



Meeting Program

NRG Oncology Summer 2021 Virtual Meeting

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Welcome to #NRG2021, the NRG Oncology Summer Virtual Meeting!



Robert Mannel, MD
NRG Group Chair

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: one ad hoc meetings. We look forward to connecting with you!



Deborah Watkins
Bruner, RN, PhD, FAAN
NRG NCORP
Research Base PI



Quynh-Thu Le, MD
NRG Group Chair

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.



Norman Wolmark, MD
NRG Group Chair

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!



Joan Walker, MD
NRG NCORP
Research Base PI



Mission Statement



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

For the Educational Objectives, we list the following:

- Inform the participants of the current state of clinical and basic oncologic research, particularly, but not exclusively as it relates to clinical trials.
- Provide participants with peer review critiques of progress (or lack of it) with the objective of self-improvement.
- Provide an opportunity to learn research administration and financial management in a cooperative group setting.
- Provide a forum for experts from diverse fields to improve research practices and patient management.

NRG
ONCOLOGY



CME INFORMATION

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.

Final Listing of Approved CME Credits

NRG Oncology Summer Virtual Meeting – July 19 – 28, 2021

The NRG Oncology virtual meeting provides the opportunity to earn up to 25 AMA PRA Category 1 Credits™.

SESSION TITLE	MON	WED	THURS	FRI	SAT	TUES	WED
Breast Cancer Committee				2			
Canadian Members Subcommittee	1						
Cancer Prevention and Control			2				
Cancer Care Delivery Research (CCDR)				2			
Cervix/Vulvar Cancer Subcommittee				2			
Developmental Therapeutics			2				
FORTE		1.5					
Genitourinary Cancer				2			
Gynecologic Cancer Committee					2		
Health Disparities Virtual Symposium							1.5
Lung Cancer Committee				2			
Medical Oncology Committee					2		
Ovarian Cancer Subcommittee				2			
Pathology Committee							2
Patient Centered Outcomes (PCOR)			2				
Pharmacy Subcommittee						1.5	
Rare Tumor Subcommittee			2				
Translational Science Gyn Subcommittee						1.5	
Translational Science Committee			2				
NCORP Town Hall				1.5			
Uterine Corpus Subcommittee				2			
PSC CTR/CRA Educational session (Morning)			2				
PSC CTR/CRA Ed Session (Afternoon)			2				
Summer Symposium “Cancer Immunotherapy: Successes, Challenges and New Frontiers”		3.5					

7.13.2021

NRG Oncology Summer 2021 Virtual Meeting



Advancing Research. Improving Lives.™

WELCOME

NRG Oncology welcomes the NRG membership and stakeholders to join our Summer 2021 Virtual Meeting!

Our core goals for the meeting include advancing our research through the continuum from concept development to reporting results and engaging our membership in that process through the meeting.

Times are listed in ET

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
12:30 - 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 Subcommittee
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 Corpus 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



NRG ONCOLOGY

SPECIAL EVENTS/
SESSIONS/WORKSHOPS

FORTE

A COLORECTAL CANCER PREVENTION TRIAL

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>

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 Trial 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.-3:25p.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
	<u>Questions and Answers</u>	
3:25 p.m.- 4:05p.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
	<u>Questions and Answers</u>	
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
	<u>Questions and Answers</u>	



NRG ONCOLOGY PLENARY

THURSDAY, JULY 22, 2021
2:45 - 3:45 PM ET

PHILIP E. CASTLE, PHD, MPH

Director of the NCI Division of Cancer Prevention

presents

"Threading the Needle: Sewing Precision into Cancer
Prevention"

*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

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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

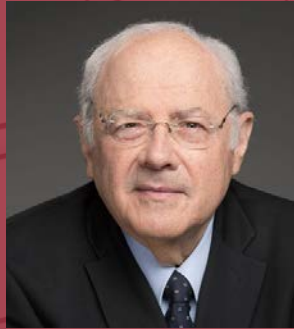
10:00 – 10:10am	Welcome NRG NCORP Updates	Deb Bruner, PhD, RN, NRG NCORP PI
10:10 – 10:20am	NRG-CC005 (FORTE)	Robert Schoen, MD, FORTE study chair
10:20 – 10:35am	PRO Compliance Collection and Best Practices	Kandie Dempsey and Marcie Ritter, NRG PRO Compliance
10:35 – 10:45am	Q&A – Open Discussion	
10:45 – 10:50am	Introduction of NCI speakers	Deb Bruner, PhD, RN, NRG NCORP PI
10:50 – 11:00am	NCI NCORP Update	Sandra Russo, MD, Community Oncology and Prevention Trials Research Group, DCP
11:00 – 11:10am	NCI CCDR Update	Kathleen Castro, RN, MS, Nurse Consultant, Office of the Associate Director of the Healthcare Delivery Research Program
11:10 – 11:25am	Q&A – Open Discussion – chat moderators	
11:25 – 11:30am	Closing Remarks	Deb Bruner/Joan Walker

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



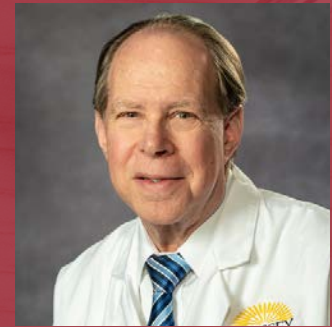
Quynh-Thu Le, MD
NRG Oncology
Group Chair



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

CCDR Breakout Sessions

July 23, 2021

1:45 - 3:45pm ET

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, FACS, FTOS, FNAK and Prajakta Adsul PhD, MBBS, MPH



#NRG2021



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
@DrSGraff
"Social Media for Career Advancement"



Jane Meisel, MD
Winship Cancer Institute
Emory University
@jane_meisel
"Engaging with Patients & Tools of Engagement"

NRG Oncology Digital Health Workshop

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

#NRG2021



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



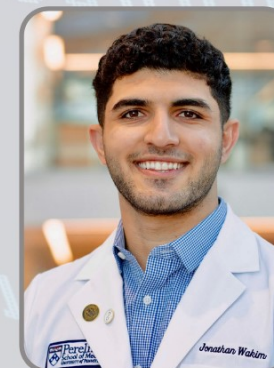
"Creating Common Data Models within Radiation Oncology"

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

NRG ONCOLOGY

NRG SCIENTIFIC COMMITTEES

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 <ul style="list-style-type: none"> • Pilot awards • Recognition of CC007CD top accruing sites 	Mary Cooley, PhD, RN, CCDR Chair; Matthew Hudson, PhD, CCDR Vice-Chair Ronald Chen MD
1:55-2:15pm	Concepts in development <ul style="list-style-type: none"> • Symptom management intervention proposal 	Alla Sikorskii PhD Terry A. Badger PhD, RN, FAPOS, FAAN
2:15-2:35	<ul style="list-style-type: none"> • Advancing Uptake of the Serious Illness Care Program for Community Cancer Care Providers. 	Joanna Paladino MD Suzanne Mitchel MD
2:35-2:45	NRG Research Fellowship Award <ul style="list-style-type: none"> • Sexual orientation and gender identity (SOGI) measurement for patient centered cancer care in sexual and gender minority (SGM) populations 	Megan Mullin PhD
2:45-3:30	Breakout sessions <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> 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:

PI1915 Dr. Moxley (disapproved), **PI1966** Simpkins, **PI2014** (GY027) Fuh, **DT2013** Doll, **DT2059** Henson, **PI2058** Richardson, **DT2106** Simpkins

PTMA (originally ETCTN)

- **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)
- **GY028 (UC2055/PTMA #100828)** Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Onstad/Westin)

10:30 AM - 11:45 AM Review of new and resubmitted concepts

- **PI2119** A Phase II study of Telaglenastat and Parp inhibitor for patients with recurrent or persistent ovarian clear cell carcinoma. (Gaillard/Wang)
- **DT2131** Pembrolizumab and Lenvatinib in Metastatic Cervical Cancer (Lea/Miller)
- **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 (Haggerty/Martin/Arend/Moore/ Zhang/Annunziata)

11:45 AM - 11:50 AM **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	PhII-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 Jason Efstathiou, MD
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 Bridget Koontz, 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 Medical Oncology Update Urology Update New Business		Phuoc Tran, MD PhD Oliver Sartor, MD Todd Morgan, MD 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 (≤ 2 cm) 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

Gynecologic Cancer Committee

Date: Saturday, July 24, 2021
Start and End Time: 10 AM - 12 PM
Chair: Carol Aghajanian, MD
Co-Chairs: Paul DiSilvestro, MD & David Gaffney, MD, PhD
Translational Science Co-Chair: Heather Lankes, PhD, MPH

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

I. General Business

- a. Call to order
- b. Approval of minutes from 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, IIIB, 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 (Jayanthy Lea/David Miller)

Studies Under Development

- a. **PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley)
- 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 +/- Selnexor 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 Konstantinopoulos)
- 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 Konstantinopoulos)
- 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 TP53-mutated 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 Subcommittee

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 naïve Mismatch Repair Deficient (dMMR) Endometrial Cancer (Floor Backes)

Active Studies:

- a. **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)
- b. **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)
- c. **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

- a. **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

- a. **MATCH COMBO**

Active Studies:

- a. **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:

- a. **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)
- b. **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)
 - Activated 08FEB2010
 - Futility limits met, Study closed to accrual 6/12/2020
 - 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
 - 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)
 - 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)
 - 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).
 - Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
 - Second-stage safety lead-in (all three arms) opened 14NOV2017
 - Group-wide activation 6/18/2018
 - Suspended at the end of phase 2 (May 2019) –
 - Re-activated to Phase III portion 8/25/2020. Bevacizumab supplied by CTEP for Phase III.
 - A9 (to detail PD-L1 endpt) posted 11/23/20. Comments rec’d by CTEP addressed in A10.

- Scheduled futility analysis -> close Arm 1 (PLD + Atezo). Study Temp Closed 2/9/21. Dear Dr/Dear Patient letters posted 2/12/21. A11 (to permanently closed Arm1 to accrual) to CTEP 02/24/21, to CIRB 3/9/21. Reopened **3/16/2021**.
 - 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/Jean 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, AI 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/Angela 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 Kinoshita/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)
 - **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).

Uterine Corpus Subcommittee

Date: Friday, July 23, 2021
Start and End time: 1:45 pm – 3:45 pm
Chair: Matthew Powell, MD
Rad Onc Co-Chair: Ann Klopp, MD
Med Onc Co-Chair: Martee Hensley, MD
TR Co-Chairs: Katherine Fuh, MD, PhD, Victoria Bae-Jump, MD, PhD
GTN subcommittee: Neil Horowitz, MD
GOG 210 Subcommittee: David Mutch, MD

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

Uterine Corpus Cancer Subcommittee ACTIVE/TEMPORARILY CLOSED Matthew Powell and Ann Klopp	Notes	Status of accrual as of 6/28/21
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) CTEP IND N=120 Stat: Enserro	Bender /Rimel/MacKay to update Open to accrual 9/4/18 Temporarily closed to accrual 6/17/19 GCSC 10/17/19 - three additional arms <ul style="list-style-type: none"> • olaparib/capivasertib • olaparib/durvalumab • cediranib/durvalumab 	120
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) CTEP IND N: 590 pMMR; 220 dMMR = 810 Central MMR testing (NeoGenomics) Stat: Sill/Huang-PRO PRO: Wenzel	Eskander to update Open to accrual 7/16/19 Temporarily closed to accrual 4/6/20 Reactivated 11/30/20. Japan and Korea to participate—	250
NRG-GY020 Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk	Backes / Powell to update Open to accrual 2/7/20	65

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	Notes	OEWG dates: Start Target Drop dead
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 – <i>submit publication plan to Dr. Tewari</i>) Stat: Miller N: 343-566 RadOnc: Alektiar	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) Stat: Sill N: 80	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) Stat: Enserro N:	Michaela Onstad / Westin to update with slides (3 max) PTMA #100828 PTMA #100828 GCC 10/11/20, RSC 2/3/21 GCSC 1/21/21, 4/15/21 (disapproved) Submit LOI – IB/II	08/19/2021 04/16/2022
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 Klopp 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 Eiriksson) 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/Paclitaxel/Atezolizumab in Patients with Advanced Recurrent Endometrial Cancer (Debra Richardson/Victoria Bae Jump) Stat: Enserro N: 97-106 Phase I Subcommittee	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) N: 250 Stat: Miller Non-Disease Specific/Solid tumors/ETCTN-NCTN Developmental Therapeutics Committee	Powell to update Open to accrual: 11/18/19 All tumor types are eligible	161
	Notes	
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)	

CC2046 Impact of SLN mapping vs lymphadenectomy on lower extremity limb dysfunction in pts with endometrial cancer (E Tanner)	Tanner to update NCORP approved 7/16/20; NRG DCP. Submitted for 3/23/2021 SXQOL Steering Committee review.	
CC2034 Endometrial cancer prevention in women with obesity with the levonorgestrel-releasing intrauterine system (Laurence Bernard)	Study design/Stats planning ongoing	
S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors	Powell to update	
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)	Powell to update	
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	Powell to update	

Head and Neck Committee

Date: Friday, July 23, 2021
Start and End Time: 1:45 – 3:45 PM ET
Chair: Quynh-Thu Le, MD, FACP, FASTRO
Co-Chair: Erich Sturgis, MD, MPH; Stuart Wong, MD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

A. Head and Neck portfolio overview 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

RTOG 1216	RT+cisplatin vs. RT+docetaxel+cetuximab vs. RT+cisplatin+atezolizumab for “high risk” resected HNSCC (Phase IIIR)	Julie Bauman Paul Harari David Rosenthal
NRG-HN006	Phase II-III SLN Biopsy vs. END in T1-2N0 oral cavity cancer	Stephen Lai
NRG-HN007	Phase III Gem/Cis vs. Gem/Cis/Nivo in 1 st line rec/met NPC	Brigitte Ma
NRG-HN008	Phase I RT + DNA-PK inhibitor in cisplatin-ineligible patients with high risk LA HNSCC	Maura Gillison Michael Samuels
RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong
RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR)	Cristina Rodriguez
NRG-HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III)	Nancy Lee
NRG-HN004	Phase II-IIIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC	Loren Mell

NRG-HN005	Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer	Sue Yom
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D. Report on publications and protocols closed to active accrual

Quynh-Thu Le, MD

Recently completed trials

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 | Saama Waqar |
| l) | ALCHEMIST Trial | Saama 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 SM Research Initiative - Tolerability Consortium	Andre Rogatko, PhD Norah Lynn Henry, MD, PhD
	NCI Tolerability Consortium Program Lead	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 Glioma Using Infinium 450K Methylation Array”**
(Wei Meng, PhD, Ohio State University)
- 3:15 – 3:35** **“New Concepts”**
(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

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

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

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|----------------------|---|
| 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 Freeman, PhD (Vanderbilt University Medical Center) |
| 12:55 – 1:10 | “Challenges and Opportunities for Combining 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) |

NRG ONCOLOGY

SCIENTIFIC CORE COMMITTEES

Health Disparities Committee
Thursday, July 22 (Virtual Meeting)
10am – 12pm ET
Agenda

<i>Chairs:</i>	<i>Chanita Hughes Halbert, PhD</i> <i>Jennifer Wenzel, PhD, RN, CCM, FAAN</i>
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 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">Clinical Trial Enrollment Updates - <i>Statistics/Metrics</i> - <i>SDMC Reports</i> -William Robinson / Reena Cecchini, PhD, MSMentorship/Education/Training- William Robinson, Chanita Hughes Halbert
11:25 – 11:45 am	Discussion: Collecting SOGI data as part of NRG trials -Marina Stassenko, MD
11:45 – 11:55 am	Opportunities to engage with the HDC - Jennifer Wenzel, Chanita Hughes Halbert <ul style="list-style-type: none">• 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	
	<ul style="list-style-type: none">• H&N:• Brain:• Breast:• Gyn:• GI:• GU:• Lung:• Sarcoma:	<p>Rathan Subramanian, MD/ Min Yao, MD Tammy Benzinger, MD / Ashok Srinivasan, MD Heidi Umphrey, MD / Mohammad Eghtedari, MD Karthik Sundaram, MD Eric Tamm, MD Ashesh Jani MD / Bill Hall, MD Michelle Ginsberg, MD Dan Pryma, MD</p>
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 –
 - 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

Medical Oncology Committee

Date: Friday July 23, 2021
Start and End Time: 4:00 pm -6:00 pm
Chairs: Corey Langer, MD; Deborah Armstrong, MD

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 | Corey Langer, MD |
| | | Deborah Armstrong, MD |
| | 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.

Time*	Topic	Speakers
10:00 am – 10:10 am	Welcome	Karen Holeva, BS
10:10 am – 10:30 am	Requesting early IRB closure for NRG trials	Erica Field, MPH, CCRP
10:30 am – 11:00 am	CTSU	Amanda Fournier, BSME
11:00 am – 12:00 pm	Importance of Workforce Diversity & Inclusion	Karen Winkfield, MD, PhD

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
PSC Vice-Chairs: Nancy Fusco RN, BSN, Cynthia Licavoli RN, BSN, MA
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

Time*	Topic	Speakers
12:30pm – 2:30pm	Best Practice Sessions- 30 minutes Sessions Choose 4 to attend	
Session 1: Organizing your workday Part A		Tiffany Elsea, BA, CCRP & Alex Kudryashev, MS, CCRP
Session 2: Organizing your workday Part B		Cynthia Licavoli, RN, BSN, MA & Erin McCaig, RN, BSN
Session 3: Study Start Up, Implementation & Management		Terry Thomas, MS, CCRC & Whitney Jacobson, RN, CCRP, OCN
Session 4: On Boarding New Coordinators (Nurse/CRA)		Karen Holeva, BS, CCRP & Alison Ivey, RN, MS, MBA, OCN, CCRP
Session 5: Audit Preparation/Management		Mary Jo Antonelli, MBA & Carole Donnelly BA, CCRP
Session 6: AE/SAE Reporting/Management		Sara McCartney, MS, RN & Donna White RN, BSN, OCN

***Please note all times listed are EASTERN TIME ZONE**

Development Therapeutics Radiation Therapy Subcommittee

Date: Monday, July 26, 2021
Start and End Time: 2:00 pm-3:00 pm EST
Chairs: Steven Lin, MD PhD and Sandip Patel, MD

- 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**
 - 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
 - RPT Dosimetry presentation
 - 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 Tsien, 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**

- IROC Houston Stephen Kry, PhD
- IROC Philadelphia RT (Contouring & Dosimetry) Ying Xiao, PhD
- IROC Philadelphia Imaging Mark Rosen, MD / Michael Boss, PhD

3:25 – 3:55 **Disease Site Reports**

- Brain Yunfeng Cui, PhD / Fang-Fang Yin, PhD
- Breast Guang-Pei Chen, PhD/ Jean Moran, PhD
- GI Adam Yock, PhD / William Parker, M.Sc.
- GU Robert Wallace, PhD / Rajat Kudchadker, PhD/Mihaela Rosu, PhD
- GYN Hayeon Kim, PhD / Cecilia Lee, PhD
- H&N Nataliya Kovalchuk, PhD / Ping Xia, PhD
- Lung Martha Matuszak, PhD/ Timothy Ritter, PhD

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**

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

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/ROG 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 IIIR 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/ROG 1308 Ph III Protons vs. photons for inoperable NSCLC
 - Other
- 5:45 – 5:50 **H & N Studies**
- IMPT for Nasopharyngeal Carcinoma (MGH Trial) A. Chan, MD
 - NRG-HN001 Nasopharynx: Ph IIR and PhIII, 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
- 6:20 – 6:25 SHIPP: Stereotactic Heavy Particles vs Protons vs Photons for Unfavorable Intermediate Risk Prostate Cancer. M. Roach, MD
- 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.

NRG ONCOLOGY

ADMINISTRATIVE COMMITTEES

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**
 - a. Accrual Update (January 1, 2021 – June 30, 2021)
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/m²) Every Three Weeks vs. Radiation with Low Dose Weekly Cisplatin (40 mg/m²) 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**

NRG ONCOLOGY

INSTITUTIONAL ACCRUAL

Accrual For Agenda Book from 1/1/2021 to 6/30/2021 Run Date: 7/2/2021

NRG Main Member (Network)	CTEP ID	Accrued to NRG Studies and Credited to NRG	Accrued to Non-NRG NCTN Studies and Credited	Total
Allan Blair Cancer Centre	11076	6	0	6
Allegheny General Hospital	PA009	6	13	19
AMITA Health Alexian Brothers Medical Center	IL280	0	3	3
Arizona Center for Cancer Care-Peoria	AZ127	0	0	0
Aurora NCI Community Oncology Research Program	AURORA	9	26	35
Avera Cancer Institute	SD021	2	12	14
Banner University Medical Center - Tucson	AZ017	12	5	17
Baptist Health Cancer Research Network	BHCRN	1	10	11
Baptist MD Anderson Cancer Center	FL003	1	3	4
Bay Area Tumor Institute NCORP	BATI	0	1	1
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	TX041	0	5	5
Baystate Medical Center	MA004	2	5	7
Berkshire Medical Center - Cancer Center	MA125	0	3	3
Boston Medical Center	MA043	0	216	216
Cancer Research Consortium of West Michigan NCORP	CRCWM	7	3	10
Cancer Research for the Ozarks NCORP	OZARKS	16	2	18
Cancer Research of Wisconsin and Northern Michigan Consortium	CROWN	15	3	18
Cancer Trials Ireland	ICORG	2	0	2
Carle Cancer Center NCI Community Oncology Research Program	CARLE	8	8	16
Carolinas Medical Center/Levine Cancer Institute	NC042	3	1	4
Catholic Health Initiatives NCORP	CORA	12	4	16
Cedars-Sinai Medical Center	CA016	2	3	5
Centre Hospitalier Universitaire de Sherbrooke-Fleurimont	11065	0	0	0
Chinese University of Hong Kong-Prince of Wales Hospital	34003	2	0	2
CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)	11073	0	0	0
CHUM - Centre Hospitalier de l'Universite de Montreal	11062	1	0	1
City of Hope Comprehensive Cancer Center	CA043	0	0	0
CIUSSEMTL-Hopital Maisonneuve-Rosemont	11060	0	0	0
Columbia University Minority Underserved NCORP	COLUMBI	1	9	10
Columbus NCI Community Oncology Research Program	COLUMBI	6	2	8
Community Cancer Center North	IN006	2	10	12
Cooper Hospital University Medical Center	NJ036	1	9	10
Covenant Medical Center-Lakeside	TX054	0	0	0
Cross Cancer Institute	11132	10	0	10
CWRU Case Comprehensive Cancer Center LAPS	LAPS-OHC	50	20	70
Dana-Farber / Partners CancerCare LAPS	LAPS-MA	6	7	13
Danbury Hospital	CT030	1	4	5
Dartmouth College - Norris Cotton Cancer Center LAPS	LAPS-NHC	7	2	9
Dayton NCI Community Oncology Research Program	DAYTON	1	0	1
Delaware/Christiana Care NCI Community Oncology Research Program	CHRISTIA	21	1	22
Dell Seton Medical Center at The University of Texas	TX063	0	0	0
Duke University - Duke Cancer Institute LAPS	LAPS-NC	5	0	5

Edward Hospital/Cancer Center	IL104	2	6	8
Einstein Medical Center Philadelphia	PA094	0	0	0
Emory University - Winship Cancer Institute LAPS	LAPS-GA0	17	12	29
Essentia Health NCI Community Oncology Research Program	ESSENTIA	0	0	0
Fox Chase Cancer Center	PA086	3	15	18
Fred Hutchinson Cancer Research Center LAPS	LAPS-WA	4	1	5
Froedtert and the Medical College of Wisconsin LAPS	LAPS-WI0	16	1	17
Geisinger Cancer Institute NCI Community Oncology Research Program	GEISINGE	11	0	11
GenesisCare USA - Farmington Hills	MI310	12	3	15
Georgia Cares Minority Underserved NCORP	GACARES	6	0	6
Georgia NCI Community Oncology Research Program	GEORGIA	8	11	19
Greater Baltimore Medical Center	MD018	4	17	21
Gulf South Minority Underserved NCORP	GULFSOU	11	1	12
Hackensack University Medical Center	NJ022	0	0	0
Hartford Hospital	CT009	3	5	8
Hawaii Minority Underserved NCORP	HAWAII	2	35	37
Heartland Cancer Research NCORP	HEARTLA	29	1	30
Henry Ford Hospital	MI026	6	1	7
Houston Methodist Hospital	TX036	8	4	12
Indiana University/Melvin and Bren Simon Cancer Center	IN007	3	4	7
Iowa-Wide Oncology Research Coalition NCORP	IWORC	1	4	5
James A. Haley Veterans Affairs Hospital	FL064	0	0	0
Jewish General Hospital	11116	0	0	0
JHU Sidney Kimmel Comprehensive Cancer Center LAPS	LAPS-MD	3	8	11
Juravinski Cancer Centre at Hamilton Health Sciences	11183	7	0	7
Kaiser Permanente NCI Community Oncology Research Program	KAISER	23	13	36
Kaiser Permanente-Gaithersburg Medical Center	MD198	0	6	6
Kantonsspital Aarau	67029	6	0	6
Lahey Hospital and Medical Center	MA017	0	3	3
Lankenau Medical Center	PA125	8	0	8
Legacy Good Samaritan Hospital and Medical Center	OR013	6	0	6
Loyola University Medical Center	IL017	4	0	4
MaineHealth Cancer Care Network	MAINE	13	6	19
Mayo Clinic LAPS	LAPS-MN	17	4	21
Medical University of South Carolina Minority Underserved NCORP	MUSC	7	6	13
MedStar Franklin Square Medical Center/Weinberg Cancer Institute	MD029	1	12	13
Memorial Sloan-Kettering Cancer Center LAPS	LAPS-NYO	39	9	48
Mercy Cancer Center - Sacramento	CA729	2	1	3
Metro Minnesota Community Oncology Research Consortium	METROM	16	6	22
Miami Cancer Institute	FL078	16	6	22
Michigan Cancer Research Consortium NCORP	MCRC	14	0	14
Michigan State University Clinical Center	MI038	0	0	0
Midwestern Regional Medical Center	IL120	3	2	5
Moffitt Cancer Center	FL065	13	20	33
Montana Cancer Consortium NCORP	MONTAN	6	0	6
Montefiore Minority Underserved NCORP	MONTEFI	4	0	4
Mount Sinai Hospital	NY021	9	4	13
National Cancer Centre Singapore	47005	7	0	7
National Institutes of Health Clinical Center	MD004	0	0	0
NCORP of the Carolinas (Greenville Health System NCORP)	GREENVIL	9	9	18

Nebraska Methodist Hospital	NE007	4	7	11
Nevada Cancer Research Foundation NCORP	NCRF	7	0	7
New Mexico Minority Underserved NCORP	NEWMEX	17	18	35
New York-Presbyterian/Brooklyn Methodist Hospital	NY075	5	4	9
NorthShore University HealthSystem-Evanston Hospital	IL018	8	1	9
Northwell Health NCORP	NORTHW	1	11	12
Northwestern University LAPS	LAPS-IL03	16	14	30
Norton Hospital Pavilion and Medical Campus	KY049	4	1	5
Odette Cancer Centre- Sunnybrook Health Sciences Centre	11118	5	0	5
Ohio State University Comprehensive Cancer Center LAPS	LAPS-OH0	31	2	33
Orlando Health Cancer Institute	FL020	1	5	6
Ottawa Hospital and Cancer Center-General Campus	11025	8	0	8
Pacific Cancer Research Consortium NCORP	PCRC	7	2	9
Parkview Regional Medical Center	IN181	1	10	11
Penn State Milton S Hershey Medical Center	PA042	3	0	3
Peter MacCallum Cancer Centre	3003	0	0	0
Piedmont Hospital	GA027	1	1	2
ProMedica Flower Hospital	OH012	7	4	11
Puerto Rico Minority Underserved NCORP	PUERTOR	8	0	8
Rabin Medical Center	40021	0	0	0
Reading Hospital	PA107	2	16	18
Rhode Island Hospital	RI005	0	0	0
Roswell Park Cancer Institute LAPS	LAPS-NY1	18	4	22
Rush University Medical Center	IL043	5	8	13
Rutgers Cancer Institute of New Jersey	NJ066	10	5	15
Saint Joseph Hospital - Orange	CA087	0	3	3
Saint Joseph's Hospital and Medical Center	AZ009	0	0	0
Saitama Medical University International Medical Center	42061	8	0	8
Sanford NCI Community Oncology Research Program of the North Central Plains	SANFORD	9	6	15
Saskatoon Cancer Centre	11120	3	0	3
Seoul National University Hospital	43002	4	0	4
Southeast Clinical Oncology Research Consortium NCORP	SCOR	35	11	46
Stanford Cancer Institute Palo Alto	CA141	13	0	13
Stony Brook University Medical Center	NY184	4	17	21
Stroger Hospital of Cook County Minority Underserved NCORP	STROGER	4	0	4
Summa Health System - Akron Campus	OH055	1	7	8
Sun Yat-sen University Cancer Center	60021	15	0	15
Sutter Cancer Research Consortium	SUTTER	4	9	13
Tel Aviv Sourasky Medical Center	40019	0	0	0
The James Graham Brown Cancer Center at University of Louisville	KY002	5	11	16
The Research Institute of the McGill University Health Centre (MUHC)	11318	2	0	2
Thomas Jefferson University Hospital LAPS	LAPS-PA1	14	6	20
Thompson Cancer Survival Center	TN038	0	0	0
Tibor Rubin VA Medical Center	CA041	0	0	0
Tom Baker Cancer Centre	11134	5	0	5
Trinity Cancer Care Center	ND026	0	3	3
Tulane University Health Sciences Center	LA001	2	6	8
UC Davis Comprehensive Cancer Center LAPS	LAPS-CA1	3	2	5
UC Irvine Health/Chao Family Comprehensive Cancer Center	CA088	2	5	7
UC San Diego Moores Cancer Center	CA249	8	1	9

UCLA / Jonsson Comprehensive Cancer Center	CA006	3	3	6
UCSF Medical Center-Mount Zion	CA136	3	28	31
UMass Memorial Medical Center - Memorial Division	MA009	2	0	2
UNC Lineberger Comprehensive Cancer Center LAPS	LAPS-NC0	6	0	6
University Health Network-Princess Margaret Hospital	11030	13	0	13
University of Alabama at Birmingham / Deep South Research Consortium LAPS	LAPS-AL0	10	12	22
University of Arkansas for Medical Sciences	AR006	13	6	19
University of Chicago Comprehensive Cancer Center LAPS	LAPS-IL05	8	14	22
University of Cincinnati/Barrett Cancer Center	OH070	15	136	151
University of Colorado Cancer Center LAPS	LAPS-CO0	4	41	45
University of Connecticut	CT002	0	0	0
University of Florida Health Science Center - Gainesville	FL015	0	27	27
University of Illinois	IL040	5	6	11
University of Iowa/Holden Comprehensive Cancer Center	IA018	4	10	14
University of Kansas Cancer Center - MCA Rural MU NCORP	KANSAS	21	0	21
University of Kentucky/Markey Cancer Center	KY010	1	5	6
University of Maryland/Greenebaum Cancer Center	MD015	10	7	17
University of Miami Miller School of Medicine-Sylvester Cancer Center	FL028	6	9	15
University of Michigan Comprehensive Cancer Center LAPS	LAPS-MIO	4	4	8
University of Minnesota/Masonic Cancer Center	MN022	0	0	0
University of Mississippi Medical Center	MS005	2	4	6
University of Nebraska Medical Center	NE003	6	0	6
University of Oklahoma Health Sciences Center LAPS	LAPS-OK0	30	42	72
University of Pennsylvania/Abramson Cancer Center	PA075	9	4	13
University of Pittsburgh Cancer Institute LAPS	LAPS-PA0	12	11	23
University of Rochester LAPS	LAPS-NY1	20	8	28
University of South Alabama Mitchell Cancer Institute	AL068	0	0	0
University of Tennessee - Knoxville	TN021	0	1	1
University of Tennessee Health Science Center	TN030	0	0	0
University of Texas Health Science Center at San Antonio	TX059	0	4	4
University of Texas MD Anderson Cancer Center LAPS	LAPS-TX0	28	1	29
University of Texas Medical Branch	TX045	0	12	12
University of Texas Southwestern Medical Center LAPS	LAPS-TX0	9	10	19
University of Utah - Huntsman Cancer Institute LAPS	LAPS-UT0	14	8	22
University of Vermont and State Agricultural College	VT004	1	2	3
University of Virginia Cancer Center	VA009	3	5	8
University of Wisconsin Carbone Cancer Center LAPS	LAPS-WIO	11	6	17
Upstate Carolina Consortium Community Oncology Research Program	UPSTATE	30	3	33
USC Norris Comprehensive Cancer Center LAPS	LAPS-CA0	4	9	13
Vanderbilt University - Ingram Cancer Center LAPS	LAPS-TN0	2	0	2
VCU Massey Cancer Center Minority Underserved NCORP	VCU	6	27	33
Veterans Administration Hospital	FL051	0	0	0
Wake Forest University Health Sciences	NC002	8	2	10
Walter Reed National Military Medical Center	MD001	5	0	5
Washington University - Siteman Cancer Center LAPS	LAPS-MO	36	11	47
Wayne State University - Karmanos Cancer Institute LAPS	LAPS-MIO	11	5	16
WellSpan Health-York Hospital	PA047	0	11	11
West Virginia University Charleston Division	WV004	5	3	8
West Virginia University Healthcare	WV025	4	10	14
Western States Cancer Research NCORP	WESTERN	1	10	11

William Beaumont Hospital-Royal Oak	MI005	3	25	28
Wisconsin NCI Community Oncology Research Program	WINCORP	3	8	11
Women and Infants Hospital	RI012	19	11	30
Women's Cancer Center of Nevada	NV049	15	0	15
Yale University - Yale Cancer Center LAPS	LAPS-CT0	9	8	17
Yonsei University Health System-Severance Hospital	43027	0	0	0

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