts and Bolts
1. Why the FORTE Trial?
Robert Schoen, MD, MPH
Principal Investigator/Study Chair—University of Pittsburgh

2. FORTE overview and eligibility
Jeffrey Dueker, MD
Protocol Co-chair—University of Pittsburgh

3. FORTE is user friendly
Robert Schoen, MD, MPH
Principal Investigator/Study Chair—University of Pittsburgh

Questions and Answers

3:25 p.m.-4:05 p.m. Part II: Retrospective Enrollment/Patient Selection
4. Site Perspectives on Patient Selection for Forte:

a. University of North Carolina
   Seth Crockett, MD, MPH
   University of North Carolina

b. University Hospitals of Cleveland
   Gregory Cooper, MD
   University Hospitals Cleveland Medical Center

c. Columbia University Medical Center
   Ben Lebwohl, MD, Fay Kastrinos, MD
   Columbia University Medical Center

5. Natural Language Processing
   Ruben Amarasingham, MD, MBA
   Founder and CEO, Pieces Technologies Inc.

Questions and Answers
4:05 p.m.-4:20 p.m.  Part III: FORTE Site Resources

6. Forms/ Vision Tree Overview  Elaina Harper, BS
NRG Oncology Statistics and Data Management Center (SDMC)

7. Study Materials  Kristen Kotsko, RN BSN
Director NRG Oncology Clinical Coordinating Department (CCD)

8. Social Media  Michelle Shepard
NRG Oncology Communications Team

Questions and Answers

4:20 p.m.-4:30 p.m.  Part IV: Call to Action

9. Call to action  Robert Schoen, MD, MPH
Principal Investigator/Study Chair—University of Pittsburgh

Questions and Answers
A broad overview of where the Department of Cancer Prevention is today and where it's going

Panelists

Julie Baumann, MD
NRG Cancer Prevention and Control Committee Vice Chair

Joan Walker, MD
NRG NCORP Research Base PI

Jeff Berenberg, MD
Hawaii Minority Underserved NCORP PI

Bill Irvin, MD
Southeast Clinical Oncology Research Consortium NCORP Co-PI
NCORP TOWN HALL

Date: Friday, July 23, 2021
Start and End time: 10:00 am – 1130am EST
Chairs: Deborah Bruner, PhD, RN, FAAN; Joan Walker, MD
Associate Chair: Lisa Kachnic, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss proposed and ongoing NRG NCORP clinical trials on cancer prevention and control and cancer care delivery
2. Recognize and prioritize areas of unmet need in cancer prevention, cancer control and cancer care delivery research
3. Identify and discuss the results and publication status of NRG NCORP trials recently completed
4. Apply standards and procedures required to design, submit, and conduct a research protocol for support by the NRG NCORP

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<th>Time</th>
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<td>10:00 – 10:10</td>
<td>Welcome NRG NCORP Updates</td>
<td>Deb Bruner, PhD, RN, NRG NCORP PI</td>
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<tr>
<td>10:10 – 10:20</td>
<td>NRG-CC005 (FORTE)</td>
<td>Robert Schoen, MD, FORTE study chair</td>
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<td>10:20 – 10:35</td>
<td>PRO Compliance Collection and Best Practices</td>
<td>Kandie Dempsey and Marcie Ritter, NRG PRO Compliance</td>
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<td>10:35 – 10:45</td>
<td>Q&amp;A – Open Discussion</td>
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<td>10:45 – 10:50</td>
<td>Introduction of NCI speakers</td>
<td>Deb Bruner, PhD, RN, NRG NCORP PI</td>
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<td>10:50 – 11:00</td>
<td>NCI NCORP Update</td>
<td>Sandra Russo, MD, Community Oncology and Prevention Trials Research Group, DCP</td>
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<td>11:00 – 11:10</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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<td>11:10 – 11:25</td>
<td>Q&amp;A – Open Discussion – chat moderators</td>
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<td>11:25 – 11:30</td>
<td>Closing Remarks</td>
<td>Deb Bruner/Joan Walker</td>
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NRG ONCOLOGY
GENERAL SESSION

Friday, July 23, 2021
12:30-1:45PM ET

Robert Mannel, MD
NRG Oncology
Group Chair

Norman Wolmark, MD
NRG Oncology
Group Chair

Quynh-Thu Le, MD
NRG Oncology
Group Chair

Mitchell Machtay, MD
Deputy Group Chair,
Research

David Miller, MD
Deputy Group Chair,
Membership

Harry Bear, MD
Deputy Group Chair,
Communications &
Publications

Richard Jordan, DDS, PhD
Biospecimen Bank
Co-Principal Investigator

James Dignam, PhD
Group Statistician

Deborah Bruner, RN, PhD
NCORP Research Base
Contact Principal
Investigator
Implementation of symptom management interventions into clinical practice

*Description:* Decades of research have contributed to a rich evidence-base for symptom management interventions, but many barriers exist to implementing these interventions into real-world practice environments. This session will briefly review the evidence for key elements of effective interventions, identify the primary challenges to integrating symptom management into oncology practice, and discuss potential implementation science approaches to advance the science and practice of symptom management.

Heidi Donovan PhD, RN, FAAN and Matthew Hudson PhD, MPH

Integrating Patient-reported outcomes (PRO) into clinical practice

*Description:* Standardized PRO assessment has been found to improve patient-clinician communication about symptoms, decrease symptom distress and improve survival. Advocacy to integrate PRO assessment into routine symptom assessment has been going on for two decades as a way to improve symptom control among cancer patients. This session will provide an exemplar of the successful integration and use of PROs at the point-of-care for patients receiving radiation for a cancer diagnosis and how this data is useful for defining the quality and value of health care. Discussion will focus on lessons learned from wide scale implementation in an academic radiation oncology department.

Neil E. Martin MD, MPH and Mary E. Cooley PhD, RN, FAAN

Optimizing survivorship outcomes through exercise and lifestyle intervention implementation

*Description:* There is a robust evidence base supporting the use of exercise and lifestyle interventions in the setting of oncology care. Translation of that evidence base into practice poses unique challenges to the field of implementation science. In this session we will outline those challenges and propose methods to address those challenges. Discussion will be focused on implementation methods to translate exercise and lifestyle interventions into clinical oncology practice.

Kathyrn Schmitz PhD, MPH, FACSM, FTOS, FNAK and Prajakta Adsul PhD, MBBS, MPH
NRG Oncology Social Media Workshop

The Next Era of Professional Social Media:
Harnessing Skills for Trials, Patients, and Career Advancement

Monday, July 26, 2021
11am-noon ET

Session Chair
Miriam Knoll, MD
Montefiore Nyack Hospital
@MKnoll_MD

Estelamari Rodriguez, MD
Sylvester Comprehensive Cancer Center
University of Miami Health System
@Latinamd
"Social Media for Clinical Trial Design & Participation"

Stephanie Graff, MD
Lifespan Cancer Institute
Brown University
@DrSGrIFF
"Social Media for Career Advancement"

Jane Meisel, MD
Winship Cancer Institute
Emory University
@jane_meisel
"Engaging with Patients & Tools of Engagement"
NRG Oncology Virtual Meeting - July 2021

NRG Oncology Virtual Meeting - July 2021

Monday, July 26, 2021
12-1:30pm EDT

Program Co-chairs

Adam Dicker, MD, PhD
FASTRO, FASCO
Thomas Jefferson University
@APDicker

Sanjay Aneja, MD
Yale School of Medicine
@SanjayAnejaMD

Heather Jim, PhD
Moffit Cancer Center

Session Speakers

Chuck Mayo, PhD
Professor, University of Michigan
@ChuckMayoPhD

"Creating Common Data Models within Radiation Oncology"

Kevyan Farahani, PhD
Program Director, National Cancer Institute

"The NCI Imaging and Cancer Research Data Commons"

Trainee Spotlight: Jonathan Wakim, BS
MD Candidate, Perelman School of Medicine at the University of Pennsylvania
@JJWakimMD

"Patient and Clinician Nudges to Improve Symptom Management in Advanced Cancer Using Patient-Generated Health Data: PROStep Randomized Controlled Trial"
NRG Oncology Health Disparities Committee
Virtual Symposium

Addressing Structural Racism in Cancer Care through Community Engagement in Clinical Research

July 28, 2021
1:00-2:30pm ET

This session will provide a discussion about the structural racism in cancer care and how institutions, policies, laws, and behaviors systemically place disparity populations at a disadvantage in terms of cancer care and identify how community engagement can mitigate the adverse effects of structural racism in racial/ethnic minorities and individuals from other medically underserved groups.

Moderator/Introductions- Chanita Hughes Halbert, PhD
Vice Chair-Research, NRG Oncology Health Disparities Committee
University of Southern California-Professor and Vice Chair for Research, Department of Preventive Medicine
Associate Director for Cancer Health Equity, Norris Comprehensive Cancer Center

Community Engagement to Address Structural Racism- Karriem Watson, PhD
Associate Executive Director-University of Illinois (UI) Health Mile Square Health Center
Associate Director Community Outreach and Engagement UI Cancer Center
Research Assistant Professor UIC School of Public Health Community Health Sciences

Structural Racism and Lung Cancer Risk- Loretta Erhunmwunsee, MD
Assistant Professor, Division of Thoracic Surgery, Department of Surgery; City of Hope's Division of Surgery, Assistant Professor
Division of Health Equities, Department of Population Sciences

Clinic Based Interventions to Address Structural Racism- Stephanie Wheeler, PhD
University of North Carolina, Chapel Hill
Professor
Department of Health Policy and Management
Associate Director of Community Outreach and Engagement
UNC Lineberger Comprehensive Cancer Center

Plan to attend the important session during the virtual NRG Oncology semiannual meeting. Register now at: https://www.nrgoncology.org/Meetings-Resources/Meetings/July-2021-Semiannual-Meeting-Resources
NRG Oncology Health Disparities Committee Virtual Symposium

Addressing Structural Racism in Cancer Care through Community Engagement in Clinical Research

Date: Wednesday, July 28, 2021
Start and end time: 1:00 pm - 2:30 pm ET

Learning Objectives:

1. Discuss structural racism in cancer care
2. Outline examples of institutional, policies, laws, and behaviors that systemically place disparity populations at a disadvantage in terms of cancer care
3. Identify ways community engagement can mitigate the adverse effects of structural racism in racial/ethnic minorities and individuals from other medically underserved groups

AGENDA

1:00-1:10pm
Introduction and Opening Remarks
Chanita Hughes Halbert, PhD, Moderator
Vice Chair-Research, NRG Oncology Health Disparities Committee
University of Southern California-Professor and Vice Chair for Research, Department of Preventive Medicine
Associate Director for Cancer Health Equity, Norris Comprehensive Cancer Center

1:10-1:35pm
Community Engagement to Address Structural Racism
Karriem Watson, PhD
Associate Executive Director-University of Illinois (UI) Health Mile Square Health Center
Associate Director Community Outreach and Engagement UI Cancer Center; Research Assistant Professor UIC School of Public Health Community Health Sciences

1:35-2:00pm
Structural Racism and Lung Cancer Risk
Loretta Erhunmwunsee, MD
Assistant Professor, Division of Thoracic Surgery, Department of Surgery; City of Hope’s Division of Surgery, Assistant Professor
Division of Health Equities, Department of Population Sciences

2:00-2:25pm
Clinic Based Interventions to Address Structural Racism
Stephanie Wheeler, PhD
University of North Carolina, Chapel Hill
Professor
Department of Health Policy and Management
Associate Director of Community Outreach and Engagement
UNC Lineberger Comprehensive Cancer Center

2:25-2:30pm
Closing Remarks
Chanita Hughes Halbert, PhD
Brain Tumor Committee

Date: Friday, July 23, 2021
Start and End Time: 10:00 am -12:00 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
B. NRG-BN007: Lassman
C. EAF 151: Tsien
D. NRG-BN010: Bagley
E. NRG-BN011: Iwamoto

NRG BRAIN METASTASES PORTFOLIO: 15 MIN
A. NCCTG CE 7: Roberge
B. Alliance A071801: Wang
C. NRG-BN009: Gondi
D. NRG-C003: Gondi
E. NRG-CC009: Gondi

NRG LOWER GRADE GLIOMA PORTFOLIO: 6 MIN
A. NRG-BN005: Grosshans
B. 1071 (Alliance CODEL): Vogelbaum

NRG OTHER TUMORS PORTFOLIO: 4 MIN
A. NRG-BN003: Rogers

NRG DEVELOPING TRIALS/CONCEPTS: 15 MIN
A. NRG-BN2048 IDO concept: Lukas
B. NRG-BN2028: Burri
C. NRG-BN2026: Sperduto
D. NSCLC met concept: Li+Gondi
E. Breast concept: Khasraw/Knisley

NRG NEW CONCEPTS: 65 MIN
A. Jiayi Huang: nGBM
B. Matt Hall: NGGCT
C. Soma Sengupta: rGBM
D. Dan Cahill: rGBM
E. John Kalapurakal: High Grade Meningioma
F. Yazmin Odia: PCNSL
G. Yazmin Odia: Midline Glioma

QUESTIONS / DISCUSSION
Breast Cancer Committee

Date: Friday, July 23, 2021
Start and End Time: 10:00 am – 12:00 pm
Chair: Eleftherios Mamounas, MD
Co-Chairs: Julia White, MD; Charles Geyer, MD; Matthew Ellis, MD

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

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

WORKSHOP AGENDA

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

10:30 – 10:45  ASCO Update  Alexandra Thomas, MD

10:45 – 11:00  NRG BR-007: 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

Residual Disease Trials in HER-2 Positive Breast Cancer

11:00 - 11:15  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

11:15 – 11:30  DESTINY BREAST-05: DS-8201a vs. T-DM-1 for high risk patients with HER2-positive residual invasive cancer following preoperative therapy  Charles Geyer, Jr., MD

11:30 – 11:45  Discussion  Charles Geyer, Jr., MD
Virginia Borges, MD

11:45 – 12:00  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
Rare and Genetically Linked Breast Cancer Subcommittee

Date: Thursday, July 8, 2021 (This Meeting has already taken place)

Start and End Time: 5:30 pm - 6:30 pm

Chair: Alexandra Thomas, MD  Co-Chair: Karen Daily, DO

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

1. Recognize challenges inherent in the design of trials of rare cancers (lessons learned from metaplastic breast cancer concept).
2. Prioritize rare breast cancer questions for concept development.
3. Identify colleagues whose expertise can be utilized to guide our group through didactic meeting presentations and/or project feedback.

AGENDA

5:30 - 5:35 pm  Welcome - Introductions - Administrative/Housekeeping Notes  Alexandra Thomas, MD
5:35 - 6:00 pm  Update on Metaplastic Breast Cancer Trial  Alexandra Thomas MD
6:00 - 6:20 pm  Brainstorming Session - Priority Concept Development  Karen Daily, DO
6:20 - 6:30 pm  Closing Questions & Answers - Future Meeting Plans  Karen Daily, DO
Cancer Prevention and Control Committee

Date: Thursday, July 22, 2021
Start and End time: 12:30 pm - 2:30 pm
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. Discuss promising translational research objectives and priorities for future clinical trials
5. Identify and prioritize areas of unmet need in cancer prevention research in each of the primary disease sites
6. Apply standards and procedures required to design, submit, and conduct a research protocol for support by the NRG

A. CPC overview – Lisa Kachnic, MD
   i. Announcements
   ii. Review of Open and Developing studies

B. Presentation of published manuscripts
   i. NRG-CC001 1 year follow up – Sunjay Shah, MD
   ii. RTOG 1203 3 year follow up – Ann Klopp, MD
   iii. GOG 0273 secondary endpoint – William Tew, MD

C. Questions

D. Breakout groups
   i. Salpingectomy recruitment strategies – Joan Walker, MD; Warner Huh, MD
   ii. Interventions to treat lymphedema in H&N cancers – Beth Beadle, MD
   iii. Tobacco related chemoprevention data – Julie Bauman, MD
Cancer Care Delivery Research (CCDR)

Date: Friday, July 23, 2021
Start and End Time: 1:45 pm – 3:45 pm EST
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

1:45 – 1:55pm  Welcome and Committee Updates
• Pilot awards
• Recognition of CC007CD top accruing sites
Mary Cooley, PhD, RN, CCDR Chair;
Matthew Hudson, PhD, CCDR Vice-Chair
Ronald Chen MD
Alla Sikorskii PhD
Terry A. Badger PhD, RN, FAPOS, FAAN

1:55-2:15pm  Concepts in development
• Symptom management intervention proposal
Joanna Paladino MD
Suzanne Mitchel MD

2:15-2:35  Advancing Uptake of the Serious Illness Care Program for Community Cancer Care Providers.
Megan Mullin PhD

2:35-2:45  NRG Research Fellowship Award
• Sexual orientation and gender identity (SOGI) measurement for patient centered cancer care in sexual and gender minority (SGM) populations

2:45-3:30  Breakout sessions
1. Integrating patient-reported outcomes into practice
2. Optimizing survivorship outcomes through exercise and lifestyle intervention implementation
3. Implementing evidence-based symptom management strategies into clinical practice
Facilitators
1. Neil Martin MD, MPH
   Mary E. Cooley PhD, RN
2. Katie Schmitz PhD
   Prajakta Adsul PhD
3. Heidi Donovan PhD, RN, FAAN
   Matt Hudson PhD

3:30-3:45  Report from breakout sessions

QUESTIONS / DISCUSSION

Group facilitators
Chat inbox facilitated by Matt Hudson
Developmental Therapeutics Committee

Date: Thursday, July 22, 2021
Start and End Time: 10:00 am – 11:55 am
Chairs: Roisin O’Cearbhaill, MD (Dev. Therapeutics)
        Michael Birrer, MD, PhD (Translational Science)
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.

10:00 AM – 10:05 AM  Introduction, Dr. O’Cearbhaill. Welcome. Review of opportunities for new investigators.
10:05 AM – 10:30 AM  Update on concepts from last meetings and studies under development:
\begin{itemize}
  \item \textbf{PI1915} Dr. Moxley (disapproved), \textbf{PI1966} Simpkins, \textbf{PI2014} (GY027) Fuh, \textbf{DT2013} Doll, \textbf{DT2059} Henson, \textbf{PI2058} Richardson, \textbf{DT2106} Simpkins
\end{itemize}

PTMA (originally ETCTN)
\begin{itemize}
  \item \textbf{GY027 (PI2054/PTMA #100805)} Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Fuh/Moore)
  \item \textbf{GY028 (UC2055/PTMA #100828)} Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Onstad/Westin)
\end{itemize}

10:30 AM - 11:45 AM  Review of new and resubmitted concepts
\begin{itemize}
  \item \textbf{PI2119} A Phase II study of Telaglenastat and Parp inhibitor for patients with recurrent or persistent ovarian clear cell carcinoma. (Gaillard/Wang)
  \item \textbf{DT2131} Pembrolizumab and Lenvatinib in Metastatic Cervical Cancer (Lea/Miller)
  \item \textbf{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)
  \item \textbf{PI2134} A Multi-Arm, Non-Comparative Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel in Combination with Pevonedistat, ZEN003694, or Birinapant in Epithelial Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer (Haggerty/Martin/Arend/Moore/Zhang/Annunziata)
\end{itemize}

11:45 AM - 11:50 AM  \textbf{Phase 1 committee} membership update (Gaillard)
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)
- **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)

Under development:

- **PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent recurrent squamous or non-squamous carcinoma of the cervix (Moxley)
  - Disapproved by CTEP with recommendation for resubmission
- **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)
- **DT2013** CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer. (Corinne Doll)
  - For submission to CTEP
- **PI2014** Phase IB of AVB500 in combination with carboplatin and paclitaxel or carboplatin and pegylated liposomal doxorubicin (Katherine Fuh)
- **DT2059**: Phase 1/2 M3814 plus hypo fractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (Henson/Moore)
  - Preclinical data now complete
- **GY027/PI2054** Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Fuh/Moore)
- **GY028/UC2055** Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Onstad/Westin)
- **PI2058**: A phase IA/IB study of ipatasertib in combination with carboplatin/paclitaxel or carboplatin/paclitaxel/atezolizumab in patients with advanced recurrent endometrial cancer (Richardson/Jump)
- **DT2106** A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent ARID1A mutated clear cell and endometrioid ovarian carcinomas (Fiona Simpkins).

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 carcinosarcoma after primary surgery (Erikson, Fader)

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)

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.
  - Submitted to CTEP to open to second stage

- 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

Ovarian Cancer Studies (prior safety lead-in):

- 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 ongoing

- 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

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) Planned for publication

Endometrial Cancer Studies:

- GOG-286B A Randomized Phase II/III Study Of Paclitaxel/Carboplatin/Metformin (Nsc#91485) Versus Paclitaxel/Carboplatin/Placebo As Initial Therapy for Measurable Stage III Or IVa, Stage IVb, Or Recurrent Endometrial Cancer (Jump). SGO 2020

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

QUESTIONS/DISCUSSION/EVALUATION
Genitourinary Cancer Committee

Date: Friday, July 23, 2021
Start and end time: 1:45 pm – 3:45pm
Chair: Felix Feng, MD
Co-Chairs: Jason Efstathiou, MD; Todd Morgan, MD; Howard Sandler, MD, Oliver Sartor, MD

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

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

WORKSHOP AGENDA
1:45 – 1:50 Opening Remarks and Update

1:50 – 3:00 Review of Active Trials

NRG GU002 Phil-III Adjuvant RT Following Radical Prostatectomy ± Adjuvant Docetaxel (RADD trial)  Mark Hurwitz, MD
NRG GU005 Phase III IGRT & SBRT vs. IGRT & Hypofrax IMRT localized prostate cancer Rod Ellis, MD
NRG GU007 Phase I/II of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer Dror Michaelson, MD, PhD Zach Zumsteg, MD
NRG GU008 Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial Ronald Chen, MD, MPH
NRG GU009 (PREDICT-RT)—recently activated! Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with High Genomic Risk (PREDICT-RT) Paul Nguyen, MD; Oliver Sartor, MD
RTOG 3506 Randomized Phase II Trial of Salvage Radiotherapy With Std vs Enhanced ADT (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features (STEEL trial) Edwin Posadas, MD Hiram Gay, MD
SWOG/NRG 1806  Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer  Jason Efstathiou, MD

ECOG/NRG EA8185  Phase 2 Study of Bladder-Sparing ChemoradiatioN with Durvalumab in Clinical Stage 3, node Positive UROthElial Carcinoma (INSPIRE)  Abhishek Solanki, MD MS

SWOG 1802  Local therapy for M1 prostate cancer, a SWOG study  Richard Valicenti, MD

EA8183  Phase III Double Blinded Study of Early Intervention After RADICAL ProstaTEctomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE).  Alicia Morgans, MD

EA8191  Phase III Study of Local or Systemic Therapy Intensification Directed in Prostate Cancer Patients with Post-Prostatectomy Biochemical Recurrence (INDICATE)  Neha Vapiwala, MD

3:00 – 3:25  Review of Pending Studies

NRG GU010 (GUIDANCE)  Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-intensification and Intensification Clinical Trial (GUIDANCE)  Neil Desai, MD; Ale Berlin, MD PhD

PSMA Addition (RTOG Foundation)  Phase III Trial of Androgen Deprivation Therapy and Abiraterone/Prednisone Alone or with 177Lu-PSMA-617 in Castration Sensitive Metastatic Prostate Cancer (mCSPC)  Oliver Sartor, MD

NRG GU011  Phase II trial of PROstate oligoMETastatic radiothErapy with or without ANdrogen deprivation therapy (NRG PROMETHEAN).  Bridget Koontz, MD

3:25– 3:40  Other issues

Translational Research  Phuoc Tran, MD PhD
Medical Oncology Update  Oliver Sartor, MD
Urology Update  Todd Morgan, MD
New Business  Group

3:40 – 3:45  Closing Remarks
Cervix Vulvar Subcommittee

Date: Friday, July 23, 2021
Start and End Time: 10:00 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 (9:00-9:30AM)
   a. Welcome, committee membership and rotation plan and review of Jan 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 (9:30-10:15AM)
   CV2133 Prospective Phase II trial of Radiation and Durvalumab in patients with Locally Advanced Cervical Cancer with contraindications to cisplatin concurrent chemotherapy. (Mayadev) CV, TS, GY
   Reviewers:

   Resubmission Review
   CV1964 (resubmission) Incorporation of Immunotherapy into The Management of Node Positive Carcinoma of the Vulva (Glaser) CV, TS, GY
   Reviewers:

   Secondary Review
   DT2131 Pembrolizumab and Lenvatinib in Metastatic Cervical Cancer. (J. Lea)
   Reviewers:

C. Questions/Future Directions for Cervical Cancer Management (10:15-10:30)
   a. Educational Session: Review of the ASCO OUTBACK presentation and the impact on the std of care for LACC (Alison Quick, MD)
D. Previously committee approved/reviewed concepts – current updates and future directions (10:30AM-10:45AM)

i. **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 GCSC (Pharma; still working on drug options)

ii. **GY0024** (Brian Slomovitz / Lillian Gien): GROINSS V3
   1. GCSC Approved
   2. United States Participation Appendix Finalized
   3. Site selection completed

iii. **CV1963** (Neil Taunk / Junzo Chino): A Randomized Phase II trial of ablative radiation therapy for women with oligometastatic gynecologic cancers
    1. Cervix only study
    2. Formal CTF review completed May 2021

iv. **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

v. **DT2013** (Corrine Doll): CB-839 before and concurrent with chemoradiotherapy in patients with locally advanced, node positive cervical cancer

vi. **CV2040**, Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARTACUS) II (Eric Leung)

vii. **DT2059**: Phase 1/2 M3814 plus hypofractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (Christina Henson; Mentor – K. Moore)

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. Predicted to have enough events this year
   iii. Planned Discussion – Does Outback impact decision to enroll?
   iv. Accrual 231/285 (81.1%)

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. Will likely close at the end of the year
   iv. Accrual 334/360 (92.8%)

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. Presented at Virtual SGO 2020
   v. Manuscript in preparation

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 373/450 (82.9%)

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. Amendment to increase sample size disapproved

**Reports from Other Committees and Groups**

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

G. Concluding Remarks and Wrap-up

**Next Semi-Annual Meeting**

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

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

WORKSHOP AGENDA

I. **General Business**
   a. Call to order
   b. Approval of minutes from January 2021
   c. Symposia (Alvarez)

II. **Committee Descriptions**

Gynecologic Cancer Committee

Cervix/Vulvar Cancer Subcommittee
- Cervical cancer – Randomized phase II, Phase II/III, Phase III
- Vulvar cancer – Phase II, Randomized phase II, Phase II/III, Phase III

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

Rare Tumor Subcommittee
- Clear Cell Tumors
- Germ Cell Tumors
- Ovarian - Low Grade Serous
- Ovarian - Mucinous
- Ovarian - Stromal Tumors

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

GYN Developmental Therapeutics Committee
• Early phase trials (Phase I, Phase I/II, Phase II), Window of opportunity trials
  ➢ Cervical cancer
  ➢ Endometrial cancer
  ➢ Ovarian cancer
  ➢ Uterine sarcoma

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

Other NCTN Group Trials & Study Champions

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

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

**NRG Oncology Study Champion**: Covens

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

This study is a collaboration between the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) and the NHMRC Clinical Trials Centre, The University of Sydney

**NRG Oncology Study Champion**: Covens

*Temporary Closure to Accrual*

AGCT1532 has reached current Part 1 accrual goals and is temporarily closed to further COG/NCTN patient entry as of January 12, 2021, pending an amendment to allow COG/NCTN sites to participate in Part 2 of the study, and contribute to the total study accrual of 500 patients.

**Small Cell Neuroendocrine, First line (NCTN, SWOG): S2012**, Phase 2/3 Trial of 1L Platinum/Etoposide +/- Atezolizumab for Extrapulmonary Small Cell Neuroendocrine Carcinoma *(Not yet activated)*

**Small Cell Neuroendocrine, Second line (ETCTN, LAO-CT018): 10315**, A Phase 2 Study of XL184 (Cabozantinib) in Combination with Nivolumab and Ipilimumab for the Treatment of Poorly Differentiated Neuroendocrine Carcinomas

**A091903**, A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma *(Not yet activated)*
III. Cervix/Vulvar Cancer Subcommittee

New Concepts

a. CV2133, Prospective Phase II trial of Radiation and Durvalumab in patients with Locally Advanced Cervical Cancer with contraindications to cisplatin concurrent chemotherapy (Jyoti Mayadev/Dmitriy Zamarin)

Studies Under Development

a. GY024, GROINSS-V III, Groningen International Study on Sentinel Nodes in Vulvar Cancer – III, A Prospective Phase II Treatment Trial
b. CV1963, Randomized Phase II trial of Ablative Radiation therapy for Women with Recurrent or Persistent Cervical Cancer and Limited Metastatic Disease (Junzo Chino)
c. CV1964, Incorporation of Immunotherapy Into The Management of Node Positive Carcinoma of the Vulva (Scott Glaser/Oladapo Yeku/Sushil Beriwal)

Active Studies:

a. RTOG-0724, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy (Anuja Jhingran)
b. GOG-0263, Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Sang Young Ryu)
c. NRG-GY006, A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (Charles Leath)

GYN Developmental Therapeutics Committee - Cervical Cancer

New Concepts

a. DT2131, Pembrolizumab and Lenvatinib in Metastatic Cervical Cancer (Jayanthi Lea/David Miller)

Studies Under Development

a. P1915, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley)
b. DT2013, CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corinne Doll)
c. DT2059, Phase 1/2 M3814 plus hypo-fractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (CrDL: Christina Henson/Kathleen Moore/Rachel Grisham)

Closed Studies, primary manuscript NOT published (Cervix): GOG-0279
Closed Studies, primary manuscript NOT published (DT): GY017
Closed Studies, primary manuscript NOT published (Outside Group): 270 (GROINSS-V) - SGO 2020, THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174) – ASCO 2021

Terminations:
IV. **Ovarian Cancer Subcommittee**

**New Concepts**

a. **OV2135**, Randomized Phase II of Paclitaxel /Carboplatin +/- Selinexor in Ovarian, Tubal, Peritoneal Carcinoma characterized as homologous recombination proficient (HRp)  
(Rebecca Arend/Kathleen Moore)

**Studies Under Development**

a. **OV2113**, 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 (Panos Konstantinopoulo)

b. **OV2056**, 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) (Panos Konstantinopoulo)

c. **OV2109**, Combination ATR and PARP Inhibitor following PARP inhibition in recurrent ovarian cancer: a comparison of ATRi monotherapy (AZD6738), PARPi and ATRi combination (olaparib and AZD6738) and standard of care platinum doublet (Fiona Simpkins)

**Active Studies:**

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

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

c. **NRG-GY023**, A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor Durvalumab in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or Durvalumab and Cediranib or Standard of Care Chemotherapy in Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab (Jung-Min Lee)

**Rare Tumor Subcommittee**

**Active Studies:**

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

**GYN Developmental Therapeutics Committee - Ovarian Cancer**

**New Concepts**

a. **PI2132**, A Phase Ib/II Study of adavosertib combined with carboplatin in women with primary platinum-resistant ovarian, fallopian tube, or primary peritoneal carcinoma with and without CCNE1 amplifications (Christina Washington/Kathleen Moore)

b. **PI2134**, A Multi-Arm, Non-Comparative Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel in Combination with Pevonedistat, ZEN003694, or Birinapant in Epithelial Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer (Ashley Ford Haggerty/Lainie Martin/ Rebecca Arend/Kathleen Moore/ Rugang Zhang/Christina Annunziata)
Studies Under Development
a. **PI1966**, A phase I study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Fiona Simpkins)
b. **GY027/PI2054** (PTMA #100805), Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Katherine Fuh/Kathleen Moore)
c. **DT2106**, A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent ARID1A mutated clear cell and endometrioid ovarian carcinomas (Fiona Simpkins)
d. **PI2119**, A Phase II study of Telaglenastat and Parp inhibitor for patients with recurrent or persistent ovarian clear cell carcinoma (Stéphanie Gaillard/Tian-Li Wang)

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

Closed Studies, primary manuscript NOT published (Ovarian): 212 (SGO 2017), GY004 (ASCO 2020), GY005, GY007

Closed Studies, primary manuscript NOT published (Rare Tumor): 264 (IGCS 2020), 268 (ASCO 2016), 281 (ESMO 2019), 283, GY016

Closed Studies (primary manuscript published): 213, 262, GY003

Terminations:

V. **Uterine Corpus Cancer Subcommitee**

Studies Under Development
a. **GY026 (UC1972)**, 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 (Britt Erickson/Amanda Nickles Fader/Alessandro Santin/Kaled Alektiar)
b. **GY025 (UC2024)**, 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 (Haider Mahdi)
c. **UC2043**, A Pilot Study of Dactinomycin plus Avelumab as First line Treatment for Selected Patients with Gestational Trophoblastic Neoplasia (Lua Eiriksson)
d. **GY028 (UC2055)** (PTMA#100828), Phase IB and Randomized Phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Michaela Onstad Grinsfelder/Shannon Westin)
e. **UC2105**, Medroxyprogesterone and Entinostat in PR+ endometrioid endometrial cancer (EC): a randomized phase II study (Katarzyna Jerzak)
f. **UC2108**, Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Women with Advanced or Recurrent AR Positive ER Low Endometrial Cancer (Katherine Kurnit)
g. **UC2120**, 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 (Floor Backes)
Active Studies:

- **NRG-GY012**, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer (Helen Mackay)
- **NRG-GY018**, A randomized phase III Placebo-Controlled Study of Pembrolizumab in addition to Paclitaxel and Carboplatin for Measurable Stage III Or IVA, Stage IVB or Recurrent Endometrial Cancer (Ramez Eskander)
- **NRG-GY020**, Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Floor Backes)

GYN Developmental Therapeutics Committee – Uterine Corpus Cancer Studies Under Development

- **PI2058**, A phase Ia/Ib study of Ipatasertib in Combination with Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Atezolizumab in Patients with Advanced Recurrent Endometrial Cancer (Debra Richardson/Victoria Bae Jump)

Closed Studies, primary manuscript NOT published (Corpus): 238, 261 (ASCO 2019)
Closed Studies, primary manuscript NOT published (DT): 286B (SGO 2020)
Closed Studies (Primary manuscript published): 188*, 258
*patient on active treatment

Terminations:

VI. Developmental Therapeutics Committee (O’Cearbhaill, Backes, Konstantinopoulos)
Studies Under Development

- MATCH COMBO

Active Studies:

- **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)

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

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

IX. Translational Science Committee Report (Birrer, Lankes)

X. Cancer Prevention and Control Committee Report (Walker)
Active Studies:

- **GOG-0278**, Evaluation of Physical Function and QoL Before and After Non-Radical Surgical Therapy for Stage IA1 (LVSI+) and IA2-IB1 Cervical Cancer (Allan Covens)
- **NRG-CC008**, A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers (SOROC) (Doug Levine)
Ovarian Cancer Subcommittee

Date: Friday, July 23, 2021
Start and End Time: 4:00-6:00 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. Discuss emerging molecular selection for ovarian cancer and how this may inform clinical trial development
4. Apply standards and review procedures required to design, submit, and conduct a research protocol within NRG, including ancillary data proposals
5. Assure strict quality control of GOG/NRG clinical trials

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

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

B. Invited Speaker: Targeting Adaptive and Acquired Resistance with Novel Agent Combinations (Geoffrey Shapiro, MD, PhD)

C. Review of Closed Studies (not-terminated)
   • GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
   • GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman).
   • GOG0218 A Phase III trial of carboplatin and paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent bevacizumab (NSC #704865, IND #7921) followed by placebo, versus carboplatin and paclitaxel plus concurrent and extended bevacizumab, in women with newly diagnosed, previously untreated, stage III and IV epithelial ovarian, primary peritoneal or fallopian tube cancer (Robert A Burger).
   • GOG0252 Phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma (Joan L Walker)
• GOG0262 A randomized phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III or IV epithelial ovarian, peritoneal or fallopian tube cancer (John K Chan)

• GOG0273 Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen) Modified dose dense cohort manuscript in draft form.

• 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-naïve 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-

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.

Accrual expected to complete ~6 months from reactivation (384/444)

- **NRG-GY014 (DT1718)** A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. (Ramez Eskander and David Hyman)
  - Activated 4/2019
  - Suspended 8/2019
  - Plan to reopen for ovarian clear cell with ARID1A mut, under development

- **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
  - 88/450

- **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
  - Temporarily closed to accrual 10/19/2020 – 2 more combo slots added and closed again - awaiting DLT review

- **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/Ian Beumer) GYN Cancer Committee: 7/14/18
  - Activated 11/2019
  - 160/250

- **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
  - 2/164

- **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
  - 50/2262

- **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
  - 516/2059
E. Review of Approved Concepts under Development

- **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
  - **OV2113 submitted CTEP 2/25/21. AOH forwarded for drug commitment.**
- **OV2056** 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
- **OV2008** A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu/Angeles Secord)
  - Submitting to GCSC 1/21/2021 meeting
  - GCSC 01/21/21 review. Resubmitted for 4/15/21 re-review. **Disapproved.**
- **OV2109** Combination ATR and PARP Inhibitor following PARP inhibition in recurrent ovarian cancer: a comparison of ATRi monotherapy (AZD6738), PARPi and ATRi combination (olaparib and AZD6738) and standard of care platinum doublet. (F Simpkins)
  - N: 330-355
  - GYN Cancer Committee 1/30/21
  - Clarifying design prior to submitting to OTF
- **PI1966:** Wee1 + ATRi in CCNE1 amplified ovarian and endometrial (Simpkins)
  - For RSC 10/29/19
  - Phase I UD
- **PI2014:** A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)
  - CRADA for AVB500 to be active in 9/2021
- **PI2054:** 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; protocol under development
- **DT2106:** A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent ARID1A mutated clear cell and endometrioid ovarian carcinomas (Yasuto Kinose/Fiona Simpkins)
  - Trial design under development
  - RSC July 2021

F. Summary of Ovarian Clinical Trials Planning Meeting (CTPM): Shannon Westin, MD and Carolyn Muller, MD

F. Review of New Concepts and Future Request for Proposals

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

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

• **RT2119** A Phase II study of Telaglenastat and Parp Inhibitor for Patients with Recurrent or Persistent Ovarian Clear Cell Carcinoma (Gaillard/Wang)
  o **Re-presentation** from 04/2021 Interim Meeting

**QUESTIONS / DISCUSSION**
Rare Tumor Subcommittee

Date: Thursday, July 22, 2021
Start and End Time: 12:30 pm – 2:30 pm
Chair: A. Covens
Co-Chair: J. 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 pre clinical data
5. Discuss new amendments to AGCT 1531 and strategies to disseminate and increase accrual (deferred)

WORKSHOP AGENDA

A. Active Studies

NRG
- **AGCT1531**: A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Covens) (517/2059)
- **NRG-GY016**: A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epacadostat (NSC #766086) in Recurrent Clear Cell Carcinoma of the Ovary (Gien). Closed
- **NRG-GY019**: A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Fader). (88/450)

GOG Partners
- **GOG-3026**: Phase II trial of letrozole + Ribociclib for women with recurrent low-grade serous carcinoma. (Slomovitz) (x/51)
- **GOG-3051**: 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
- **GOG-3052**: A Phase 2 study of VS-6766 (dual RAF/MEK inhibitor) alone and in combination with defactinib (FAK inhibitor) in recurrent low-grade serous ovarian cancer. (Grisham) (x/100)

B. Proposed Studies/in development

- **RT1841**: A phase II evaluation of ixazomib for recurrent sex-cord stromal ovarian tumors (Gien). Revised based upon preclinical data. Rejected by RSC
- **A091903**: A Randomized Phase II Trial Of Adjuvant Nivolumab With Or Without Cabozantinib In Patients With Mucosal Melanoma. (Vicus) Alliance will lead. Approved pending BMS and Exelixis provide drug.
C. New concepts

- **PI2119**: A Phase II study of Telaglenastat and Parp Inhibitor for Patients with Recurrent or Persistent Ovarian Clear Cell Carcinoma (Gaillard). Resubmission, secondary committee. Reviewers- Grisham, Farley

D. Discussion Topics:

a) Committee discussion on Strategies to improve concept development for rare tumours including procurement of pre clinical data- invitees from 2 ovarian cancer spore groups, and GOG Partners

b) Amendments to AGCT1531- Dr. Shaikh (COG) (deferred)

**ATTACH List of Concepts**

**PI2119**: A Phase II study of Telaglenastat and Parp Inhibitor for Patients with Recurrent or Persistent Ovarian Clear Cell Carcinoma (Gaillard).
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 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

<table>
<thead>
<tr>
<th>Uterine Corpus Cancer Subcommittee</th>
<th>Notes</th>
<th>Status of accrual as of 6/28/21</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIVE/TEMPORARILY CLOSED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matthew Powell and Ann Klopp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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/Bender/Rimel)</td>
<td>CTEP IND</td>
<td>Bender /Rimel/MacKay to update</td>
</tr>
<tr>
<td>N=120</td>
<td></td>
<td>Open to accrual 9/4/18</td>
</tr>
<tr>
<td>Stat: Enserro</td>
<td></td>
<td>Temporarily closed to accrual 6/17/19</td>
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<td></td>
<td></td>
<td>GCSC 10/17/19 - three additional arms</td>
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<tr>
<td></td>
<td></td>
<td>• olaparib/capivasertib</td>
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<tr>
<td></td>
<td></td>
<td>• olaparib/durvalumab</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• cediranib/durvalumab</td>
</tr>
<tr>
<td>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)</td>
<td>CTEP IND</td>
<td>Eskander to update</td>
</tr>
<tr>
<td>N: 590 pMMR; 220 dMMR = 810</td>
<td></td>
<td>Open to accrual 7/16/19</td>
</tr>
<tr>
<td>Central MMR testing (NeoGenomics)</td>
<td></td>
<td>Temporarily closed to accrual 4/6/20</td>
</tr>
<tr>
<td>Stat: Sill/Huang-PRO</td>
<td></td>
<td>Reactivated 11/30/20. Japan and Korea to participate—</td>
</tr>
<tr>
<td>PRO: Wenzel</td>
<td></td>
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<tr>
<td>NRG-GY020 Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk</td>
<td>Backes / Powell to update</td>
<td>Open to accrual 2/7/20</td>
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</tbody>
</table>
mismatch repair deficient (dMMR) endometrioid endometrial cancer (Backes)  CTEP IND  
N: 168 (2:1 randomization)  
Stat: Sill/Huang-PRO  
RadOnc: Klopp  
PRO: Wright

Closed Studies, primary manuscript NOT published (Corpus): 238, 261 (ASCO 2019)  
Closed Studies, primary manuscript NOT published (DT): 286B (SGO2020), GY011 (SGO 2021, CCR)  
Closed Studies, primary manuscript published: 188*, 258  
*patient on active treatment

**Terminations:**

### Uterine Corpus Cancer Subcommittee

#### Developing Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Notes</th>
<th>OEWG dates:</th>
</tr>
</thead>
</table>
| GY026 (UC1972) | 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 – submit publication plan to Dr. Tewari) | Erikson /Fader to update with slides (3 max) | 07/14/2021  
03/11/2022  
UTF 6/19/20  
RSC 7/18/20  
GCSC 9/17/20,  
11/19/20 (AOH – 11/30/20)  
GCSC Approval 2/23/21 |
| GY025 (UC2024) | 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 (Haider Mahdi) | Mahdi / to update with slides (3 max) | 07/15/2021  
03/12/2022  
UTF 5/15/20,  
7/24/20  
RSC 10/21/20  
GCSC 12/17/20,  
2/18/21 (AOH – 3/2/21)  
GCSC Approval 3/18/21 |
| UC2055 | Phase IB and Randomized Phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer. (Westin/Onstad) | Michaela Onstad / Westin to update with slides (3 max) | 08/19/2021  
04/16/2022  
PTMA #100828  
PTMA #100828  
GCC 10/11/20, RSC 2/3/21  
GCSC 1/21/21, 4/15/21 (disapproved)  
Submit LOI – IB/II |
| UC2105 | Medroxyprogesterone and Entinostat in PR+ endometrioid endometrial cancer (EC): a randomized phase II study (Jerzak) | Kasia Jerzak /Duska/MacKay) to update with slides (3 max) | RSC 4/26/18,  
GCC 1/30/21  
UTF 3/26/21 |

### Uterine Corpus Concepts NEW & Tabled
| Discussion regarding Radiation trial in the NRG (Ann Klop to lead discussion) |
| UC2120 A Phase III Randomized Trial of PD1/PDL1 inhibitor +/- radiation or chemotherapy inhibitor for Newly Diagnosed Completely Resected Stage III-IVA or recurrent chemo naïve Mismatch Repair Deficient (dMMR) Endometrial Cancer (Backes) |
| Backes to update |
| GYN Cancer Committee 4/9/21 |
| UC2043 A Pilot Study of Dactinomycin plus Avelumab as First line Treatment for Selected Patients with Gestational Trophoblastic Neoplasia (Lua Eriksson) |
| Uterine Corpus Subcommittee |
| Horowitz to update |
| UC2108 Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Women with Advanced or Recurrent AR Positive ER Low Endometrial Cancer (Kurnit) |
| Katherine Kurnit to update |
| PI2058 A phase Ia/ib study of Ipatasertib in Combination with Carboplatin/Paclitaxel or Carboplatin/Atezolizumab in Patients with Advanced Recurrent Endometrial Cancer (Debra Richardson/Victoria Bae Jump) |
| Richardson/Bae Jump to update with slides |

| Relevant STUDIES FROM OTHER COMMITTEES/Groups |
| Notes |
| Accrual |
| NRG-GY022 Assessment of carboplatin clearance predictors: a PK study to NCI-sponsored clinical trials or standard of care treatments using carboplatin (Taylor/Beumer) |
| Powell to update |
| Open to accrual: 11/18/19 |
| All tumor types are eligible |
| N: 250 |
| Stat: Miller |
| Non-Disease Specific/Solid tumors/ETCTN-NCTN Developmental Therapeutics Committee |

<p>| MATCH COMBO Developmental Therapeutics Committee |
| Powell to update |
| Approved: |
| EA191- N1 TKI + TDM1 (withdrawn by sponsor) |
| EA191- N2 MEKi + fulvestrant |
| EA191- N3 G12Ci+CDK4/6i (needs phase I trial first) |
| EA191- N4 PARPi + MEKi-Approval on Hold, to Drug Co 03/19/21. |
| EA191- N5 TKI +CDK 4/6i HER2+ |
| EA191- Nx MEKi + BCL2i (need substitute BCL2i) |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>Update Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC2046</td>
<td>Impact of SLN mapping vs lymphadenectomy on lower extremity limb dysfunction in pts with endometrial cancer (E Tanner)</td>
<td>Tanner to update NCORP approved 7/16/20; NRG DCP. Submitted for 3/23/2021 SXQOL Steering Committee review.</td>
</tr>
<tr>
<td>CC2034</td>
<td>Endometrial cancer prevention in women with obesity with the levonorgestrel-releasing intrauterine system (Laurence Bernard)</td>
<td>Study design/Stats planning ongoing</td>
</tr>
<tr>
<td>S1609, DART</td>
<td>Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors</td>
<td>Powell to update</td>
</tr>
<tr>
<td><strong>Small Cell Neuroendocrine, First line (NCTN, SWOG): S2012</strong></td>
<td>Phase 2/3 Trial of 1L Platinum/Etoposide +/- Atezolizumab for Extrapulmonary Small Cell Neuroendocrine Carcinoma (Not yet activated)</td>
<td>Powell to update</td>
</tr>
<tr>
<td><strong>Small Cell Neuroendocrine, Second line (ETCTN, LAO-CT018): 10315</strong></td>
<td>A Phase 2 Study of XL184 (Cabozantinib) in Combination with Nivolumab and Ipilimumab for the Treatment of Poorly Differentiated Neuroendocrine Carcinomas</td>
<td>Powell to update</td>
</tr>
</tbody>
</table>
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
   Quynh-Thu Le, MD

B. Actively developing studies
   - HN009 trial: Phase II-III HD vs. weekly cisplatin in high risk LA HNSCC
     Paul Harari, MD
   - HN2127 concept (formerly HN004): Phase II evaluation of HER2 targeted therapies in HER2 positive and low-expressing recurrent/metastatic SDC and SGC
     Alan Ho, MD, PhD
   - NRG-HN2115 LOI: Phase II randomized trial of chemo-immunotherapy vs. immunotherapy in patients with recurrent/persistent PD-L1 enriched SCCHN undergoing SS with life-long morbidity
     Nabil Saba, MD

C. Review on active studies
   Actively accruing trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Description</th>
<th>Principal Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTOG 1216</td>
<td>RT+cisplatin vs. RT+docetaxel+cetuximab vs. RT+cisplatin+atezolizumab for “high risk” resected HNSCC (Phase IIIR)</td>
<td>Julie Bauman, Paul Harari, David Rosenthal</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>
<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>
</tr>
<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>RTOG 3507</td>
<td>Phase IIIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC</td>
<td>Stuart Wong</td>
</tr>
<tr>
<td>RTOG 1008</td>
<td>Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-III)</td>
<td>Cristina Rodriguez</td>
</tr>
<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-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>
</tr>
</tbody>
</table>
NRG-HN005  |  Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer  |  Sue Yom  

D. Report on publications and protocols closed to active accrual  |  Quynh-Thu Le, MD  

Recently completed trials  

| Trial Code | Description | Investigator  
|------------|-------------|---------------|
| NRG HN003  | Phase I of Adjuvant Chemoradiotherapy +/- Pembrolizumab in High Risk, HPV(-) HNSCC | Julie Bauman  
| RTOG 3504  | Phase IR of CRT +/- Nivolumab in intermediate/high risk HNSCC | Quynh-Thu Le  
| NRG HN002  | Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good-Prognosis Advanced-Stage Oropharyngeal Cancer | Sue Yom  
| RTOG 0912  | Phase IIR of Concurrent radiation + chemotherapy + pazopanib for Anaplastic Thyroid Cancer | Eric Sherman  
| RTOG 3501  | Phase IIR of CRT +/- Lapatinib in high risk stage III-IV HNSCC | Stuart Wong  

E. NRG Core Membership  |  Quynh-Thu Le, MD  

F. NRG Champion Trials update  |  Quynh-Thu Le, MD  

G. HNC Translational activities  |  Neil Hayes, MD, MPH  

H. NCI Head and Neck Steering Committee update  |  Sue Yom, MD, PhD  

QUESTIONS / DISCUSSION
Lung Cancer Committee

Date: Saturday, July 24, 2021
Start and end time: 10:30 am - 12:30 pm
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 III chemo +/- SBRT for Stage IV Puneeth Iyengar
c) NRG-LU004: Phase I/II anti-PD1 concurrent with RT Steven Lin
d) NRG/Alliance-LU005: Limited-stage SCLC Kristin Higgins
e) NRG-LU006: Phase III; Dose-painting IMRT for mesothelioma Andreas Rimner
f) RTOG 3515 / PAC 4: SBRT +/- durva for medically-inoperable Stage I Cliff Robinson
g) SWOG S1914/NRG LU: – SBRT +/- neoadjuvant atezo for Stage I Charles Simone
h) NRG-LU007: Phase II/III ES-SCLC; chemo + atezo +/- RT Quynh-Nhu Nguyen
i) NRG-CC003: Hippocampal avoidance brain Vinai Gondi
j) NRG-CC009: SRS vs HA-WBRT for SCLC brain mets Gondi / Rusthoven
k) Lung-MAP SWOG S-1400 Saiama Waqar
l) ALCHEMIST Trial Saiama Waqar

QUESTIONS / DISCUSSION
Patient Centered Outcomes Research (PCOR) Committee

Date: Thursday, July 22, 2021
Start and End Time: 4:00 pm – 6:00 pm
Co-Chairs: Benjamin Movsas, MD; Patricia Ganz, MD; Lari Wenzel, PhD

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

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

4:00 – 4:05 Session Introduction and Welcome

4:05 – 4:45 Cancer Moonshot℠ Research Initiative - Tolerability Consortium
        Andre Rogatko, PhD
        Norah Lynn Henry, MD, PhD
        Lori Minasian, MD
        Deputy Director for the Division of Cancer Prevention

4:45 – 5:05 PRO Data Compliance
        Marcie Ritter, PhD
        Kandi Dempsey, DBA, MS, RN, OCN

5:05 – 5:15 Update on PROTEUS and the NCTN
        Lari Wenzel, PhD

5:15 – 5:55 Developing Concepts/Protocols

NRG-GY026: Phase II/III Study of Paclitaxel/Carboplatin Alone or Combined with Either Trastuzumab or Trastuzumab/Pertuzumab in HER2 Positive, Stage I-IV Endometrial Serous Carcinoma or Carcinosarcoma

NRG-BR2126: A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER+/HER2-Negative Breast Cancer and RS < 25

5:55 – 6:00 Closing Remarks
        PCOR Co-Chairs
Translational Science Committee

Date: Thursday, July 22, 2021
Start and End Time: 4:00pm – 6:00pm EST
Chair: Michael Birrer, MD, PhD
Co-Chairs: Adam Dicker, MD, PhD / Matthew Ellis, MD, PhD

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

1. To understand the ongoing and emerging translation research in lung cancer.
2. To understand the importance of power of radiomics as applied to cancer.
3. To understanding ongoing proteomic research efforts in NRG Oncology.

WORKSHOP AGENDA

“NRG Oncology Translational Science Lung Committee Updates”
Bo Lu, MD, PhD (Thomas Jefferson University)

“Radiomics and Deep Learning – Explainable AI for Cancer Imaging”
Fred Pryor

“Proteogenomic Analysis of Chemotherapy Response in Triple-Negative Breast Cancer”
Meenakshi Anurag, PhD (Baylor College of Medicine)

QUESTIONS / DISCUSSION
Translational Science Brain Cancer Subcommittee &
Low Grade Glioma Working Group

Date: Tuesday, July 20, 2021
Start and End Time: 2:00 pm – 4:00 pm EST Virtual Meeting

2:00 – 2:15  Introduction
(Arnab Chakravarti, MD)

2:15 – 2:35  “Identifying Genetic Risk Factors Using a SNP-Set Analysis of Genome-Wide Association Data- Example on ALS- Proposal for Gliomas”
(Prof. Dr. Pierre Robe, UMC Utrecht)

2:35 – 2:55  “Update: Prognostic and Predictive RNA Biomarkers in NRG/RTOG 9802 & 9813” (Jessica Fleming, PhD, Ohio State University)

2:55 – 3:15  “Reconstruct Three-Dimensional Chromosome Structures of Low Grade GliomaUsing Infinium 450K Methylation Array”
(Wei Meng, PhD, Ohio State University)

(Feng Geng, PhD, Ohio State University)

3:35 – 3:55  “Update on FLASH Technology”
(Jessica Fleming, PhD, Ohio State University)

3:55 – 4:00  Roundtable Discussions
Translational Science GYN Subcommittee

Date: Tuesday, July 27, 2021
Start and End Time: 11:00 am – 12:30 pm
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

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>11:00-11:05</td>
<td>Opening Remarks</td>
<td>Michael Birrer, MD, PhD</td>
</tr>
<tr>
<td>11:05-11:10</td>
<td>Biospecimen Bank/Translational Science Update</td>
<td>Heather Lankes, PhD, MPH</td>
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<tr>
<td></td>
<td>GYN Subcommittee Translational Science Updates</td>
<td>(including Concept Review/Questions/Discussion)</td>
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<tr>
<td>11:10-11:25</td>
<td>Cervix/Vulva Cancer Subcommittee</td>
<td>Dmitriy Zamarin, MD, PhD</td>
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<tr>
<td>11:25-11:40</td>
<td>Ovarian Cancer Subcommittee</td>
<td>Rebecca Arend, MD</td>
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<td>Rare Tumor Subcommittee</td>
<td>Elizabeth Swisher, MD</td>
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<td>Gloria Huang, MD</td>
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<tr>
<td>11:40-11:55</td>
<td>Uterine Corpus Cancer Subcommittee</td>
<td>Vickie Bae-Jump, MD, PhD</td>
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<td>Katherine Fuh, MD</td>
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<tr>
<td>11:55-12:10</td>
<td>GYN Developmental Therapeutics</td>
<td>Panagiotis Konstantinopoulos, MD, PhD</td>
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<tr>
<td>12:10-12:30</td>
<td>MP2PRT Update</td>
<td>Krishnansu Tewari, MD</td>
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<td>Anjali Hari, MD</td>
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<tr>
<td>12:30</td>
<td>Closing Remarks</td>
<td>Michael Birrer, MD, PhD</td>
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</tbody>
</table>
Translational Science GU Cancer Subcommittee

Date: Tuesday, July 27, 2021
Time: 1:00 pm-3:00 pm EST
Chairs: Phuoc Tran, MD, PhD

1:00 – 1:05
Introduction and Welcome
Phuoc Tran, MD, PhD (Johns Hopkins)

1:05 – 1:35
“Update on NRG-GU-TS006 (NRG/RTOG 9202 9413 9902)”
Paul Nguyen, MD (Dana-Farber)

1:40 – 2:10
“Introduction to Olink Technology”
Marijana Rucevic, PhD / Xu Weining, PhD (Olink)

2:15 – 2:45
“Update on NRG-GU-TS013 (NRG/RTOG 0524 0712)” Matthew Deek, MD (Rutgers)

2:50 – 2:55
General TS Project Updates
Phuoc Tran, MD, PhD (Johns Hopkins)

2:55 – 3:00
Closing Remarks and Discussion
Phuoc Tran, MD, PhD (Johns Hopkins)
Translational Science Head & Neck Cancer Subcommittee

Date: Tuesday, July 20, 2021
Time: 10:00am – 11:00am EST
Chair: Neil Hayes, MD, MPH

10:00 – 10:05 Introduction/Overview
   Neil Hayes, MD, MPH

10:05 – 10:30 “Targeting the PIK3CA-mTOR Signaling Network: HN Cancer Prevention & Treatment in the New Era of Precision Medicine & Immunotherapies”
   J. Silvio Gutkind, PhD (University of California, San Diego)

10:30 – 10:55 “NSAIDs and Head and Neck Cancer: Can We PIK the Patients Who Benefit?”
   Julie E. Bauman, MD, MPH (University of Arizona)

10:55 – 11:00 Closing Remarks and Discussion
   Neil Hayes, MD, MPH
**Translational Science LU Cancer Subcommittee**

**Date:** Tuesday, July 20, 2021

**Time:** 12:00 PM - 2:00 PM EST

**Chairs:** Bo Lu, MD, PhD

---

12:00 – 12:10  **Introduction and Welcome**  
Bo Lu, MD, PhD (Thomas Jefferson University)

12:10 – 12:25  **“Analysis of Metabolic Tumor Markers”**  
Theos Tsakiridis, MD, PhD, FRCPC (McMaster University)

12:25 – 12:40  **“Validation of RSI/GARD in RTOG 0617: Submission Update”**  
Javier Torres-Roca, MD (Moffitt Cancer Center)

12:40 – 12:55  **“Targeting NPM1 in Non-Small Cell Lung Cancer”**  
Michael Freemen, PhD (Vanderbilt University Medical Center)

12:55 – 1:10  **“Challenges and Opportunities forCombining Radiation Therapy and Immunotherapies in the Treatment of Lung Cancers”**  
Zachary Morris, MD, PhD (University of Wisconsin)

1:10 – 1:25  **“A Tumor “Personality” Test to Predict Response to Immunotherapy”**  
Alexander Bagaev, PhD (BostonGene)

1:25 – 1:50  **“Exosomes as Potential Biomarkers and Therapeutics”**  
Lucia Languino, PhD (Thomas Jefferson University)

1:50 – 2:00  **Closing Remarks and Discussion**  
Bo Lu, MD, PhD (Thomas Jefferson University)
Health Disparities Committee  
Thursday, July 22 (Virtual Meeting)  
10am – 12pm ET  
Agenda

Chairs:  
Chanita Hughes Halbert, PhD  
Jennifer Wenzel, PhD, RN, CCM, FAAN

10:00 - 10:05 am  Welcome/Announcements – Jennifer Wenzel, Chanita Hughes Halbert

10:05 – 10:25 am  Member Spotlight-Engaging Older Adults in the NCI Clinical Trials Network- Report & Discussion-William Tew, MD

10:25 – 10:35 am  Older Adult Research SIG update – William Tew

10:35 – 10:50 am  HDC Research Concept Development SIG update - Chanita Hughes Halbert  
• Multimorbidity Management in Cancer Survivors using Telehealth  
• Complementary and Alternative Strategy for Enhancing Physical Activity in Cancer Patients

10:50 – 11:05 am  Rural Health Research SIG Update – Na Tosha Gatson, MD, PhD, FAAN

11:05 – 11:25 am  Research Implementation (Education/Training/Mentorship) SIG update –  
William Robinson, MD, Victoria Bae-Jump, MD, PhD

Clinical Trial Enrollment Updates - Statistics/Metrics - SDMC Reports -William Robinson  
/ Reena Cecchini, PhD, MS

Mentorship/Education/Training- William Robinson, Chanita Hughes Halbert

11:25 – 11:45 am  Discussion: Collecting SOGI data as part of NRG trials-Marin Stasenko, MD

11:45 – 11:55 am  Opportunities to engage with the HDC - Jennifer Wenzel, Chanita Hughes Halbert  
• Diversity Co-Chairs on NRG Protocols  
• Recruitment and Retention templates

11:55 am – 12:00 pm  Closing remarks/Summary/Adjournment
IMAGING COMMITTEE MEETING

Zoom meeting Link: info will be through the NRG Oncology Meeting Registration

Date: Monday, July 19, 2021
Start and End Time: 1PM-3PM Eastern/12PM-2PM Central/10AM-12PM 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

1:00-1:05 Greetings Amy Fowler, MD
1:05-1:25 Disease Site Reports
   • H&N: Rathan Subramanian, MD/ Min Yao, MD
   • Brain: Tammy Benzinger, MD / Ashok Srinivasan, MD
   • Breast: Heidi Umphrey, MD / Mohammad Eghtedari, MD
   • Gyn: Karthik Sundaram, MD
   • GI: Eric Tamm, MD
   • GU: Ashesh Jani MD / Bill Hall, MD
   • Lung: Michelle Ginsberg, MD
   • Sarcoma: Dan Pryma, MD

1:25-1:35 Update from IROC PHL for NRG Oncology Trials Michael Boss, PhD

1:35-2:00 The Effect of PSMA PET/CT on Prostate Cancer Trials Felix Feng, MD/ Michael Morris, MD

2:00-2:10 Discussion of Retrospective Image Collection Lalitha Shankar, MD

2:10-2:30 What is the Best Way to Develop RPT Trials within NRG Oncology Open Discussion

Imaging and Medical Physics Seminar

2:30 – 3:00 Joint session with NRG Medical Physics Subcommittee
   • MR Guided RT –
     o Carri K. Glide-Hurst, PhD, DABR, FAAPM
       Associate Professor, Dept. of Human Oncology
       Director of Radiation Oncology Physics
       University of Wisconsin
     o William A. Hall, MD
       Associate Professor of Radiation Oncology
       Medical College of Wisconsin
LEARNING OBJECTIVES
Following this activity, participants will be better able to:
1. Update clinical trial outcomes in major disease entities from ASCO 2021
2. Define the criteria for arms of the Combo-Match study
3. Identify NRG Phase I trials

WORKSHOP AGENDA

I. Introductions
   - Corey Langer, MD
II. Pharmacy Subcommittee Update
    - Judith Smith, PharmD
III. Combo-Match Update
     - Roisin O’Cearbhaill, MD
IV. NRG Phase I Program Update
    - Stephanie Gaillard, MD
       - Russell Schilder MD
V. Critical post-ASCO updates: 10 min each
   a. Breast
      - Alexandra Thomas, MD
   b. GYN
      - Krishnansu Tewari, MD
   c. HNC
      - Stu Wong, MD
   d. Thoracic
      - Corey Langer, MD; Martin Edelman, MD
   e. GU
      - Oliver Sartor, MD
VI. Other business
    - Corey Langer, MD; Deborah Armstrong, MD

DISCUSSION
Pharmacy Subcommittee Workshop

Date: Tuesday, July 27, 2021
Start and End Time: 12:00 pm – 2:00 pm
Chair: Judith Smith, Pharm.D.

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

1. Review the challenges with treatment with TKIs.
2. Explain approaches for the management and prevention of TKI toxicity.
3. Address updates for tracking biosimilar usage on NRG protocols.
4. Understand the rationale and benefits of standardizing drug information for research protocols.
5. Discuss updates on standardization of pre-medication components and supportive care bowel regimens.

WORKSHOP AGENDA

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

II. CE Presentation: “Addressing the Challenges with Use of TKI Agents” (25 min)

III. Update on tracking use of biosimilars on NRG protocols (3 min)

IV. Protocol Drug Information Update (20 min)
   a. Updates to standardized pre-medications for chemotherapy templates.
   b. Review of Bowel Regimen supportive care resource for NRG Oncology protocols

V. Updates for CTEP Pharmacy Team (5 min)

VI. Updates/Discussion of any Pharmacy Related Issues Identified in Other NRG Committee Meetings (5 min)
   a. Any issues that the Pharmacy Subcommittee should follow up on regarding new protocol proposals presented at the other committee meetings.

VII. Evaluation
Pathology Committee

Date: Friday, July 28, 2021
Start and End Time: 3:00 pm – 5:00 pm EST
Chair: Jeffry Simko, MD
Co-Chairs: Peter Lucas, MD, PhD / Tan Ince, MD, PhD

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

1. To provide pathology and biomarker testing expertise.
2. To optimize evaluation, design, and execution of NRG Oncology clinical trials.
3. To support/encourage educational activities within NRG Oncology.
4. To ensure inclusion of pathology experts from development to conclusion of every NRG Oncology clinical trial.

COMMITTEE AGENDA

“Committee Membership, Organization, and Responsibilities Update”
Jeffry Simko, MD, PhD (University of California – San Francisco)

“Novel Biospecimen Collections and Their Use in Translational Research”
Tan Ince, MD, PhD (Co-Chair)

“Reports from Pathology Representatives for Their Disease Sites (Clinical Trials, Translational Science)”
Chairs/Attendees

“Digital Pathology Discussion”
Chairs/Attendees

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

Date: Thursday, July 22, 2021
Start and End Time: 10:00am ET–12:00pm ET
PSC Chair: Terry Thomas MS, CCRC
PSC Vice-Chairs: Nancy Fusco RN, BSN, Cynthia Licavoli RN, BSN, MA
Lead Facilitator: Karen Holeva, BS, CCRP
Co - Facilitator: Melinda Weiblen, BS, Chrisann Winslow RN, MSN

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

1. Discuss and identify the process for request of early IRB closure for NRG trials.
2. Identify current procedures and approval with CTSU.
3. Discuss and identify how inclusion relates to research.
4. Describe and explain diversity into the workplace.
5. Identify and describe generational differences.

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<th>Time*</th>
<th>Topic</th>
<th>Speakers</th>
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<tr>
<td>10:00 am – 10:10 am</td>
<td>Welcome</td>
<td>Karen Holeva, BS</td>
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<tr>
<td>10:10 am – 10:30 am</td>
<td>Requesting early IRB closure for NRG trials</td>
<td>Erica Field, MPH, CCRP</td>
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<td>10:30 am – 11:00 am</td>
<td>CTSU</td>
<td>Amanda Fournier, BSME</td>
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<td>11:00 am – 12:00 pm</td>
<td>Importance of Workforce Diversity &amp; Inclusion</td>
<td>Karen Winkfield, MD, PhD</td>
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Please note all times listed are EASTERN TIME ZONE
Protocol Support Committee
Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session

Date: Thursday, July 22, 2021
Start and End Time: 12:30 pm ET – 2:30 pm ET
PSC Chair: Terry Thomas MS, CCRC
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Lead Facilitator: Karen Holeva, BS, CCRP
Co - Facilitators: Melinda Weiblen, BS, Chrisann Winslow RN, MSN

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

1. Identify and discuss Ideas for Clinical Trial Workday Organization.
2. Identify and discuss the Concept of Study Startup.
3. Describe and apply how to Onboard New Coordinators.
4. Identify and discuss Audit Preparation and Quality Assurance Management.
5. Describe and apply AE/SAE Reporting and Attributions.

Participants will have the opportunity to attend four (4) of the six (6) 30- minute sessions offered

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<td>12:30pm – 2:30pm</td>
<td>Best Practice Sessions- 30 minutes Sessions  Choose 4 to attend</td>
<td>Tiffany Elsea, BA, CCRP &amp; Alex Kudryashev, MS, CCRP</td>
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<td>Session 1: Organizing your workday Part A</td>
<td>Cynthia Licavoli, RN, BSN, MA &amp; Erin McCaig, RN, BSN</td>
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<td>Session 2: Organizing your workday Part B</td>
<td>Terry Thomas, MS, CCRC &amp; Whitney Jacobson, RN, CCRP, OCN</td>
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<td>Session 3: Study Start Up, Implementation &amp; Management</td>
<td>Karen Holeva, BS, CCRP &amp; Alison Ivey, RN, MS, MBA, OCN, CCRP</td>
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<td>Session 4: On Boarding New Coordinators (Nurse/CRA)</td>
<td>Mary Jo Antonelli, MBA &amp; Carole Donnelly BA, CCRP</td>
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<td>Session 5: Audit Preparation/Management</td>
<td>Sara McCartney, MS, RN &amp; Donna White RN, BSN, OCN</td>
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<td>Session 6: AE/SAE Reporting/Management</td>
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*Please note all times listed are EASTERN TIME ZONE
I. 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
   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)
   c. Genitourinary (Committee Liaison: Zackary 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 complete 5/5/21; re-open to next cohort 9/5/21
   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: 0/42 patients
         ii. Developing concept: HN1935 (S. Wong): Intermediate risk post op study +/- PD1—Approved by Research Strategy in Nov; discussions with Genentech, no final decision re pharma support
   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)
   g. GI-non colorectal (Committee Liaison: Terence Williams, MD)
      i. GI007: Phase I trial with expansion cohort of opb-301 (telomelysin) and definitive chemoradiation for patients with locally advanced esophageal and gastroesophageal adenocarcinoma who are not candidates for surgery (PI: Geoffrey Ku, MD)
   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. GY017: Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer. (PI: Jyoti Mayadev, MD)
         1. Met accrual
ii. **GY027**: Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (PI: Katherine Fuh, MD); CTEP approved 5/13/21. Protocol is under development

iii. **GY028**: A Phase IB and Randomized Phase II Trial of Medroxyprogesterone Acetate +/- Ipatasertib in Recurrent/Metastatic Endometrioid Endometrial Cancer (PI: Shannon Westin, MD) CTEP Approval on hold; pending industry collaborator drug commitment.

iv. **PI1966**: Wee1 kinase and ATR kinase inhibition CCNE1 amp OV & Em ca (PI: F Simpkins, MD); Approved by Research Strategy. LOI under development for submission to CTEP.
Radiation Oncology Committee Virtual Meeting

CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Zoom Link: Will be through the NRG Meeting Registration

Date: Wednesday, July 21, 2021
Start and End Time: 1:00 PM - 3:00 PM (Eastern) / 12:00 PM – 2:00 PM (Central) / 10:00 AM – 12:00 PM (Pacific)
Chair: Jeff Michalski, MD. M.B.A.
Vice Chairs: Ivy A. Petersen, MD / Evan Wuthrick, MD
NRG Staff Support: Elizabeth (Betty) O’Meara / Theresa Powell

AGENDA

(Eastern times - PM)
1:00 – 1:02 Welcome / Introduction - J. Michalski, MD
1:02 – 1:07 NRG Oncology Updates - J. Michalski / E. Wuthrick, MD / I. Petersen, MD

1:07 – 1:17 Imaging Committee Update - Dan Pryma, MD
- July 19th meeting update: Medical physics/ Imaging Seminar - Joint session with NRG Imaging Committee
  o MR Guided RT
- The Effect of PSMA PET/CT on Prostate Cancer Trials
- Discussion: What is the Best Way to Develop RPT Trials within NRG Oncology - Dan Pryma, MD / Jeff Michalski, MD

1:17 – 1:27 Update on NCTN Cooperative Cores
- IROC RT – Stephen Kry, PhD / Ying Xiao, PhD / Denise Manfredi, BS
- IROC Imaging - Mark Rosen, MD / Michael Boss, PhD

1:27 – 1:37 Medical Physics Subcommittee Update –Ying Xiao, PhD/ Stan Benedict, PhD
- NRG/CIRO Medical Physics Subcommittee
- NCI NCTN Physics Committee – Ceferino Obcemea, PhD
  o RPT Dosimetry presentation
  o NRG Oncology – CIRO Website

1:37 – 1:47 NRG Particle Work Group (formerly Proton WG) update – Charles Simone, MD / Paige Taylor, MS
- Zoom meeting – July 21st 5 pm – 6:30 pm Eastern/ 4 pm – 5:30 pm Central/ 2 pm – 3:30 pm Pacific

Updates from Protocol Status Report - Disease Site Liaisons

(Updates on Concepts near Development)
1:47 – 1:55 H&N Sue Yom, MD / Min Yao, MD
1:55 – 2:03 Brain Christina Tsen, MD / Tony Wang, MD
2:03 – 2:11 Breast Steven Chmura, MD / Simona Shaitelman, MD
2:11 – 2:19 Gyn Sushil Beriwal, MD / Mark Bernard, MD
2:19 – 2:27 GI Evan Wuthrick, MD / Emma Holliday, MD
2:27 – 2:37 GU Dan Krauss, MD / Hiram Gay, MD
2:37 – 2:47 Lung Charles Simone, MD / Pamela Samson, MD
2:47 – 2:52 Sarcoma Philip Wong, MD

2:52 – 3:00 Other Business
Medical Physics Subcommittee Virtual Meeting
CENTER FOR INNOVATION IN RADIATION ONCOLOGY (CIRO)

Zoom meeting Link: info will be through the NRG Oncology Meeting Registration

Date: Monday, July 19, 2021
Start and End Time: 2:30 PM - 4:30 PM (Eastern) / 1:30 PM – 3:30 PM (Central) / 11:30 AM – 1:30 PM (Pacific)
Chair: Ying Xiao, PhD
Vice Chair: Stanley Benedict, PhD
NRG Staff Support: (Betty) Elizabeth O’Meara

(Eastern Times - PM)

2:30 – 3:00 Medical physics/ Imaging Seminar - Joint session with NRG Imaging Committee
- Dan Pryma, MD
  - MR Guided RT –
    - Carri K. Glide-Hurst, PhD, DABR, FAAPM
    - Associate Professor, Dept. of Human Oncology
    - Director of Radiation Oncology Physics
    - University of Wisconsin
    - William A. Hall, MD
    - Associate Professor of Radiation Oncology
    - Medical College of Wisconsin

3:00 – 3:02 Introductions / Subcommittee Updates
- Ying Xiao, PhD/Stanley Benedict, PhD

3:02 – 3:10 NCI/NCTN Updates
- Ceferino Obcemea, PhD
  - NCI Communications
  - NCTN Medical Physics

3:10 – 3:25 NRG QA Report
- Stephen Kry, PhD
- Ying Xiao, PhD
- Mark Rosen, MD / Michael Boss, PhD

3:25 – 3:55 Disease Site Reports
- Yunfeng Cui, PhD / Fang-Fang Yin, PhD
- Guang-Pei Chen, PhD/ Jean Moran, PhD
- Adam Yock, PhD / William Parker, M.Sc.
- Robert Wallace, PhD / Rajat Kudchadker, PhD/Mhaela Rosu, PhD
- Hayeon Kim, PhD / Cecilia Lee, PhD
- Nataliya Kovalchuk, PhD / Ping Xia, PhD
- Martha Matuszak, PhD/ Timothy Ritter, PhD

3:55 – 4:05 Modality Technology Reports
- Notable technologies(Proton)
  - Proton SBRT
- Chris Beltan, PhD
- Liyong Lin, PhD

4:05 – 4:28 Working Group and Other Updates
- Michael Boss, PhD/Mark Rosen, MD
  - Imaging Templates
  - Recommendations and Guidelines for Clinical Trials involving Artificial Intelligence Assisted Automated Segmentation in Radiotherapy
    - Sharon Qi, PhD / Yi Rong, PhD
  - RPT Dosimetry
  - FLASH
  - SFRT
  - Radiomics Phantom
  - Jacek Capala, PhD
  - Jennifer Zou, PhD
  - Heng Li, PhD
  - Jason Sohn, PhD

4:28 Other Business
- Questions / Discussions

4:30 Adjournment
Particle Therapy Working Group
(formerly Proton WG) Virtual Meeting

CENTER FOR INNOVATION IN RADIATION ONCOLOGY (CIRO)
Zoom meeting Link: info will be through the NRG Oncology Meeting Registration

Date: Wednesday, July 21, 2021
Start and End Time: 5:00 PM - 6:30 PM (Eastern) / 4:30 PM – 5:30 PM (Central) / 3:00 PM – 4:30 PM (Mountain) / 2:00 PM – 3:30 PM (Pacific)
Interim Chair/Moderator: Ted Hong, MD
Incoming Chair: Charles Simone, MD
NRG Staff Support: Theresa Powell / Elizabeth (Betty) O’Meara

AGENDA
(Eastern times - PM)
5:00 – 5:05 Welcome/Introduction/ Moderator Ted Hong, MD
• Ted Hong, MD will be the Interim Chair / Moderator for this July NRG Proton WG Meeting.
• Chuck Simone, MD has accepted the Chair position as successor to Tom DeLaney, MD
5:05 – 5:10 Update from NCI Jeff Buchsbaum, MD

Protocol(s) / Concept(s) Update from Members
5:10 – 5:20 Update on Proton Center Credentialing by IROC Houston P. Taylor, MS

5:20 – 5:30 GI Studies
Liver/Esophageal
• NRG/RTOG 1112 (Closed to accrual 3/20/21) Ph III, SBRT, sorafenib, hepatocellular CA L. Dawson, MD / T. Hong, MD
• NRG-GI003 Ph III Protons vs. Photons for Hepatocellular Carcinoma T. Hong, MD

• NRG-GI006 Ph III R Proton Beam Therapy (PBT) vs IMRT for Treatment of Esophageal CA S. Lin, MD
• Other

5:30 – 5:40 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
• Other

5:40 – 5:45 Lung Studies
Z. Liao, MD
• NRG/RTOG 1308 Ph III Protons vs. photons for inoperable NSCLC
• Other

5:45 – 5:50 H & N Studies
A. Chan, MD
• IMPT for Nasopharyngeal Carcinoma (MGH Trial)
• NRG-HN001 Nasopharynx: Ph IIR and Philll, 2 cohorts based on EBV DNA level, chemo/RT +/- adj. chemo N. Lee, MD
• Other
5:50 – 5:55  Phase II/III Randomized Study of IMPT vs IMRT for Oropharyngeal (MD Anderson Trial)  S. Frank, MD

5:55 – 6:10  **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  Karen 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  Jason 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)  Brian Baumann, MD
- Other

6:10 – 6:15  Patient-Centered Outcomes Research Institute (PCORI)

- COMPARE: COMparative Study of Outcomes of Proton and Photon Radiation in Prostate Ca  N. Mendenhall, MD

6:15 – 6:20  Patient-Centered Outcomes Research Institute (PCORI)

- RADCOMP: Pragmatic Randomized Trial of Proton vs. Photon Therapy for Non-Metastatic Breast  S. MacDonald, MD / Li-Ming Christine Fang, MD
- Other


6:25 – 6:30  Other Business / Questions

- Remaining 2021 Dates: September 3rd, November 5th
- Time: 6:00AM (Pacific) / 7:00AM (Mountain) / 8:00AM (Central) / 9:00AM (Eastern)
- NRG Oncology Proton Work Group calls scheduled on the 1st Friday of every other month.
- Conference calls set up for now will be changed to Zoom meetings for the remainder of 2021 and moving forward.
Canadian Members Subcommittee Meeting

Date: July 19, 2021
Start and End Time: 10:00 am – 11:00 am 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
   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

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

IV. New Protocols
   a. NRG-HN009: Randomized Phase II/III Trial of Radiation with High Dose Cisplatin (100 mg/m^2) Every Three Weeks vs. Radiation with Low Dose Weekly Cisplatin (40 mg/m^2) for Patients with Locoregionally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN) (Paul Harari, MD)
   b. NRG-GU010: Parallel Phase III Randomized Trials of Genomic Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-Intensification and Intensification Clinical Trial Evaluation (GUIDANCE) (Alejandro Berlin, MD)

V. New Business, General Questions, Discussion, Next Meeting
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<th>NRG Main Member (Network)</th>
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