



# NRG Oncology Semiannual Meeting

January 9-11, 2020

Marriott Marquis - Houston, Texas

Program Book



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## Welcome to the January 2020 NRG Oncology Semiannual Meeting

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

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

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

### Meeting highlights include:

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

The use of PARP inhibitor (PARPi) therapy has ushered in a new era and dramatically changed the management of ovarian cancer as well as several different solid tumor malignancies. "It's a PARP World After ALL" GOG Foundation Symposium provides an excellent opportunity to explore the use of PARPi in ovarian, cervical, endometrial, breast, prostate, and pancreatic cancers. The latest practice-chang-

ing clinical trial results will be provided and reviewed in context with challenging clinical practice scenarios in cancer patients treated with PARPi. This symposium activity will provide evidence-based perspectives regarding controversial topics in ovarian and breast cancer management. The information that will be provided has potential practice-changing implications that be translated into clinical arena immediately. Moreover mechanisms of resistance to PARPi as well as the latest information on combination PARPi combinations will be reviewed. Interactive case vignettes will help attendees to better identify, manage, and mitigate PARPi toxicity. Ongoing and planned pivotal clinical trials will be discussed and the future of clinical trial design in the era of PARPi therapy will be explore.

**Thursday, January 9th at 8.00 am.**

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

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

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

NRG Oncology will be holding a kick-off meeting for NRG-CC008, "A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers (SOROC)" on **Friday, January 10th during the CPC Workshop at 2:30 pm.** The protocol is anticipated to activate early 2020, and the session is open to all attendees.

Social Media Workshop Twitter 1 on 1 is scheduled for **Saturday, January 11th 8:00 am – 9:00 am**. Social media experts from the NRG Oncology Communications Committee can help you with the setup of your social media account and answer any question you have about social media use and best practices.

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

Welcome to Houston!

*Welcome to Houston!*



Walter J. Curran, Jr., MD  
NRG Oncology Group Chair

*Walter J. Curran, Jr. MD*



Robert Mannel, MD  
NRG Oncology Group Chair

*Robert S. Mannel, MD*



Norman Wolmark, MD  
NRG Oncology Group Chair

*Norman Wolmark*

**#NRG2020**



# NRG Oncology Mission Statement

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

For the Educational Objectives, we list the following:

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

## Disclosure Information

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

# Continuing Medical Education (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 25.5 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

## CME/Certificate Instructions - NEW!

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

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

Additional information will be available at the CME desk.



Continuing Medical Education Program

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

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

For questions or comments about this CME activity, please contact:  
Michelle N. Small, Director, Education Programs/CME Compliance of The GOG Foundation, Inc. at: [msmall@gog.org](mailto:msmall@gog.org).

# FINAL LISTING OF APPROVED CME CREDITS

The following sessions/workshops have been approved to receive CME credits  
Accredited by the GOG Foundation, Inc. in Houston, TX January 9-11, 2020  
*AMA PRA Category 1 credits™*

	THURSDAY	FRIDAY	SATURDAY
Symposium –“It’s PARP World After All”	4.5		
<b>WORKSHOP AGENDAS</b>			
Brain Tumor workshop		2	
Breast Cancer workshop			3
Breast Cancer Rare and Genetically Linked Subcommittee Workshop		1	
Canadian Members workshop			1
Cancer Care Delivery Research CDDR		1.5	
Cancer Prevention and Control workshop		2	
Cervix Cancer workshop		2	1
Gastrointestinal Cancer workshop (Not approved as of 12/16/2019, Disclosures not in)			2
Genitourinary Cancer workshop			2
Gynecologic Cancer workshop			2
GYN Developmental Therapeutics workshop/Phase I			1
GYN Dev. Therapeutics/Phase I/Translational Science workshop	2		
Head and Neck Cancer workshop			2
Immunotherapy and Immune Modulation workshop	2		
Lung Cancer workshop			2
Medical Oncology workshop			1
NRG Oncology Plenary Session		2	
NRG Protocol Workshop G1004, G1002 and G1005		1	
NRG Protocol Workshop: NRG BR003 and BR004		1	
NRG Surgical Oncology workshop			1
Ovarian Cancer workshop		3	1
Patient Centered Outcomes Research (PCOR)	2		
Pharmacy Subcommittee workshop		1	
Radiation Development Therapeutics		1.5	
Rare Tumor workshop		2	
Social Media and Mobile Technology workshop		1	
Translational Science workshop	1.5		
Translational Science GYN		2	
Translational Science Lung Cancer workshop		2	
Uterine Corpus Cancer workshop		3	1
<b>PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD’s</b>			
PSC-Introduction to Clinical Trials: Principles of Clinical Management	4.5		
PSC Afternoon Breakout sessions .75 for each Breakout session	3		
PSC-Clinical Trial Nurse/Clinical Research Assoc Ed Session Roundtables		3.5	



## **WHAT'S NEW?**

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

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

- **New Meeting Registration System:** Choose "New Account Profile" when first registering. The account you created for this meeting will be used for all future meetings.

# NRG Oncology Semi Annual Meeting

**Stay up-to-date** with updates and announcements from the NRG Oncology Semiannual Meeting 2020 on Twitter and Facebook



**TWITTER**

**JOIN The Conversation On Twitter: @NRGONC #NRG2020**



**FACEBOOK**

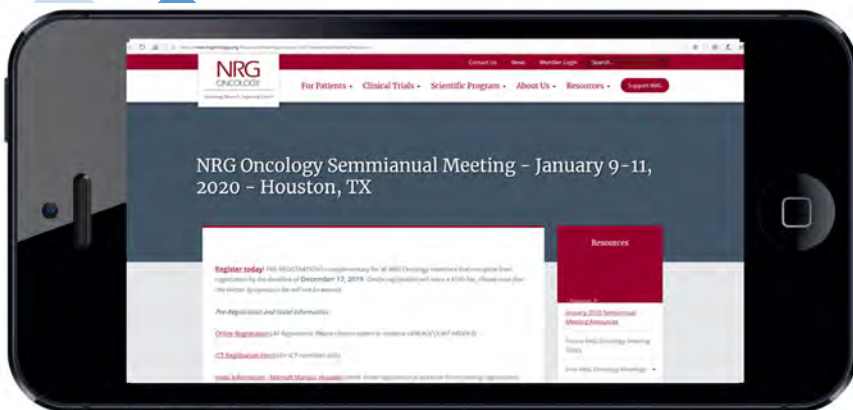
**<https://www.facebook.com/nrgoncology/>**

**WIFI**

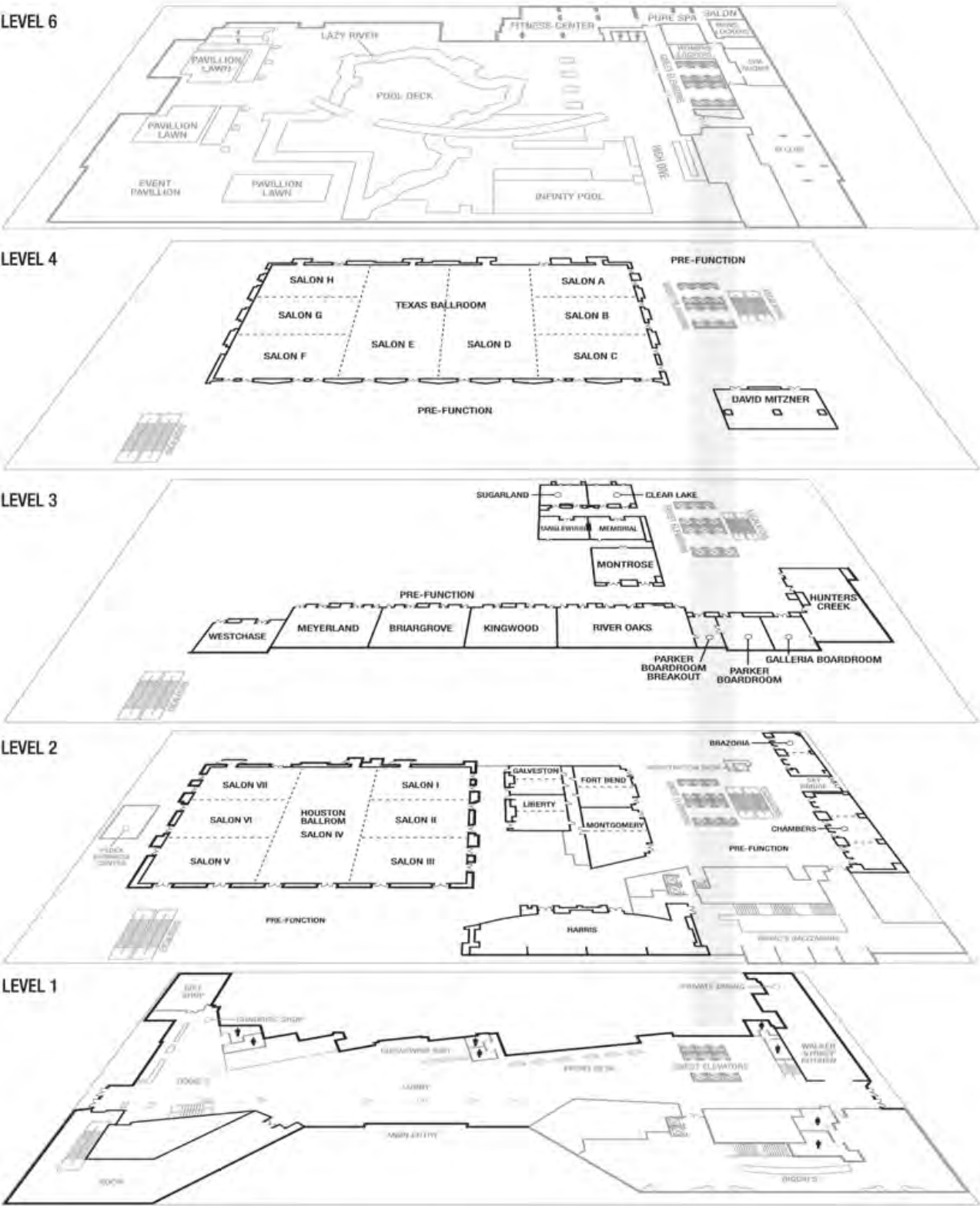
**Complimentary wifi is available for meeting attendees:**

**Network Login: nrgmeeting**

**Passcode: n1r2g345**



All Floors





Advancing Research. Improving Lives.™

# NRG ONCOLOGY SEMIANNUAL MEETING

## FINAL SCHEDULE

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

Thursday, January 9, 2020		
6:30 am – 8:30 am	Symposium Breakfast	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 8:00 am	PSC CTN/CRA Workshop and Educational Session Breakfast	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 6:00 pm	Registration/CME/Information Desk	Texan Foyer/4 <sup>th</sup> Level
9:40 am – 9:55 am	Symposium Coffee Break	Texan D/4 <sup>th</sup> Level
11:30 am – 12:30 pm	Symposium Lunch	Texan D/4 <sup>th</sup> Level
1:00 pm – 5:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Memorial/3 <sup>rd</sup> Level
4:00 pm – 6:00 pm	Exhibit Setup	Texan Foyer/4 <sup>th</sup> Level
7:30 am – 12:00 pm	Introduction to Clinical Trials: Principles of Clinical Trial Management	Texan ABC/4 <sup>th</sup> Level
8:00 am – 12:00 pm	Imaging and Radiation Oncology Core (IROC) RT Focused Staff Meeting *	Kingwood B/3 <sup>rd</sup> Level
8:00 am – 1:45 pm	Winter Symposium - <b><i>“It’s a PARP World After All”</i></b>	Texan FG/4 <sup>th</sup> Level
9:00 am – 12:00 pm	NRG DMC Panel A *	Liberty AB/2 <sup>nd</sup> Level
9:00 am – 1:00 pm	SOCRA Certification Exam	Fort Bend A/2 <sup>nd</sup> Level
1:00 pm – 2:00 pm	VisionTree Workshop	Sugarland/ 3 <sup>rd</sup> Level
1:00 pm – 4:00 pm	NRG DMC Panel B *	Liberty AB/2 <sup>nd</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Patient Screening & Enrollment	Meyerland A/3 <sup>rd</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Treatment Modalities	Briargrove A/3 <sup>rd</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Data Management	Briargrove B/3 <sup>rd</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Adverse Event Reporting	Meyerland B/3 <sup>rd</sup> Level
2:00 pm – 4:00 pm	GYN Developmental Therapeutics/Phase 1/Translational Science Workshops	Texan E/4 <sup>th</sup> Level
2:00 pm – 4:00 pm	Immunotherapy and Immune Modulation Workshop	Texan H/4 <sup>th</sup> Level
2:30 pm – 4:00 pm	Comparative Effectiveness Research (CER) Committee *	Kingwood A/3 <sup>rd</sup> Level
3:00 pm – 5:00 pm	NRG-Harvard-Ohio State-Case Western R01 Grant Meeting *	Kingwood B/ 3 <sup>rd</sup> Level
4:00 pm – 5:15 pm	An Introduction to NRG Oncology: New Investigator Educational Session	Texan ABC/4 <sup>th</sup> Level
4:00 pm – 5:30 pm	Translational Science Workshop	Texan FG/4 <sup>th</sup> Level
4:00 pm – 6:00 pm	Patient Centered Outcomes Research (PCOR) Workshop	Texan H/4 <sup>th</sup> Level
4:30 pm – 6:30 pm	PSC Education & Training Working Group *	Kingwood A/3 <sup>rd</sup> Level
4:30 pm – 6:30 pm	PSC Mentorship Working Group *	Galleria/3 <sup>rd</sup> Level
4:30 pm – 6:30 pm	PSC Protocol Review Working Group *	River Oaks/3 <sup>rd</sup> Level
5:15 pm – 6:00 pm	New Investigators Mini-Reception	Texan ABC/4 <sup>th</sup> Level
5:30 pm – 7:00 pm	PSC Quality Control Working Group *	Galveston A/2 <sup>nd</sup> Level
5:30 pm – 8:00 pm	Translational Science Brain Cancer Subcommittee/Low-Grade Glioma Working Group	Sugarland/3 <sup>rd</sup> Level
6:00 pm – 7:00 pm	Early Phase Trial Oversight Committee *	Kingwood B/3 <sup>rd</sup> Level
6:00 pm – 7:00 pm	Communications Committee *	Montrose/3 <sup>rd</sup> Level

Revised 12/16/2019

\*Sessions for Committee Member



NRG ONCOLOGY SEMIANNUAL MEETING  
FINAL SCHEDULE  
Marriott Marquis Houston  
Houston, Texas  
January 9 – 11, 2020

Thursday, January 9, 2020		
6:00 pm – 8:00 pm	NCORP Concept Review <i>(Invitation Only)</i>	Hunter's Creek/3 <sup>rd</sup> Level
6:00 pm – 8:00 pm	NRG Oncology Japan Meeting	Liberty/2 <sup>nd</sup> Level
6:00 pm – 8:00 pm	Ancillary Projects Committee *	Galveston B/2 <sup>nd</sup> Level

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## FINAL SCHEDULE

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

Friday, January 10, 2020		
6:30 am – 8:30 am	Continental Breakfast	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 5:00 pm	Exhibits	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 5:30 pm	Registration/CME/Information Desk	Texan Foyer/4 <sup>th</sup> Level
8:00 am – 5:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Memorial/3 <sup>rd</sup> Level
10:00 am – 11:00 am	General Coffee Break	Texan Foyer/4 <sup>th</sup> Level
2:00 pm – 3:30 pm	General Coffee Break	Texan Foyer/4 <sup>th</sup> Level
6:45 am – 9:00 am	Patient Advocates Meeting *	Galleria/3 <sup>rd</sup> Level
7:00 am – 8:00 am	Digital Health Working Group	Houston 3/2 <sup>nd</sup> Level
7:00 am – 8:00 am	GYN Cancer Committee Executive Session *	Kingwood B/3 <sup>rd</sup> Level
7:00 am – 8:00 am	Local Regional Breast Cancer Subcommittee *	Montrose/3 <sup>rd</sup> Level
7:00 am – 8:00 am	Pharmacy Subcommittee	<b>Hunter's Creek/3<sup>rd</sup> Level</b>
7:00 am – 8:30 am	Translational Science Breast Cancer Subcommittee	Texan B/4 <sup>th</sup> Level
7:00 am – 9:00 am	Clinical Trials Nurse/Clinical Research Associate Subcommittees Combined Meeting * ( <i>Open for first hour</i> )	Texan H/4 <sup>th</sup> Level
7:00 am – 12:00 pm	GYN/RT Case Review	Memorial/3 <sup>rd</sup> Level
7:30 am – 8:30 am	NRG SDMC Executive Committee *	Fort Bend AB/2 <sup>nd</sup> Level
7:30 am – 9:30 am	NRG-BN006 Training Session	Houston 4/2 <sup>nd</sup> Level
7:30 am – 9:30 am	Sarcoma Working Group	Sugarland/3 <sup>rd</sup> Level
8:00 am – 9:00 am	Breast Cancer Rare and Genetically Linked Subcommittee Workshop	Houston 7/2 <sup>nd</sup> Level
8:00 am – 9:00 am	Social Media and Mobile Technology Workshop	Montgomery/2 <sup>nd</sup> Level
8:00 am – 9:00 am	Protocol 210 Subcommittee	Montrose/3 <sup>rd</sup> Level
8:00 am – 10:00 am	Cervix Cancer Workshop	Texan E/4 <sup>th</sup> Level
8:00 am – 10:00 am	Rare Tumor Workshop	Texan A/4 <sup>th</sup> Level
8:00 am – 10:00 am	Radiation Oncology Committee Meeting	Texan FG/4 <sup>th</sup> Level
8:00 am – 12:00 pm	Pathology Workshop & Review	Chambers/2 <sup>nd</sup> Level
8:00 am – 9:30 am	Cancer Prevention and Control Committee Meeting *	River Oaks/3 <sup>rd</sup> Level
8:30 am – 9:30 am	Protocol Operations Management *	Kingwood A/3 <sup>rd</sup> Level
9:00 am – 10:00 am	Member Site Accrual Best Practices	Texan C/4 <sup>th</sup> Level
10:00 am – 12:00 pm	Plenary Session (Combined Scientific & General Sessions)	Texan D/4 <sup>th</sup> Level
12:00 pm – 1:00 pm	Final Review of Contours from the NRG GU 2020 Nodal Atlas Update *	Kingwood B/3 <sup>rd</sup> Level
12:00 pm – 1:00 pm	GYN GTN Subcommittee	Texan B/4 <sup>th</sup> Level
12:00 pm – 1:00 pm	Older Adult Working Group	River Oaks/3 <sup>rd</sup> Level
12:00 pm – 1:00 pm	Pathology Committee	Chambers/2 <sup>nd</sup> Level
12:00 pm – 1:00 pm	New Investigators Committee and Working Group *	Meyerland B/3 <sup>rd</sup> Level
12:00 pm – 1:30 pm	Immunotherapy and Immune Modulation Workshop	Texan H/4 <sup>th</sup> Level
12:00 pm – 2:00 pm	Neurosurgical Subcommittee	Harris/2 <sup>nd</sup> Level
12:00 pm – 2:00 pm	NRG Oncology Foundation Board of Directors *	<b>Hunter's Creek/3<sup>rd</sup> Level</b>

Revised 12/16/2019

\*Sessions for Committee Member



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## FINAL SCHEDULE

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Houston, Texas  
January 9 – 11, 2020

Friday, January 10, 2020		
12:30 pm – 2:00 pm	Radiation-Developmental Therapeutics Workshop	Houston 5-6/ 2 <sup>nd</sup> Level
12:30 pm – 2:30 pm	Imaging Committee	Fort Bend AB/2 <sup>nd</sup> Level
1:00 pm – 1:30 pm	Protocol 225 Information Session	Meyerland B/ 3 <sup>rd</sup> Level
1:00 pm – 2:00 pm	NRG BR003 and NRG BR004 Workshops	Texan C/4 <sup>th</sup> Level
1:00 pm – 2:00 pm	NRG-GU008 Kick-Off Session	Meyerland A/3 <sup>rd</sup> Level
1:00 pm – 2:00 pm	NRG-GU1919 Team Meeting *	Kingwood B/3 <sup>rd</sup> Level
1:00 pm – 2:30 pm	Cancer Care Delivery Research Workshop	Houston 7/2 <sup>nd</sup> Level
1:00 pm – 4:00 pm	Ovarian Cancer Workshop	Texan E/4 <sup>th</sup> Level
1:00 pm – 4:00 pm	Uterine Corpus Cancer Workshop	Texan A/4 <sup>th</sup> Level
2:00 pm – 3:00 pm	NRG GI004, GI002, and GI005 Workshop	Texan C/4 <sup>th</sup> Level
2:00 pm – 3:00 pm	CTEP/NRG/Merck Meeting NRG-GY018/MK 3475-868 *	Kingwood A/3 <sup>rd</sup> Level
2:00 pm – 3:00 pm	Translational Science Head & Neck Cancer Subcommittee	Montgomery/2 <sup>nd</sup> Level
2:00 pm – 3:30 pm	Publications Committee *	Montrose/3 <sup>rd</sup> Level
2:00 pm – 4:00 pm	Translational Science GU Cancer Subcommittee	River Oaks/3 <sup>rd</sup> Level
2:00 pm – 5:00 pm	Brain Tumor Core Committee *	Houston 1-2/2 <sup>nd</sup> Level
2:00 pm – 6:00 pm	Clinical Trial Nurse/Clinical Research Associate Workshop - Educational Session	Texan FG/4 <sup>th</sup> Level
2:30 pm – 4:30 pm	Medical Physics Subcommittee Meeting	Meyerland B/3 <sup>rd</sup> Level
2:30 pm – 4:30 pm	Cancer Prevention and Control Workshop	Houston 7/2 <sup>nd</sup> Level
2:30 pm – 6:00 pm	Breast Cancer Working Group *	Houston 5-6/2 <sup>nd</sup> Level
3:00 pm – 4:00 pm	NRG-LU003 Information Session	Meyerland A/3 <sup>rd</sup> Level
3:00 pm – 5:00 pm	Health Disparities Committee	Texan B/4 <sup>th</sup> Level
3:00 pm – 6:00 pm	Head & Neck Cancer Core Committee *	Houston 3/2 <sup>nd</sup> Level
3:30 pm – 4:30 pm	NRG Oncology Human Research Committee *	Kingwood B/3 <sup>rd</sup> Level
4:00 pm – 5:00 pm	Radiation Oncology GYN Working Group	Texan A/4 <sup>th</sup> Level
4:00 pm – 5:00 pm	VA/MTF Meeting	Fort Bend AB/2 <sup>nd</sup> Level
4:00 pm – 6:00 pm	Genitourinary Cancer Core Committee *	River Oaks/3 <sup>rd</sup> Level
4:00 pm – 6:00 pm	Translational Science GYN Workshop	Texan H/4 <sup>th</sup> Level
4:00 pm – 6:00 pm	Translational Science Lung Cancer Workshop	Montgomery/2 <sup>nd</sup> Level
5:00 pm – 6:00 pm	Brain Tumor Workshop	Houston 1-2/2 <sup>nd</sup> Level
5:00 pm – 6:00 pm	Veterans Radiation Oncology Consortium (VetROC)	Galleria/3 <sup>rd</sup> Level
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group Meeting	<b>Hunter's Creek/3<sup>rd</sup> Level</b>
6:00 pm – 8:00 pm	NRG Oncology Welcome Reception	Texan D/4 <sup>th</sup> Level

Revised 12/16/2019

\*Sessions for Committee Member

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## FINAL SCHEDULE

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

Saturday, January 11, 2020		
6:30 am – 8:30 am	Continental Breakfast	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 2:00 pm	Exhibits	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 3:00 pm	Registration/CME/Information Desk	Texan Foyer/4 <sup>th</sup> Level
8:00 am – 1:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Memorial/3 <sup>rd</sup> Level
10:00 am – 12:00 pm	General Coffee Break	Texan Foyer/4 <sup>th</sup> Level
7:00 am – 8:00 am	Surgical Oncology Workshop	Houston 5-6/2 <sup>nd</sup> Level
7:00 am – 8:00 am	Canadian Members Meeting	Meyerland A/3 <sup>rd</sup> Level
7:00 am – 8:00 am	NRG SDMC Data Management Working Group *	Kingwood A/3 <sup>rd</sup> Level
7:00 am – 8:00 am	NRG SDMC Statistical Working Group *	Montrose/3 <sup>rd</sup> Level
7:00 am – 8:00 am	Medical Oncology Workshop	Texan C/4 <sup>th</sup> Level
7:00 am – 8:30 am	Proton Working Group Meeting	Houston 1-2/2 <sup>nd</sup> Level
7:00 am – 9:30 am	Protocol Support Committee Business Meeting *	Houston 3/2 <sup>nd</sup> Level
7:30 am – 9:30 am	GI Colorectal Cancer Subcommittee *	Texan A/4 <sup>th</sup> Level
8:00 am – 9:00 am	GYN Developmental Therapeutics/Phase I Workshops	Texan E/4 <sup>th</sup> Level
8:00 am – 9:00 am	Twitter 101 Session	Meyerland B/3 <sup>rd</sup> Level
8:00 am – 9:30 am	Safety Review Committee *	Kingwood B/3 <sup>rd</sup> Level
8:00 am – 10:00 am	NCORP PI & Administrators Meeting	Texan C/4 <sup>th</sup> Level
8:00 am – 10:00 am	Genitourinary Cancer Workshop	Houston 4/2 <sup>nd</sup> Level
8:00 am – 10:00 am	Head & Neck Surgical Subcommittee	Houston 7/2 <sup>nd</sup> Level
8:00 am – 10:00 am	Lung Cancer Core Committee *	River Oaks/3 <sup>rd</sup> Level
8:30 am – 9:30 am	Chordoma Research Working Group *	Fort Bend AB/2 <sup>nd</sup> Level
9:00 am – 10:00 am	Ovarian Cancer Workshop	Texan E/4 <sup>th</sup> Level
9:00 am – 10:00 am	Cervix Cancer Workshop	Texan B/4 <sup>th</sup> Level
9:00 am – 10:00 am	Uterine Corpus Cancer Workshop	Texan H/4 <sup>th</sup> Level
9:00 am – 10:00 am	Quality Assurance Audit Meeting *	Kingwood A/3 <sup>rd</sup> Level
9:00 am – 1:00 pm	Breast Cancer Workshop	Texan FG/4 <sup>th</sup> Level
9:30 am – 11:30 am	GI Non-Colorectal Cancer Subcommittee *	Texan A/4 <sup>th</sup> Level
10:00 am – 11:30 am	Membership Committee *	Montrose/3 <sup>rd</sup> Level
10:00 am – 12:00 pm	Gynecologic Cancer Workshop	Texan E/4 <sup>th</sup> Level
10:00 am – 12:00 pm	Lung Cancer Workshop	Houston 1-2/2 <sup>nd</sup> Level
10:00 am – 12:00 pm	Head & Neck Cancer Workshop	Houston 4/2 <sup>nd</sup> Level
11:30 am – 1:00 pm	Gastrointestinal Cancer Workshop	Texan C/4 <sup>th</sup> Level
12:00 pm – 1:00 pm	NRG-LU005 Study Update/Information Session ( <a href="#">Lunches will be provided to those who register for the session prior to December 17<sup>th</sup></a> )	Houston 1-2/2 <sup>nd</sup> Level
12:00 pm – 1:00 pm	Voting Members PI Meeting *	Harris/2 <sup>nd</sup> Level
12:30 pm – 5:00 pm	NRG-HN006 Surgeon Education/Training	Houston 4/2 <sup>nd</sup> Level

Revised 12/16/2019

\*Sessions for Committee Member



NRG ONCOLOGY SEMIANNUAL MEETING  
FINAL SCHEDULE  
Marriott Marquis Houston  
Houston, Texas  
January 9 – 11, 2020

Saturday, January 11, 2020		
1:00 pm – 4:00 pm	Research Strategy Meeting *	Texan D/4 <sup>th</sup> Level
4:00 pm – 5:30 pm	Executive Committee *	Galleria/3 <sup>rd</sup> Level

# Information Technology Resource Center

**NRG Oncology  
Semiannual Meeting  
Houston, TX  
January 9 - 11, 2020**

**Marriott Marquis Houston  
Memorial Room  
3<sup>rd</sup> Level**

**Open  
Thur. Jan 9: 1PM-5PM  
Fri. Jan 10: 8AM-5PM  
Sat. Jan 11: 8AM-1PM**



<http://www.nrgoncology.org>



## **The Self-Service Resource Center will feature:**

Internet Access  
Email  
Printing  
Copier/Scanner

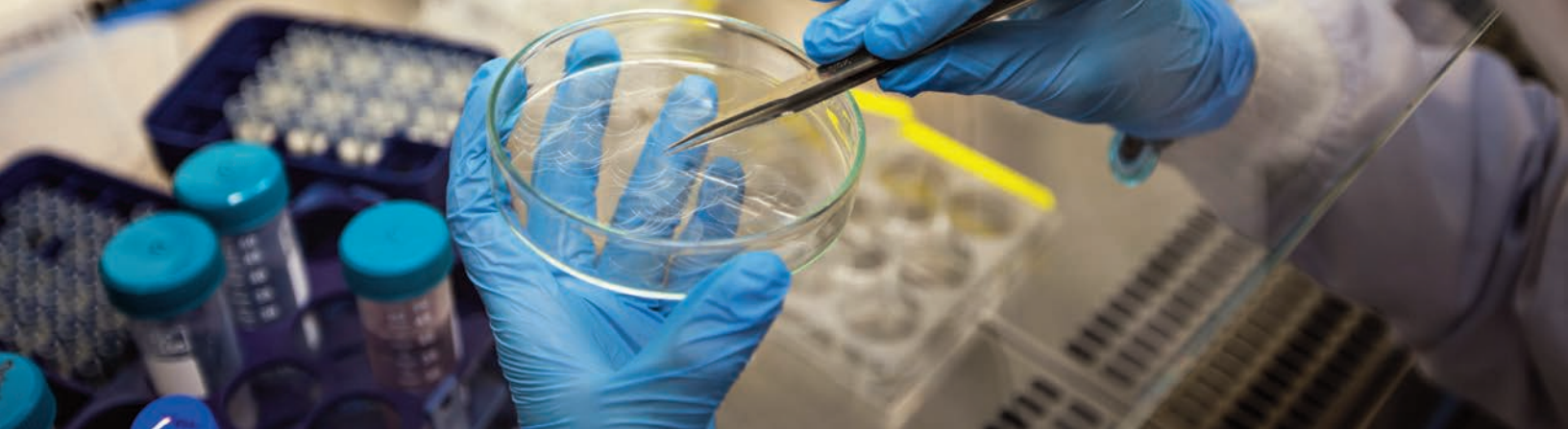
### **WIFI**

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

Network SSID: nrgmeeting  
Passcode: n1r2g345

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

## Sessions/Special Events



# NRG Oncology Translational Science Workshop

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

## Program Co-Chairs:



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



**Adam Dicker, MD, PhD, FASTRO**  
Thomas Jefferson University



**Matthew Ellis, MB, BCHIR, PhD**  
Baylor College of Medicine

## Session Speakers:



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



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



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



# NRG Oncology Digital Health Workshop

Held at the NRG Oncology January 2020 Semiannual Meeting

Friday, January 10, 2020, 7:00-8:00am

Room: Houston 3

Marriott Marquis - Houston, Texas

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

## Session Speakers:



**Colin Carpenter, PhD**

CEO of Siris Medical, Inc.

*"Accelerating the prior authorization process with Siris - Artificial Intelligence"*



**Benjamin Kann, MD**

Dana Farber Cancer Institute

*"Deep Learning for Identification of Extranodal Extension in Head and Neck Cancer: The Path to Clinical Integration"*



**Benjamin Smith, MD & Stephen Grant, MD**

MD Anderson Cancer Center

*"Experience with user-centered design and implementation of an oncology-specific EHR"*



## Program Co-Chairs:



**Adam Dicker, MD,  
PhD, FASTRO**

Thomas Jefferson University



**Sanjay Aneja, MD**  
Yale School of Medicine



# NRG Oncology Social Media Workshop

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

## Session Speakers:



**Clifford Robinson, MD**

Washington University School of Medicine in  
 St. Louis  
*"Hashtag Oncology and Twitter for Beginners"*  
 @SBRT\_CR



**Deanna Teoh, MD, MS**

University of Minnesota  
*"The Doctor Is In: Engagement Through Social  
 Media Platforms"*  
 @DeannaTeoh



**Dee Sparacio, MS**

Kaleidoscope of Hope Ovarian Cancer  
 Foundation, Women of Teal Blog  
*"Benefits and Support of Twitter Cancer  
 Communities"*  
 @WomenofTeal

## Session Chairs:



**Rebecca Previs, MD**  
 Duke University

NRG Oncology Communications  
 Committee Member  
 @BeccaPrevisMD



**Thomas Julian, MD**

Allegheny Health Network  
 NRG Oncology Communications  
 Committee Chair  
 @TBJulianMD

## Social Media and Mobile Technology Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

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

### QUESTIONS / DISCUSSION

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

### SURVEY

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

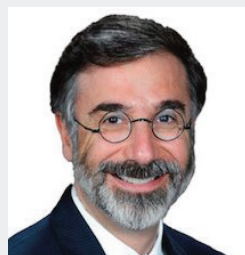
### SUPPLEMENTAL SESSIONS:

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

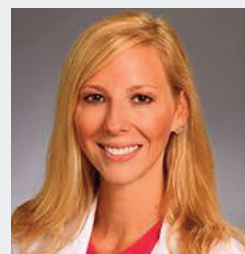
# NRG Oncology Plenary Session

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

## Session Speakers:



**Samir N. Khleif, MD**  
Georgetown University  
*"Overcoming Immune Resistance, the Next Frontier"*



**Kristin Higgins, MD**  
Emory University  
*"NRG-LU005: Limited stage small cell lung cancer (LS-SCLC): a phase II/III randomized study of chemoradiation versus chemoradiation plus atezolizumab"*



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



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

## Group Chairs & NCORP PI:



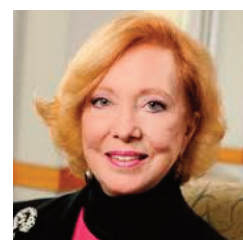
**Walter J. Curran, Jr., MD**  
Emory University  
*"Outstanding Publications Awards & Leadership Recognition"*



**Robert S. Mannel, MD**  
The University of Oklahoma  
Moderator



**Norman Wolmark, MD**  
UPMC Hillman Cancer Center  
*"Bernard Fisher, MD Tribute"*



**Deborah W. Bruner, RN, PhD**  
Emory University  
NRG NCORP Research Base PI



## NRG Oncology Plenary Session

**Date:** Friday, January 10, 2020

**Start and End Time:** 10:00 am – 12:00 pm

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

**Learning Objectives:**

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

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

### WORKSHOP AGENDA

10:00 – 10:30 am	Welcome Outstanding Publications Awards Leadership recognition?	Walter J Curran, Jr., MD
10:00 – 10:30 am	NRG NCORP Research Base Report	Deborah W. Bruner, RN, PhD
10:30 – 10:50 am	Bernard Fisher, MD Tribute	Norman Wolmark, MD
10:50 am – Noon	Moderator	Robert S Mannel, MD
10:50 – 11:10 am	Overcoming Immune Resistance, the Next Frontier	Samir N Khlief, MD
11:10 – 11:20 am	NRG-LU005: Limited stage small cell lung cancer (LS-SCLC): a phase II/III randomized study of chemoradiation versus chemoradiation plus atezolizumab	Kristin A Higgins, MD
11:20 – 11:30	NRG-GY018: A phase III randomized, placebocontrolled study of pembrolizumab (MK-3475, NSC #776864) in addition to paclitaxel and carboplatin for measurable stage III or IVA, stage IVB OR recurrent endometrial cancer”	Ramez N Eskander, MD
11:30 – 11:50	Immune-related Adverse Events: Innovation & infrastructure	Jarushka Naidoo, MBBCh



# NRG Oncology Twitter 1-on-1

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

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



**Rebecca Previs, MD**  
Duke University



**Michael Cowher, MD**  
West Virginia University



**Michelle Shepard**  
NRG Oncology



**Angela LaPenta**  
NRG Oncology



**Jon Kiddy**  
Roswell Park Comprehensive Cancer Center



*Advancing Research. Improving Lives.*

*Join us at the*  
***Welcome Reception***

**January 10, 2020  
6 pm - 8 pm  
Texan D - 4th Level**



**NRG Oncology Semiannual Meeting**  
**January 2020**

# NRG Scientific Committees

## Brain Tumor Workshop

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### AGENDA:

#### 1. Ongoing Studies:

	STUDY	NAME	DX	START	N	COMMENTS
1	BN 001	Hypofractionated Dose escalated Photon IMRT or PBT vs Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide	nGBM	10/14	Photon: 302/288; 41/30 for advanced imaging Proton: 188/288	IIR: Mehta/Gondi; photon arm accrued. Proton arm projected to close Jun 2021
2	BN 003	Meningioma RT vs Obs	Menin	6/17	68/133	Rogers; Aug 2021 closure
3	BN 005	LGG Photons vs Protons	LGG	8/17	25/120	Grosshans; Nov 2025 closure
4	CC 003	Phase II/III PCI WBRT +/- HA	SCLC PCI	12/15	172/172 and ?/132	Gondi: P2 accrued; P3 accruing

	STUDY	NAME	DX	START	N	COMMENTS
5	1071	NCCTG N0577/Endorsed Study: Phase III CODEL PFS endpoint. RT/PCV vs RT/TMZ, NI P3 study	G2/3 Glios	9/09	172/360	Vogelbaum; 60 from NRG
6	CCTG CE.7	SRS vs. HA-WBRT	BM		11/206	Roberge/Gondi
7	Alliance A071401	Meningioma targeted agents, 3 arms (SMO, AKT, NF2)	Menin	8/15	40/56	Brastianos; 3 from NRG
8	Alliance A071601	BRAF/MEK	Cranio	8/15	11/32	Brastianos
9	Alliance A071801	Phase III SRS vs. SRT	Postop BM		?/208	Brown
10.	EAF151	Imaging	GBM		43/165	Tsien

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

**3. Studies Activating soon:**

	STUDY	NAME	DX	START	N	COMMENTS
1	BN 006	Phase II/III Toca511	GBM	02/20	312	Ahluwalia
2.	BN 007	PII/III Ipi/Nivo	GBM			Lassman
3.	BN 008	ONC 201 for H3K27M Glioma	Glioma			Odia

## Breast Cancer Workshop Agenda

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

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

11:15 – 11:45

**Immunotherapy Trials**

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

Charles Geyer, Jr., MD

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

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

Eleftherios Mamounas, MD

11:45 – 12:00

**NRG BR003** A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Weekly Carboplatin in Women with Node-Positive or High-Risk Node-Negative Triple Negative Invasive Breast Cancer

Vicente Valero, MD

## Breast Cancer Rare and Genetically Linked Subcommittee Workshop

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

<b>8:00 - 8:05</b>	BR1901 (Metaplastic) Update	<b>Alexandra Thomas, MD</b>
<b>8:05 - 8:35</b>	NF1 and Breast Cancer	<b>Matthew Ellis, MB BChir, PhD</b>
<b>8:35 - 8:45</b>	Phyllodes/Indolent Rare Breast Tumors Concept	<b>Karen Daily, DO</b> <b>Simona Shaitelmann, MD</b>
<b>8:45 – 9:00</b>	Committee Discussion <ul style="list-style-type: none"><li>• New trial proposals</li><li>• July 2020 meeting speaker suggestions</li></ul>	<b>Alexandra Thomas, MD</b> <b>Karen Daily, DO</b>

## NRG Protocol Workshop: NRG-BR003 NRG-BR004

**Date:** Friday, January 10, 2020

**Start and End Time:** 1:00 pm – 2:00 pm

### Learning Objectives

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

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

### WORKSHOP AGENDA

<b>1:00-1:15</b>	Overview of NRG-BR004 A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer	Priya Rastogi, MD
<b>1:15-1:30</b>	Clinical Logistics	Mary Pat Matisko, RN, BSN
<b>1:30-1:40</b>	Overview of NRG-BR003 A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel With or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Breast Cancer	Kristen Kotsko, RN, BSN
<b>1:40-1:50</b>	Clinical Logistics	Kristen Kotsko RN, BSN
<b>1:50-1:55</b>	Questions/Discussion	
<b>1:55-2:00</b>	Evaluation	

## Cancer Prevention and Control Workshop

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

### NRG CPC Committee Workshop

#### Learning Objectives

Following this activity, participants will be better able to:

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

#### A. NRG-CC008 Kick off meeting – Douglas Levine, MD

#### B. Introduction & Review of Committee Aims

#### C. Review of Open Studies:

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

#### D. Review of Approved Concepts & Protocols in Development:

- **NRG-CC005:** FORTE – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (R. Schoen)
- **NRG-CC1925:** Adaptive Intervention for Smoking Cessation in Women with Breast, Cervical, Endometrial and Vaginal Cancer prior to Radiation Therapy (T. Crane)
- **NRG-CC1928:** Utility of Gonadotropin-releasing Hormone Agonists (GnRHa) to Protect Ovarian Reserve for Women Undergoing Chemotherapy (H. Burks)
- **Surgery and Chemotherapy vs. Chemotherapy Alone as Primary Treatment for Older Women with Advanced Staged Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Carcinomas (A. Ahmed)**
- **NRG-CC1974:** Stereotactic Radiosurgery (SRS) Versus Hippocampal-avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer (V. Gondì, C. Rusthoven)
- **Impact of Sentinel Lymph Node Mapping on Lymphedema Associated Impairment of Health Related Quality of Life in Endometrial Cancer (E. Tanner)**

#### E. Other Updates

- C. Xiao and K. Sturgeon – Pilot project update/report

## Cancer Care Delivery Research (CCDR) Workshop Agenda

**Date:** Friday, January 10, 2020

**Start and End Time:** 1:00pm – 2:30pm

**Co-Chair:** Mary Cooley, PhD, RN

**Co-Chair:** Matthew F. Hudson, PhD, MPH

**Call-in number:** 1-866-670-5102, Passcode: 374778#

### Learning Objectives

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

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

### WORKSHOP AGENDA

### SPEAKERS

#### Session I

- |  |  |
|--|--|
| A. Welcome and Committee Updates/Information   | Mary Cooley, PhD; Matthew Hudson, PhD  |
| B. Emerging Concepts   | Mary Cooley, PhD; Matthew Hudson, PhD  |
| C. Update on CCDR Pilot Awards   |  |
| a. PROTECT: Patient Reported Outcomes to Enhance Care on Treatment   | Alexi Wright, MD                       |
| b. Physical Activity Monitoring to Predict Hospitalization in Advanced Cancer Patients   | Nitin Ohri, MD                         |
| c. Rurality, neighborhood socioeconomic and environmental deprivation and patient-reported outcomes for men with cancer in RTOG 0415             | Jinbing Bai, PhD, MSN, RN              |
| D. NCI CCDR updates  | Kate Castro, RN & Ann Geiger, MPH, PhD |
| E. Discuss symposium for the July meeting related to CCDR research; preparing applications from concept to implementation.                       | Mary Cooley, PhD                       |
| F. NRG-CC007CD: "Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy" Update | Ron Chen, MD, MPH                      |

### QUESTIONS / DISCUSSION

## GYN Developmental Therapeutics/Phase I/Translational Science Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

#### Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

Discussion Topic - Current priorities of the Committee

2:00 PM – 2:05 PM	Introduction, Drs. O’Cearbhaill and Birrer. Welcome. Review of opportunities for new investigators.
2:05 PM – 2:10 PM	Update on concepts from last meeting, Dr Backes: PI1915 Dr. Moxley, DT1951 Hensley, DT 1959 Hensley, DT 1953 Mahdi, DT1955 Geller, DT 1958 Gaillard, PI1966 Simpkins.
2:10 PM – 2:25 PM	How to write a successful LOI, Charles Kunos, MD, PhD, Medical Officer and Coordinator, Investigational Therapeutics & Radiation, Investigational Drug Branch, CTEP
2:25 PM – 3:50 PM	Review of new concepts <ul style="list-style-type: none"><li>• 5-minute presentation of concept (by proposing investigator)</li><li>• Review of concepts</li></ul>
3:50 PM – 4:00 PM	ComboMATCH study and discussion by committee of potential concepts, Dr. O’Cearbhaill (NRG Representative for the ComboMATCH study).

Concepts Approved from last meeting:

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

New Concepts:

**QUESTIONS / DISCUSSION:**

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

## GYN Developmental Therapeutics/Phase I Workshop

**Date:** Saturday, January 11, 2020  
**Start and End Time:** 8:00 AM – 9:00 AM  
**Chair:** Roisin O’Cearbhaill, MD (Developmental Therapeutics)  
**Translational Research Chair:** Panagiotis Konstantinopoulos, MD, PhD (Developmental Therapeutics)  
**Co-Chairs:** Floor Backes, MD (Phase II), Russell Schilder, MD (Phase I);  
Stephanie Gaillard, MD, PhD (Phase I)

### Learning Objectives:

Following this activity, participants will be better able to:

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

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

**8:00 AM - 9:00 AM** Russell Schilder, MD (Phase I); Stephanie Gaillard, MD, PhD (Phase I)

- Active
- Studies under development
- Closed studies
- New concepts: 5-minute presentation of concept (by proposing investigator)
- Review of concepts
- Discussion of Phase I Membership application and the Phase I Program Procedure Manual.

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

**8:45 AM – 9:00 AM** Floor Backes, MD

- Active
- Studies under development
- Closed studies
- New concepts

### List of Studies

#### Under development:

- **NRG-GY022** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Taylor/ Beumer)
- **PI1915** A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Moxley)
- **NRG- GY021** A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Adams) safety lead-in
- **PI1966**, A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Simpkins)

- **DT1959**, Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Hensley)
- **DT1958**, Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Gaillard)
- **DT1953**, Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ serous endometrial cancers (Mahdi)
- **DT1951**, Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Hensley)

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

##### **Cervical Cancer Studies:**

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

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

##### **Ovarian Cancer and Endometrial cancer studies:**

- **NRG-GY014** A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid/clear cell carcinoma of the ovary, and recurrent endometrioid endometrial adenocarcinoma (R Eskander) CTEP CRDL LOI. First stage completed accrual August 2019

##### **Ovarian Cancer Studies (prior safety lead-in):**

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

#### **Closed DT/Phase I studies:**

##### **Cervical Cancer**

- **9926** A phase I evaluation of extended field radiation therapy with concomitant cisplatin chemotherapy followed by paclitaxel and carboplatin chemotherapy in women with cervical carcinoma metastatic to the para-aortic lymph nodes (C Boardman) Gyn Onc 2018
- **9929** A phase I trial of sequential ipilimumab after chemoradiation for the primary treatment of patients with locally advanced cervical cancer stages IB2/IIA with positive para-aortic lymph nodes only and stage IIB/IIIB/IVA with positive lymph nodes (J Mayadev/R Schilder) CTEP/CRDL. ASCO 2017 JAMA Onc 2019
- **NRG-GY002** A phase II evaluation of nivolumab, a fully human antibody against PD-1, in the treatment of persistent or recurrent cervical cancer (A Santin) ASCO 2018 (A Santin) manuscript submitted
- **265** A phase II evaluation of ADXS11-001 in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix (W Huh) Safety lead in performed by Phase I subcommittee - completed. ASCO 2016 (Stage 1 of Phase II). SGO 2017

### Endometrial Cancer Studies:

- **2290** A randomized phase II study with a safety lead-in to assess the antitumor efficacy of the MEK inhibitor trametinib alone or in combination with GSK2141795, an AKT inhibitor, in patients with recurrent or persistent endometrial cancer (S Westin) Closed after safety lead in. CTEP/CRDL. SGO 2016. Gyn Onc 2019
- **NRG-GY011**, A Randomized Surgical Window Pilot Investigation of the Relationship of Short Term Medroxyprogesterone Acetate Compared to Medroxyprogesterone Acetate Plus Entinostat on the Morphologic, Biochemical, and Molecular Changes in Primary Endometrioid Adenocarcinoma of the Uterine Corpus (Linda Duska)
- **NRG-GY008** A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA mutations (A Santin) manuscript submitted

### Ovarian Cancer Studies

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

### QUESTIONS/DISCUSSION/EVALUATION

## Gastrointestinal Cancer Committee Workshop Agenda

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

Time	Discussion/Study Information	Speaker
1:00PM	Introduction and Opening Remarks	Christopher Crane, MD Thomas George, MD
1:05PM	<b>CRC SUBCOMMITTEE – Review of Upcoming Trials</b>	Thomas George, MD
1:15PM	<b>Active CRC Studies</b>	
	<b>NRG-GI002</b> TNT Trial	Thomas George, MD
	<b>S0820 (PACES)</b> Eflornithine & <i>Sulindac</i> for polyp prevention after CRC	Jenny Dorth, MD
	<b>NRG-GI005</b> cfDNA as a decision tool for stage II colon cancer treatment	Kyle Van Morris, MD
	<b>A021502 (ATOMIC)</b> MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab	Asha Dhanarajan, MD
	<b>NRG-GI004/S1610 (COMMIT)</b> MSI-H mCRC 1L Immunotherapy Study	Caio Rocha Lima, MD
	<b>SOLARIS</b> Vitamin D supplementation in untreated mCRC	Christina Wu, MD
	<b>S1613</b> HER2 Amplified mCRC Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan	Marwan Fakih, MD
	NCTN Portfolio of NET Studies	Heloisa Soares, MD Walid Shaib, MD
2:00PM	<b>NON-CRC SUBCOMMITTEE</b>	
	<b>Active Studies</b>	
	<b>RTOG 1112</b> Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma	Laura Dawson, MD
	<b>NRG GI003</b> Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma	Ted Hong, MD
	<b>EA2165</b> Nivolumab after Combined Modality Therapy in Treating Patients with High Risk Stage II-III B Anal Cancer	Paul Romesser, MD

2:20PM	<b>S1815</b>	A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers	Khalid Matin, MD
	<b>Review of Upcoming Trials</b>		
	<b>NRG GI1426</b>	Phase III Randomized Trial of Protons vs. Photons for Esophageal Carcinoma	Steven Lin, MD
	<b>NRG 1824</b>	Phase I trial of chemoradiation and telomolysin for inoperable esophageal and GEJ ACA	Geoff Ku, MD
	<b>NRG GI1976</b>	GI1976 (1862) G.Ku RPh II study of tislelizumab and chemoradiation followed by adjuvant tislelizumab in PET chemotherapy locally advanced esophageal squamous	Geoff Ku, MD
	<b>NRG XXX</b>	Ablative RT +/- checkpoint inhibition in IHCC	Ted Hong, MD
	<b>S1922</b>	Randomized Phase II Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma	Mohamed Salem, MD

## NRG Oncology Protocols GI004/GI002/GI005 Workshop

**Date:** Friday, January 10, 2020

**Start and End Time:** 2:00 pm - 3:00 pm

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

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

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

### WORKSHOP AGENDA

#### NRG-GI004/SWOG-S1610

**Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study:**

**A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer**

*and*

#### NRG-GI002

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

*and*

#### NRG-GI005

**Phase II/III Study of Circulating Tumor DNA as a Predictive Biomarker in Adjuvant Chemotherapy in Patients with Stage IIA Colon Cancer (COBRA)**

2:00 pm – 2:20 pm	Overview of GI004	Caio Max S. Rocha Lima, MD
2:20 pm – 2:30 pm	GI002 Update	Thomas George, MD, FACP
2:30 pm – 2:50 pm	Overview of GI005	Van Morris, MD
2:50 pm – 3:00 pm	Question and Answer	

## Genitourinary Cancer Workshop Agenda

**Date:** Saturday, January 11, 2020  
**Start and End Time:** 8:00 am – 10:00 am  
**Chair:** Felix Feng, MD  
**Co-Chairs:** Jason Efstathiou, MD; Leonard Gomella, 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

**8:00 – 8:05**      **Opening Remarks and Update**

**8:05 – 8:45**      **Review of Active Trials**

NRG GU002	PhII-III Adjuvant RT Following Radical Prostatectomy ± Adjuvant Docetaxel	Mark Hurwitz, MD
NRG GU005	Phase III IGRT & SBRT vs. IGRT & Hypofrax IMRT localized prostate cancer	Rod Ellis, MD
NRG GU006	Phase IIR biomarker stratified trial with a lead in to phase III testing the benefit of salvage RT +/- apalutamide in patients with a low PSA pre-treatment.	Dan Spratt, MD
NRG GU007	Phase I/IIR of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer	Zach Zumsteg, MD
RTOG 3506	Randomized Phase II Trial of Salvage Radiotherapy With Std vs Enhanced ADT (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features	Edwin Posadas, MD Hiram Gay, MD
SWOG/NRG 1806	Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer	Jason Efstathiou, MD
SWOG 1802	Local therapy for M1 prostate cancer, a SWOG study	Richard Valicenti, MD

AGCT 1531	Phase III Study of Active Surveillance for Low Risk and A Randomized Trial of Carboplatin vs Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumours	Allan Covens, MD
<b>8:45 – 9:35      Review of Pending Studies</b>		
NRG GU008 (formerly GU1817)	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
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
NRG 1864 (developing concept)	Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with High Genomic Risk	Paul Nguyen, MD; Oliver Sartor, MD
Alliance/ NRG (concept # TBD)	Phase III Trial of Androgen Deprivation Therapy and Abiraterone/Prednisone Alone or with 177Lu-PSMA-617 in Castration Sensitive Metastatic Prostate Cancer (mCSPC)	Oliver Sartor, MD
<b>9:35 – 9:55      Other issues</b>		
Translational Research Medical Oncology Update Urology Update New Business		Phuoc Tran, MD PhD Oliver Sartor, MD Leonard G. Gomella, MD Group
<b>9:55 – 10:00      Closing Remarks</b>		

## Cervix Workshop Agenda

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

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

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

### Learning Objectives:

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

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

### WORKSHOP AGENDA

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

- A. Introduction (10:00 – 10:10)
  - a. Welcome, committee membership and rotation plan and review of July 2019 minutes
- B. Scientific updates (10:10 – 10:45)
  - a) HPV related cancers: lessons from Head and Neck ca: Dr. Maura Gillison, MD, PhD
  - b) Early Stage Cervical Cancer Surgical Mgmt and International Collaboration: Pedro Ramirez, MD
  - c) Non-CTEP Relevant Cervical Cancer Trials
    - a. GCIG (Dr. David Gaffney)
    - b. GOG Partners (Dr. Leslie Randall)
  - d) Previously committee approved/reviewed concepts – current updates and future directions
    - o CV1922 (Ritu Salani): PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer
    - o CV1923 (Brian Slomovitch) : GROINS V3
    - o UC1963: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)
    - o **PI1915** A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley) **CTEP IND**

C. **New proposed concepts**

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

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

D. **Closed Studies**

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

E. **Active / Recently Completed Trials**

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

- iv. Accrual 36/52 total (69.2%)
- g. **NRG-GY006:** A randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, stage II, IIIB, or IVA Cancer of the uterine cervix or Stage II-IVA vaginal cancer. (Trey Leath, Loren Mell)
  - i. Opened January 15, 2016
  - ii. Accrual 101/188 (53.7%)
  - iii. Amendment to CTEP re: increase in accrual size and transition to Randomized phase 3
- h. **NRG-GY017:** Phase I trial using anti PD-L1 (atezolizumab) as immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer. (Jyoti Mayadev)
  - Opened October 26, 2018

#### Reports from Other Committees and Groups

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

Next Semi-Annual Meeting

## QUESTIONS / DISCUSSION

## Gynecologic Cancer Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

#### I. General Business

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

#### II. Committee Descriptions

##### Gynecologic Cancer Committee

##### **Cervix/Vulvar Cancer Subcommittee**

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

##### **Ovarian Cancer Subcommittee**

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

##### **Rare Tumor Subcommittee**

- Clear Cell Tumors
- Germ Cell Tumors
- Ovarian - Low Grade Serous
- Ovarian - Mucinous
- Ovarian - Stromal Tumors
- Vulvar/Vaginal Melanoma

##### **Uterine Corpus Cancer Subcommittee**

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

#### GYN Developmental Therapeutics Committee

- Early phase trials, Window of opportunity trials
  - Cervical cancer
  - Endometrial cancer
  - Ovarian cancer
  - Uterine sarcoma

#### GYN Phase I Subcommittee

- Safety lead-ins
- Phase I

#### Other NCTN Group Trials & Study Champions

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

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

**NRG Oncology Study Champion: Covens**

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

**NRG Oncology Study Champion: Covens**

**EAE161**, Perfusion CT to Predict Progression-free Survival and Response Rate in Bevacizumab and Paclitaxel Treatment of Platinum-Resistant, Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Peritoneal Carcinoma. ECOG-ACRIN Study Available to Alliance, NRG, SWOG

Temporarily closed to accrual 3/20/2019

**NRG Oncology Study Champions: Mannel/Schilder**

### III. Cervix/Vulvar Cancer Subcommittee

#### New Concepts

##### **a.**

- **CV2005**: A Phase II Study of Combined chemo-immunotherapy with cisplatin-pembrolizumab and radiation for unresectable vulvar squamous cell carcinoma (Olapado Yeku)
- **UC1963**: A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

#### Studies Under Development

- a. CV1912**, Phase II study of nelfinavir and chemoradiotherapy for locally advanced vulvar cancer (Lilie Lin)
- b. CV1922**, PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer (Ritu Salani)
- c. CV1923**, GROINS V3
- d. CV1962**, FIGO 2018 stage 1B2 ( $\geq 2\text{cm}$  -  $< 4\text{ cm}$ ) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (CoNteSSa) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F) (Allan Covens/Lauren Cobb)
- e. CV1964**, Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (Scott Glaser)

#### *Active Studies:*

- a. RTOG-0724**, Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy (Anuja Jhingran)
- b. GOG-0263**, Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Sang Young Ryu)
- c. GOG-0279**, A Phase II Trial Evaluating Cisplatin and Gemcitabine Concurrent with Intensity-Modulated Radiation Therapy (IMRT) for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva (Neil S Horowitz)
- d. NRG-GY006**, A Randomized Phase III Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer (Charles Leath)

#### Rare Tumor Subcommittee – Mucosal Melanoma

##### Studies Under Development

- a. DT1822**, A Randomized Phase II Trial of Adjuvant nivolumab with or without cabozantinib in patients with resected mucosal melanoma (Danielle Vicus) – Alliance lead group

#### GYN Developmental Therapeutics Committee - Cervical Cancer

1. **DT2010**: Phase II study of dasatinib in recurrent low grade endometrial stromal sarcoma (Lilian Gien)  
**DT2013**: CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corrine Doll)

#### Studies Under Development

- 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)

#### *Active Studies:*

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

#### NCORP

#### *Active Studies:*

- 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)

*Closed Studies (Primary manuscript NOT published):* 270 (GROINSS-V), THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174), 265, GY002

#### *Terminations:*

### **IV. Ovarian Cancer Subcommittee**

#### **New Concepts**

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

#### Studies Under Development

- a. **OV1838/1839**, Copanlisib and Olaparib (Panagiotis Konstantinopoulos)
- b. **OV1913**, A randomized phase II trial of triplet therapy (PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy with olaparib/cediranib or durvalumab/cediranib in women with platinum resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung-Min Lee)
- c. **OV1954**, Maintenance therapy after platinum based treatment of platinum sensitive recurrence in patients who received PARP inhibitor maintenance after upfront therapy (John Nakayama)
- d. **OV1960**, HIPEC

*Active Studies:*

- a. **NRG-GY005**, A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS). (Jung-Min Lee)
- b. **NRG-GY007**, A Phase I/II Study of Ruxolitinib with Front-Line Neoadjuvant and Post-Surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer. (Robert Burger)
- c. **NRG-GY009**, A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer. (Roisin O’Cearbhaill)
- d. **NRG-GY021**, A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Sarah Adams)

Rare Tumor Subcommittee

New Concepts

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

Studies Under Development

- a. **RT1849**, A phase II trial of durvalumab and cediranib in recurrent ovarian sex cord stromal tumors (Danielle Vicus)
- b. **RT1969**, A phase II trial of nivolumab, ipilimumab with sargramostim for recurrent clear cell ovarian cancer (Danielle Vicus)

*Active Studies:*

- a. **GOG-0264**, A Randomized Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide and Cisplatin for Newly Diagnosed Advanced Stage and Recurrent Chemo-Naive Sex Cord-Stromal Tumors of the Ovary. (Jubilee Brown)
- b. **NRG-GY016**, Randomized phase II evaluation pembrolizumab + epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
- c. **NRG-GY019**, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum. (Amanda Fader)

GYN Developmental Therapeutics Committee - Ovarian Cancer

New Concepts

- a. **OV2008**: A Randomized Phase II trial of PARPi combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)
- b. **PI2014**: A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)

Studies Under Development

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

*Active Studies:*

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

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

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

*\*patient on active treatment*

*Terminations:* 218, 255

## V. **Uterine Corpus Cancer Subcommittee**

### New Concepts

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

### Studies Under Development

- a. **UC1731**, Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study. (Katarzyna Jerzak/Helen Mackay/Linda Duska)
- b. **NRG-GY020**, Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer. (Floor Backes)
- c. **UC1926**, Randomized phase II trial of adjuvant therapy with either paclitaxel/carboplatin or everolimus/letrozole in stage III endometrial cancer with no residual disease. (Brian Slomovitz)
- d. **UC1963**, A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

*Active Studies:*

- a. **GOG-0238**, A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus. (Jonathan Micha Feddock)

- b. **NRG-GY012**, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay)
- c. **NRG-GY018**, A randomized phase III Placebo-Controlled Study of Pembrolizumab in addition to Paclitaxel and Carboplatin for Measurable Stage III Or IVA, Stage IVB or Recurrent Endometrial Cancer. (Ramez Eskander)

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

##### New Concepts

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

##### Studies Under Development

- a. **DT1951**, Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Martee Hensley)
- b. **DT1959**, Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Martee Hensley)
- c. **DT1953**, Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) in HER2+ serous endometrial cancers (Haider Mahdi)
- d. **DT1958**, Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Stephanie Gaillard)

##### Active Studies:

- a.

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

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

\*patient on active treatment

*Terminations:* 210

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

##### Studies Under Development

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

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

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

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

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

#### **QUESTIONS / DISCUSSION**

## Ovarian Workshop Agenda

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

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

#### A. Introduction

- Review of learning objectives
  - Statements regarding potential conflict of interest
  - Committee membership updates
- 

#### B. Summary of Key Discussion Items (from this Agenda)

- Discussion of biomarkers in Gyn cancers C. Aghajanian /H. Lankes
  - Discussion of molecular selection in ovarian cancer and impact on clinical trials/ TBD
- 

#### C. Review of Closed Studies (not-terminated)

- GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
- GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman).
- GOG0218 A Phase III trial of carboplatin and paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent bevacizumab (NSC #704865, IND #7921) followed by placebo, versus carboplatin and paclitaxel plus concurrent and extended bevacizumab, in women with newly diagnosed, previously untreated, stage III and IV epithelial ovarian, primary peritoneal or fallopian tube cancer (Robert A Burger).

- GOG0252 Phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma (Joan L Walker)
- GOG0262 A randomized phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III or IV epithelial ovarian, peritoneal or fallopian tube cancer (John K Chan)
- GOG0273 Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen) Modified dose dense cohort manuscript in draft form.
- GOG3001 A phase 3 randomized, double-blind, placebo-controlled, multi-center study of AMG 386 with paclitaxel and carboplatin as first-line treatment of subjects with FIGO stage III-IV epithelial ovarian, primary peritoneal or fallopian tube cancers (Amgen TRINOVA-3 NCT01493505) (Bradley J Monk)
- GOG3004 (SOLO1) A phase III, randomised, double blind, placebo controlled, multicentre study of olaparib maintenance monotherapy in patients with BRCA mutated advanced (FIGO stage III-IV) ovarian cancer following first line platinum based chemotherapy. (Paul A DiSilvestro and Kathleen Moore). Manuscript Oct 2018
- GOG3005 (AbbVie Study No.: M13-694) A Phase 3 Placebo-Controlled Study of Carboplatin/Paclitaxel With or Without Concurrent and Continuation Maintenance Veliparib (PARP inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Rob Coleman). NEJM manuscript Oct 2019
- NRG-GY003 Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (Bob Burger) Presented IGCS 2018/manuscript submitted
- GOG0281 RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson). Presented at IGCS 2019

#### D. Review of Active Studies (all metrics are as of 11/2019)

- GOG0264 RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Jubilee Brown)
  - Activated 08FEB2010
  - Enrollment 58/128 (as of 11/19)
  - 1 event short of interim analysis
- NRG-GY004 Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Joyce Liu and Ursula Matulonis). Expanded overall accrual to 550 patients, closed to accrual 10-NOV-2017
  - Primary analysis expected Q1-2 2020
- NRG-GY005: A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory

Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Jung-Min Lee and Angeles Alvarez Secord)

- Suspended 17JUN2017 (n = 213) for analysis of randomized phase II component
  - Re-opened to phase 3 without monotherapy olaparib arm 12/17/2018
  - Reminder to sites regarding completion of scheduled QOL assessments
  - Enrollment 362/562
  - Discussion of feasibility given anticipated approval of PARPi beyond BRCA in front line? (Mike Sill/Jung Min Lee/Angeles Alvarez Secord)
- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer. Activated for Phase I accrual. (Robert A Burger)
  - 122/147
  - Discussion of impact of cross over to PARPi maintenance among patients completing chemotherapy proximal to new approvals? Do we need a similar amendment to what was done for BRCA associated cancers? (M Sill/Burger)
- NRG-GY009 A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Roisin O’Cearbhaill, Carol Aghajanian).
  - Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
  - Second-stage safety lead-in (all three arms) opened 14NOV2017
  - Group-wide activation 6/18/2018
  - Suspended at the end of phase 2 (May 2019)
- NRG-GY014 (DT1718) A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. (Ramez Eskander and David Hyman)
  - Activated 4/2019
  - Suspended 8/2019
- NRG-GY016 - phase 2 pembrolizumab + epacadostat (IDO inhibitor) in recurrent clear cell of the ovary (L Gien)
  - Activated Oct 2018/suspended for first phase accrual completion 4/2019
  - Amendment pending
- 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
  - 5/450
- NRG-GY021 Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams)
  - Activated Oct, 12 2019
  - Safety call will be coordinated through DT committee

- NRG-GY022 (DT1833): Assessment of carboplatin clearance predictors: PK protocol to allow for extra sample collection and collection of demographic data, laboratory values, and outcome data. (Liz Villaruz/Jan Beumer) GYN Cancer Committee: 7/14/18
  - Activated 11/2019
- AGCT1531 (RT1205) Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, AI Covens NRG)
  - Activated group-wide 30MAY2017
  - 254/1680

#### Ovarian Cancer Subcommittee

##### E. Review of Approved Concepts under Development

- OV1838/OV1839 PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib vs Standard Chemotherapy in Patients with Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos) LOI submitted 10/2018
  - Submitted to OTF 11/20 for Dec review
- OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (R Arend/ M Birrer/ K Moore)
  - Concept submitted 11/2018
  - Ovarian Cancer task force review 12/18/18
- OV1913 A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) vs doublet therapy (durvalumab and cediranib) in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung Min Lee)
  - Approved by GCSC 9/19; awaiting confirmation of drug supply
- **OV1954** Treatment of platinum sensitive recurrence in BRCA mutated patients with olaparib with or without cediranib maintenance after upfront treatment with olaparib maintenance therapy. (Nakayama)
  - Needs to be re-presented to committee
- OV1960 A phase III randomized trial of heated intraperitoneal chemotherapy (HIPEC) with cisplatin at the time of interval cytoreductive surgery versus intravenous chemotherapy only followed by niraparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer. (Crispens)
  - Submitted to OTF 11/20 for 12/2019 meeting
- DT1955: : N-803 and Durva recurr EOC, tubal and primary peritoneal (M Geller)
  - For RSC 10/29/19
- DT1907: Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial, fallopian tube and primary peritoneal cancer- (Floor Backes)

- On hold until Merck review received. If approved by Merck, RSC July 20, 2019
- P11966: Wee1 + ATRi in CCNE1 amplified ovarian and endometrial (Simpkins)
  - For RSC 10/29/19
- RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus) LOI. RSC review Feb '19
  - RSCX 3/5/19
  - Awaiting submission of LOI pending feedback from CTEP
- RT1906: A randomized Phase II/III trial of chemotherapy versus pembrolizumab versus radiation therapy in the treatment of Stage IC 2,3 and II Ovarian or fallopian tube Clear Cell Carcinoma (John Farley)
  - Administratively disapproved due to feasibility
- RT1969: Nivolumab, Ipilimumab, Sargramostim in recurrent clear cell ovarian cancer (Vicus)
  - RSCX 11/25/19
- NRG-CC008 (CC1923) (NC1427) (CPC1206) A non-randomized prospective clinical trial comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers (SOROC) (Doug Levine). Submitted for NCORP review. Submitted to DCP

#### F. Review of **New Concepts** and Future Request for Proposals

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

## QUESTIONS / DISCUSSION

## Rare Tumor Workshop

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

#### Session I

##### A. Closed Studies

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

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

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

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

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

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

NRG-GY001: A Phase II Trial of Cabozantinib in Women with Recurrent Clear Cell Carcinoma of the Ovary, Fallopian Tube, or Peritoneum (Farley)

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

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

**B. Presentation:**

**C. Active Studies**

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

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

CLEE011XUS5IT: Phase II trial of letrozole + Ribociclib for women with recurrent low-grade serous carcinoma. (Slomovitz) **GOG Partners**

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

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

**D. Proposed Studies/in development**

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

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

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

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

**E. New concepts**

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

**F. Discussion Topics:**

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

**QUESTIONS / DISCUSSION**

## Uterine Corpus Workshop

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

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

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### NOTE:

GTN subcommittee: FRIDAY 12:00-1:00 (Lead Neil Horowitz, MD)

GOG 210 Subcommittee: FRIDAY 8:00-9:00 (Lead David Mutch, MD)

### Workshop Agenda

- A. Introduction (Powell):
- B. Review of Closed Studies [Sat AM Session]

1. **GOG0188:** Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [[Gynecol Oncol 120\(2\): 185-8, 2011](#)]:
2. **GOG0209:** A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer (**David Scott Miller to discuss**) [[Gynecol Oncol 125: 771-3, 2012](#)] Submission
3. **GOG0210:** A Molecular Staging study of Endometrial Carcinoma (William T Creasman) : **Mutch in separate report**
4. **GOG0249:** Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy [doi:10.1016/j.ygyno.2014.07.078](#): Accepted JCO
5. **GOG0258:** A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma. (Daniela Matei)
6. **GOG0261:** A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus
7. **GOG0275** A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia (**Julian C Schink to discuss**)

8. [GOG0286B](#) A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (**Victoria L Bae-Jump to discuss**)
9. **NRG-GY008**: A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA and PIK3R1/R2 mutations (A Santin) ; **Manuscript in development; (Backes to discuss)**
10. **NRG-GY011** (UC1406): A Randomized Surgical Window Pilot Investigation of the Relationship of Short Term Medroxyprogesterone Acetate (NSC #26386) Compared to Medroxyprogesterone Acetate Plus Entinostat (NSC #706995) on the Morphologic, Biochemical, and Molecular Changes in Primary Endometrioid Adenocarcinoma of the Uterine Corpus (**Duska to discuss**)

#### C. Review of Active Studies

##### 1. Endometrial Protocols:

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

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

##### 1. **GOG-0210**

- a. **UC0905**: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (**Mutch to discuss in 210 report**)
- b. **GOG-8032 (UC1102)**: A clinico-pathologic analysis of high-grade uterine carcinomas (grade 3 endometrioid, serous, and clear cell carcinoma) and carcinosarcomas from GOG-0210 (Richard Zaino/ Ian Hagemann):
- c. **GOG-8040 (UC1107)**: An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino/ Ian Hagemann):
2. **NRG TS008 (UC1601)**: Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black Women with Endometrioid Endometrial and Uterine Serous Cancer (**L. Maxwell to discuss**)
3. **NC1603**: Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (**Tanner to discuss**)
4. **UC1731** Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study (Jerzak/ Mackay/ **Duska to discuss**) **N: 120 Stat: Sill ; Await preliminary data from GY011 before submitting to GCSC. (Duska to discuss)**

5. **UC1844** Efficacy of immunotherapy with immune checkpoint inhibitors in patients with deficient mismatch repair system or POLE mutated advanced stage or recurrent endometrial carcinoma: A randomized phase II/III trial (Mahdi) **(Mahdi to discuss ) Rejected by GCSC**
6. **GY020 (UC1805)** Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Backes) **N: 168 (2:1 randomization). Stat: Sill (Backes to discuss)**
7. **GY022 (DT1833)** Assessment of carboplatin clearance predictors: a companion PK study to NCI-sponsored clinical trials or standard of care treatments using carboplatin **(Taylor/Beumer)N: 250 Stat: Miller (Backes to discuss)**
8. **UC1926:** Randomized Phase II Trial of Adjuvant Therapy with either Carboplatin/Paclitaxel or Everolimus/Letrozole in Stage III Endometrial Cancer with No Residual Disease **(Slomovitz to discuss)**
9. **UC1963** A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Chino).
10. **UC1968** Molecular classification-directed care in endometrial carcinoma: a prospective cohort study (Temkin) Move to NCORP/Health Disparities

#### E. Proposed studies:

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

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

#### G. New Business

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

## Head and Neck Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDAS

#### A. Actively Developing studies

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

#### B. Review on active studies (list below)

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

**D. CTG H&N Committee activities** John Waldron, MD

**E. Translational Research Program update**

Neal Hayes, MD

**F. Surgical subcommittee update**

Erich Sturgis, MD

**G. NCI Head and neck Steering Committee update**

Christine Chung, MD

**QUESTIONS / DISCUSSION****Actively accruing trials**

RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR)	Cristina Rodriguez
RTOG 1216	RT-cisplatin vs. RT-Docetaxel + Cetuximab vs. cisplatin + Atezolizumab for “high risk” resected HNSCC (Phase IIIR)	Julie Bauman; Paul Harari; David Rosenthal
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
RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong

**Recently completed trial**

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 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
RTOG 0920	Phase III IMRT/IGRT + cetuximab for “intermediate risk” resected HNSCC	Quynh-Thu Le

**ECOG trials**

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

## Lung Cancer Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### 4. Active Studies:

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

### QUESTIONS / DISCUSSION

**Lung Committee Core Agenda**  
**Saturday, January 11, 2020**  
**8-10am**

- |  |          |         |
|--|----------|---------|
| 1.) EGFR/ALK Oligomets TKI +/- LCT                         | (10 min) | Elamin  |
| 2.) PII in St III - RT dose/fractionation trial            | (20 min) | Higgins |
| 3.) NRG CC1974: SCLC brain mets; SRS vs HA-WBI             | (20 min) | Gondi   |
| 4.) PII in St III with safety run-in using N-803 after CRT | (20 min) | Lin     |
| 5.) Lung-MAP RadScopal                                     | (10 min) | Nguyen  |

## Patient Centered Outcomes Research (PCOR) Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

<b>4:00 – 4:30</b>	<b>Improving the Measurement of Individual and Group Change in FACIT-Fatigue in a Clinical Trial of Endometrial Cancer: an NRG Oncology Group/Gynecologic Oncology Group Study</b> Comments/Audience Q & A	David Cella, PhD
<b>4:30 – 4:45</b>	<b>PCOR Compliance Update</b> Comments/Audience Q & A	Ron Chen, MD
<b>4:45 – 4:55</b>	<b>Digital Health Update</b>	Adam Dicker, MD
<b>4:55 – 5:40</b>	<b>Concepts in Development</b>  <b>Protocols in Development</b>	Patricia Ganz, MD Lari Wenzel, PhD
<b>5:40 – 5:50</b>	<b>NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates</b>	Patricia Ganz, MD Lari Wenzel, PhD Laura Havrilesky, MD Jason Efstathiou, MD
<b>5:50 – 6:00</b>	<b>Other Business</b>	Patricia Ganz, MD Lari Wenzel, PhD

**SARCOMA WORKING GROUP AGENDA**  
**DIAN WANG, M.D, PH.D., CHAIR**  
**Peter Houghton, Ph.D., TRP Liaison**  
**Friday, Jan 10, 2020**  
**7:30AM – 9:00AM**

**A. Active Studies**

1. Phase Ib Study To evaluate Neoadjuvant p53/MDM2 inhibitor combined with IMRT for Soft Tissue Sarcomas (Welliver/Wang)
2. MGH/NRG: Phase I/II Trial of Preoperative Intensity Modulated Radiation Therapy (IMRT) For Retroperitoneal Sarcoma using a Simultaneous Integrated Boost (DeLaney/Wang)

**B. New concept:**

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

**C. Developing Concepts:**

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

**D. Sarcoma TRP**

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

**E: New Business**

## Translational Science Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

4:00 – 4:05	Opening Remarks and Introduction	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD
4:05 – 4:20	CPTAC Updates	Matthew Ellis, MB, BCHIR, PhD (Baylor)
4:20 – 4:35	“Imaging & Informatics for Big Data in Multi-Site Trials: Innovation & Infrastructure”	David Fuller, MD, PhD (MD Anderson)
4:35 – 4:50	“High Immune Tolerance Associates with Poor Clinical Outcomes in Liminal Breast Cancer”	Meenakshi Anurag, Asst. Prof. (Baylor)
4:50 – 5:05	“Biomarker-Driven Patient Selection for Breast Cancer Immunotherapy”	Leisha Emens, MD, PhD (UPMC Hillman)
5:05 – 5:30	Closing Remarks and Discussion	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD

# Translational Science Brain Cancer Subcommittee and Low Grade Glioma Working Group

**Thursday January 9<sup>th</sup>, 2020**  
**Marriott Marquis, Houston, Texas**  
**5:30 PM – 8:00 PM**

## **Introduction**

**(Arnab Chakravarti, MD)**

- |                    |  |
|--------------------|--|
| <b>5:30 – 5:45</b> | <b>“The Utility of “Digital Twins” for Risk Stratification of CNS Malignancies”</b><br>(Sanjay Aneja, MD, Yale University)   |
| <b>5:45 – 6:00</b> | <b>“Identifying Genetic Risk Factors Using a SNP-Set Analysis of Genome-Wide Association Data- Example on ALS- Proposal for Gliomas”</b><br>(Prof. Dr. Pierre Robe, UMC Utrecht) |
| <b>6:00 – 6:15</b> | <b>“NFKBIA Haploinsufficiency in Diffuse Glioma”</b><br>(Markus Bredel, MD, PhD, University of Alabama at Birmingham)  |
| <b>6:30 – 6:45</b> | <b>“miRNAs and GBM: Biomarkers &amp; Mechanisms”</b><br>(Tiantian Cui, Ohio State University)  |
| <b>6:45 – 7:00</b> | <b>“Update of Correlative Endpoints within NRG/RTOG Low-Grad Glioma Trials”</b><br>(Erica Bell, PhD, Ohio State University)  |
| <b>7:00 – 7:15</b> | <b>“Assessing Circulating Tumor DNA in Pediatric Brain Tumors”</b><br>(Rameen Beroukhim, MD, PhD, Dana-Farber Cancer Institute)  |
| <b>7:15 – 7:30</b> | <b>“Update: Prognostic and Predictive RNA Biomarkers in NRG/RTOG 9802 &amp; 9813”</b><br>(Jessica Fleming, PhD, Ohio State University)   |
| <b>7:30 – 7:45</b> | <b>“Reconstruct Three-Dimensional Chromosome Structures of Low Grade Glioma Using Infinium 450K Methylation Array”</b><br>(Wei Weng, Ohio State University)                      |
| <b>7:45 – 8:00</b> | <b>Roundtable Discussions</b>  |

## Translational Science GYN Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

4:00-4:05	Opening Remarks Biospecimen Bank/Translational Science Update	Michael Birrer, MD, PhD Heather Lankes, PhD, MPH
	GYN Subcommittee Translational Science Updates <ul style="list-style-type: none"><li>• update on select trials approved at July 2019 meeting</li><li>• summary of disease site January 2020 concept review, including issues raised</li></ul>	
4:05-4:35	Ovarian Cancer Subcommittee  Rare Tumor Subcommittee	Rebecca Arend, MD Elizabeth Swisher, MD Gloria Huang, MD
4:35-5:05	Cervix/Vulva Cancer Subcommittee	Dmitriy Zamarin, MD
5:05-5:35	Uterine Corpus Cancer Subcommittee 210 Subcommittee	Doug Levine, MD David Mutch, MD
5:35-5:55 MD, PhD	GYN Developmental Therapeutics	Panagiotis Konstantinopoulos,
5:55-6:00	Closing Remarks	Michael Birrer, MD, PhD

### New Concepts:

- **CV2005:** A Phase II Study of Combined chemo-immunotherapy with cisplatin-pembrolizumab and radiation for unresectable vulvar squamous cell carcinoma (Olapado Yeku)
- **OV2008:** A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)

- **DT2010**: Phase II study of dasatinib in recurrent low grade endometrial stromal sarcoma (Lilian Gien)
- **DT2013**: CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corrine Doll)
- **UC2006**: Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer: Additional arm NRG-GY012 protocol (Haider Mahdi)

## Translational Science Lung Cancer Workshop Agenda

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

### Learning Objectives:

Following this activity, participants will be better able to:

1. Evolving Role of Radiotherapy in the Management of Lung Cancer in the Era of Immunotherapy.
2. Use of ICIs in Treating Stage III NSCLC.
3. Novel biomarkers and their model-building relevant to Lung Cancer.

### WORKSHOP AGENDA

**Intro/Overview:** Bo Lu, MD, PhD

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

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

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

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

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

### QUESTIONS / DISCUSSION

# Scientific Core Committees

## Health Disparities Committee

Friday, January 10, 2020

3pm-5pm

### Agenda

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

#### Welcome/Announcements

- HD committee membership update

#### HDC Research Concepts/Protocol Updates

##### Clinical Trial Enrollment

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

##### CPC Grants- HDC support for:

- CC005/FORTE
- CC008/Salpingectomy
- Other

##### NRG Communications Committee /Patient Engagement Working Group

- Website Patient Landing Pages
- Social Media
- NRG Member Communications

##### Education/Training/Mentorship

- HDC Workshop - July 2020 (Community Outreach/Engagement)

##### NRG Committee Reports - HDC Disease Site Liaisons

<u>Breast</u>	Eleanor Walker	(Alternate: Kathie-Ann Joseph)
<u>Brain</u>	Na Tosha Gatson	(Alternate: Marianne Matzo)
<u>GI</u>	Edith Mitchell	
<u>GU</u>	Mack Roach	(Alternate: Leon Hwang)
<u>Gyn-Ovarian</u>	Melissa Simon	(Alternate: Dana Chase)
<u>Gyn-Cervix</u>	Wendy Brewster	
<u>Gyn-Uterine</u>	Anuja Jhingran	(Alternate: Marianne Matzo, Kathleen Darcy)
<u>Head &amp; Neck</u>	Steven Chang	
<u>Rare Tumors</u>	Mary Scroggins	
<u>Lung (Thoracic)</u>	Tom Simon	
<u>Older Adult Working Group</u>	William Tew	
<u>Protocol Support Committee (PSC)</u>	Tiffany Elsea, Donna White	

##### NCORP Overview

- Cancer Prevention & Control (CPC)
- Cancer Care Delivery Research (CCDR)
- Patient Centered Outcomes Research (PCOR)

##### Other Business / Discussion

## Imaging Committee Meeting Agenda

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

### MEETING AGENDA

<b>12:30-12:35</b>	<b>Opening Remarks</b>	Dan Pryma, MD
<b>12:35-12:50</b>	<b>Report from IROC on Imaging QA in NRG trials</b>	Mark Rosen, MD
<b>12:50-1:00</b>	<b><u>Updates on Concepts near Development</u></b>	
	a. H&N	Rathan Subramanian, MD/ Min Yao, MD
	b. Brain	Tammy Benzinger, MD / Ashok Srinivasan, MD
	c. Breast	Heidi Umphrey, MD / Mohammad Eghtedari, MD
	d. Gyn	Katherine Maturen, MD / Aradhana Venkatesan, MD
	e. GI	Eric Tamm, MD
	f. GU	Ashesh Jani MD / Bill Hall, MD
	g. Lung	Michelle Ginsberg, MD
	h. Sarcoma	Dan Pryma, MD
<b>1:00-1:30</b>	<b>HN006: PET/CT, Sentinel lymphoscintigraphy with SPECT/CT and Radiomic Analyses</b>	Rathan Subramanian, MD
<b>1:35-1:50</b>	<b>Questions, comments, concerns &amp; suggestions</b>	Dan Pryma, MD
<b>1:50- 2:10</b>	<b>Discussion of BIQ for GU009 (GU1864)</b>	Ashesh Jani, MD
<b>2:10-2:30</b>	<b>Functional Imaging Correlates for LU1746</b>	Dr. Steven Lin, MD

## Medical Oncology Workshop

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

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

- |      |  |  |
|------|--|--|
| I.   | Introductions  | Corey Langer, MD;<br>Deborah Armstrong, MD |
| II.  | Pharmacy Subcommittee  | Judith Smith Pharm.D                       |
|      | A. Biosimilars – NRG Accommodations and Implications                     |  |
|      | B. Carboplatin Dosing Harmonization and Position Paper                   |  |
|      | C. Update on Protocol Drug Information Database/Forms and Review Process |  |
| III. | Marker Specific, Disease Agnostic FDA Approvals                          | Corey Langer, MD                           |
| IV.  | Combo MATCH  | Roisin O'cearbhaill, MD<br>Stu Wong, M     |
| V.   | I-MATCH  | Corey Langeer, MD                          |
| VI.  | Critical post-ASCO and ESMO updates                                      | Corey Langer, MD;<br>Deborah Armstrong, MD |
| VII. | Other business   | Corey Langer, MD<br>Deborah Armstrong, MD  |

### QUESTIONS / DISCUSSION

## Pharmacy Subcommittee Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

- I. Introduction **(2 min)**
  - a. Committee purpose and goals
- II. CE Presentation: “Integration of the FDA-Approved Biosimilars into Clinical Trials setting: benefits and limitations ”- Judith A. Smith, PharmD, BCOP, CPHQ **(25 min)**
- III. Update on Placebo position statement **(3 min)**
- IV. Planning to have updates from Disease State NRG Committee Meetings **(10 min)**
  - a. Approval of standardized pre-medications for chemotherapy templates
- V. Draft of Biosimilars Position/Policy review/discussion **(15 min)**
- VI. Updates for CTEP Pharmacy Team **(5 min)**
- VII. Action Items/Summary

### QUESTIONS / DISCUSSION

## Immunotherapy and Immune Modulation Committee Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### New Concepts for Review and discussion:

To be added

### Active Protocols:

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

### Recently Reviewed Immunotherapy Concepts:

- **LU005:** Limited stage small cell lung cancer: A phase II/III randomized study of chemoradiation versus chemoradiation plus anti PD-1 immunotherapy (PI: Kristin Higgins, MD and Helen Ross, MD)

*It activated on May 28<sup>th</sup> and ready to enroll*

- **GY018:** Prospective randomized phase 3 trial of carboplatin and paclitaxel with or without pembrolizumab in the treatment of primary advanced stage (3 or 4) or recurrent endometrial cancer (**Ramez N. Eskander, MD & Amanda N. Fader, MD**)  
*received final approval from CTEP and CIRB today, and it should be open and active to accrual shortly.*
- **GY021:** A randomized phase II trial of olaparib + tremelimumab vs platinum-based physician choice chemotherapy in HRD+ and HRD- platinum sensitive recurrent ovarian cancer (**PI: Sarah Adams, MD**) *CTEP approved and the NRG number is now GY021. Target activation 3Qtr2019. the study was submitted to CIRB last week. It was also selected for the CIMAC program for translational studies in collaboration with the MDACC team which I'm very happy about.*
- **DT1831:** A Phase II study of combination pegylated liposomal doxorubicin with durvalumab in women with microsatellite stable recurrent endometrial cancer (**PI: Bradley Corr MD**)  
*Protocol will not move forward*
- **UC1844** Efficacy of second line immunotherapy with dual checkpoint inhibitors (CPI) vs. monotherapy in patients with deficient mismatch repair system or POLE mutated recurrent endometrial carcinoma: A randomized phase II trial (**PI: Haider Mahdi, MD, MPH**)  
*Changed from a Phase 2 to a Phase 2/3 depending on the arm that is best in the phase II. Using Nivo in MSI EMCA. Discussion over whether this should be a bucket trial with other MSI tumors.*
- **NRG RT1849** (PI Danielle Vicus) A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors.  
*concept has successfully passed through RSC and a conf call with NCI is scheduled for next week*
- **NRG-DT1911** (PI Dmitriy Zamarin) A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with paclitaxel and carboplatin in patients with recurrent platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer.  
*the concept was approved by Research Strategy. Based on the feedback from the OTF and the overall lack of enthusiasm for nivolumab/carbo/taxol arm (based on negative data from Javelin 100), we decided to drop the arm. The trial has been modified to standard chemo+/- bev (or PARP maintenance per physician choice) vs. carbo/taxol/ipi/nivo. It is going for GCSC review next month. Keeping my fingers crossed.*
- **NRG-RT1906** (PI John Farley) A randomized Phase II/III trial of chemotherapy versus pembrolizumab versus radiation therapy in the treatment of Stage IC 2,3 and II Ovarian or fallopian tube Clear Cell Carcinoma  
*On hold*
- **BN1855:** Randomized Phase III Open Label Study of Ipilimumab and Nivolumab vs Temozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-methylguanine DNA Methyltransferase) Glioblastoma. (PI: Andrew Lassman)

Submitted to BMSC for Review on February 14, 2019 meeting.

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

NRG is aiming for March HNSC review.

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

Pending

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

Pending

- **UC1814:** A phase III randomized study of carboplatin, paclitaxel, atezolizumab, and bevacizumab plus atezolizumab and bevacizumab maintenance versus carboplatin, paclitaxel, bevacizumab and bevacizumab maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer (**PI: Debra L. Richardson, MD**)
- **NRG-DT1907:** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer (**PI: Floor Backes, MD, Co-PI: David O'Malley**)
- **NRG-BN1856:** A Phase III Trial of Ipilimumab + Nivolumab vs Ipilimumab + Nivolumab + Stereotactic Radiosurgery (SRS) for Melanoma Patients with  $\leq 15$  Symptomatic Brain Metastases (**PI: Paul Spreduto, MD**)
- **CV1964** Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (**PI: Scott Glaser**)
- **RT1969** A phase II trial of Nivolumab, Ipilimumab with Sargramostim for recurrent clear cell ovarian cancer (**PI: Danielle Vicus**)
- **LU1866:** Phase II Trial of Consolidation XRT + Immunotherapy for ES-SCLC (**PI: James Welsh, MD; Stephen Chun**)
- **DT1952** Phase II study investigating the efficacy of rationale combination immunotherapy in recurrent endometrial cancer with deficient mismatch repair system post progression on anti-PD1 therapy (**PI: Haider Mahdi**)

**Protocol Support Committee**  
**Introduction to Clinical Trials: Principles of Clinical Trial Management**

**Date:** Thursday, January 9, 2020

**Start and End Time:** 7:30 am – 4:10 pm

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

**Learning Objectives**

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

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

**AGENDA**

<u>Time</u>	<u>Topic</u>	<u>Speakers</u>
7:30am- 7:40 am	Welcome RN, MA	Sharon Stockman, BA, CCRP & Cindy Licavoli
7:40 am-7:55 am	NRG Oncology Overview	Kati Stoermer, MSBA
7:55 am-8:15 am	NRG Membership	Mimi Passarello, MBA

8:15am-8:45 am	IRB's: Who, What, Where, When and How	Lynne Lippmann, BA, CCRP
8:45 am-9:15 am	Serious Adverse Event Reporting	Sara McCartney, MS, RN
9:15 am-9:35 am	Investigational Drug Management	Nancy Knudsen, RN, BSN
9:35am-9:50 am	Break	
9:50 am- 10:15 am	Medidata Rave	Joseph Mroziak
10:15 am-10:45 am	Quality Assurance Audits	Tamara McLaughlin, MHA, MPH
10:45 am-11:10 am	Pathology/Biospecimen Collections	Lisa Beaverson, BA, CCRP Sandy DeVries, MA
11:10 am-11:40 am	RECIST	Mark Shahin, MD
11:40 am – 11:50 am	Mentorship Program	Nancy Fusco, RN, BSN
11:50 am- 12:00 pm	QOL	Sharon Stockman, BA, CCRP
12:00 am – 12:05 pm	Morning Closing Remarks	Sharon Stockman, BA, CCRP
12:05 pm – 1:15 pm	Lunch (on your own)	
1:15 pm – 4:10 pm	Afternoon Breakout Sessions- All sessions run concurrently (40 minutes/session)	

<b>Topic</b>	<b>Speaker</b>
Patient Screening and Enrollment	<i>Lead Facilitator-</i> Cindy Licavoli, RN, BSN, MA Joni Shortt, RN, BSN, CCRC Tiffany Elsea, BA, CCRP
Treatment Modalities in Clinical Trial Management	<i>Lead Facilitator-</i> Joyce Neading, RHIT, CTR Chrisann Winslow, RN, MSN Karen Holeva, BS
Data Management	<i>Lead Facilitator-</i> Lynne Lippmann, BA, CCRP Sue Eaton, CCRP Whitney Jacobson, RN, BSN, CCRP
Adverse Event Reporting	<i>Lead Facilitator-</i> Mary Smrekar, RN, MSN, CNP Donna White, RN, BSN, OCN Alison Ivey, RN, MS, OCN, CCRP
4:10pm – 4:30pm	Evaluation
QUESTIONS/DISCUSSION EVALUATION	

**Protocol Support Committee Workshop  
Education & Training Working Group (CLOSED)**

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

**Learning Objectives**

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

1. Discuss alternative methods of education
2. Provide the PSC with potential topics and speakers for the 2020 Summer Meeting & 2021 Winter Meeting
3. Have a structured working group agenda

**WORKSHOP AGENDA**

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

QUESTIONS/DISCUSSION

EVALUATION

**Protocol Support Committee Workshop  
Mentorship Working Group (CLOSED)**

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

**Learning Objectives:**

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

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

**Workshop Agenda:**

**\*\*First hour: meeting with mentors**

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

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

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

**QUESTIONS/DISCUSSION**

**EVALUATIONS**

**Protocol Support Committee Workshop  
Protocol Review Working Group (CLOSED)**

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

**Learning Objectives**

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

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

**WORKSHOP AGENDA**

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

**Agenda Items**

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

**QUESTIONS/DISCUSSION  
EVALUATION**

**Protocol Support Committee Workshop  
Quality Control Working Group (CLOSED)**

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

**Learning Objectives**

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

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

**Workshop Agenda**

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

QUESTIONS/DISCUSSION  
EVALUATION

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

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

**Learning Objectives:**

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

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

**Agenda:**

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

QUESTIONS/DISCUSSION  
EVALUATION

**Protocol Support Committee Workshop  
Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session**

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

**Learning Objectives**

Following this activity, participants will be better able to:

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

**AGENDA**

<u><b>Time</b></u>	<u><b>Topic</b></u>	<u><b>Speakers</b></u>
2:00-2:10	Introduction/Welcome	Karen Holeva, BS
2:10-2:20	Welcome	Katie Stoermer, MSBA Executive Director, NRG Oncology
2:20-3:00	Updates and information from CTSU	Amanda Fournier
3:00-3:25	Update on NRG Oncology QA Audits, monitoring and Institution Performance reports	Mimi Passarello, MBA
3:25-3:35	break	

3:35 -4:20	Patient reported outcomes: Why we do it and how we do it	David Cella, PhD
4:20-5:05	Ethics related to care of the Oncology research Patient: moving concern to courage	Karen Iseminger PhD, ANP-BC, FNP
5:05-5:50 CCRC	Basics of Breast Cancer	Brenda Lee Steele BSN, RN, OCN,
5:50-6:00	Questions and evaluation	

QUESTIONS/DISCUSSION  
EVALUATION

## Radiation Development Therapeutics Workshop

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

### Learning Objectives

Following this activity, participants will be better able to:

1. Critically appraise optimal statistical designs for phase I trials
2. Evaluate the landscape of early phase drug-radiation combination studies at the NRG

### WORKSHOP AGENDA

- I. Introduction
  - A. General Business **Steven Lin, M.D., PhD**
- II. Scientific Talk: Statistical Considerations for Designing and Conducting a Phase I Clinical Trial **Pedro Torres-Saavedra, PhD** 15 min
- III. Basket Trial concept under development: RadScopal trial **James Welsh, MD** 10 min
- IV. Disease Site Working Group Updates
  - a. **Sarcoma:** DT001: A Phase IB Trial of Neoadjuvant AMG-232 Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma (STS) (Meng Welliver, MD) 10 min
- V. Disease Site Committee Updates
  - a. **Genitourinary (Committee Liaison: Chad Tang, MD)** 10 min
    - 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)
  - b. **Lung (Committee Liaison: Steven Lin, MD, PhD)** 10 min
    - i. LU004: Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined with MEDI4736 (Durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1)
    - ii. **New concept:** Phase II randomized trial with safety run-in of consolidation N-803 after chemoradiation
  - c. **GI-non colorectal (Committee Liaison: Terence Williams, MD)** 10 min
    - 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)
  - d. **GI-colorectal (Committee Liaison: Theodore Hong, MD)** 10 min
    - i. GI002: A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer: Arm 3: AN0025
  - e. **GYN (Committee Liaison: Jyoti Mayadev, MD)** 10 min
    - i. GY017: Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer.
    - ii. **New concept:** Phase II Nelfinavir with radiation in vulvar cancer (PI: Lillie Li, MD)

### QUESTIONS / DISCUSSION

## Medical Physics Subcommittee Workshop Agenda

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

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

#### WORKSHOP AGENDA

<b>2:30 – 2:35</b>	<b>Introductions / Subcommittee Updates</b>	Ying Xiao/Stanley Benedict, PhD
<b>2:35 – 2:40</b>	<b>NCI Communications/NCTN Medical Physics</b>	Ceferino Obcemea, PhD
<b>2:40 – 2:55</b>	<b>NRG QA Report</b> <ul style="list-style-type: none"><li>• IROC Houston</li><li>• IROC Philadelphia RT (Contouring &amp; Dosimetry)</li><li>• IROC Philadelphia Imaging</li></ul>	Stephen Kry, PhD Ying Xiao, PhD Mark Rosen, MD / Michael Boss, PhD
<b>2:55 – 3:30</b>	<b>Disease Site Reports</b> <ul style="list-style-type: none"><li>• Brain</li><li>• Breast</li><li>• GI</li><li>• GU</li><li>• GYN</li><li>• H&amp;N</li><li>• Lung</li></ul>	Fangfang Yin fa/ Yunfeng Cui X Allen Li / Jean Moran Adam Yock / William Parker Rajat Kudchadker / Robert Wallace Cecilia Lee /Hayeon Kim Nataliya Kovalchuk/ Ping Xia Martha Matuszak / Tim Solberg
<b>3:30 – 3:40</b>	<b>Modality Technology Reports</b> <ul style="list-style-type: none"><li>• Notable technologies</li><li>• Monte Carlo Updates</li></ul>	Zoufeng Li Liyong Lin
<b>3:40 – 4:15</b>	<b>Working Group and Other Updates</b> <ul style="list-style-type: none"><li>• Adaptive QA</li><li>• Deformable QA</li><li>• SBRT Practice Survey</li><li>• TRT Updates</li></ul>	Carrie Glide-Hurst Stan Benedict Jason Sohn Jacek Capala / Stan Benedict
<b>4:15 – 4:25</b>	<b>Other Business/Discussions</b>	
<b>4:25 – 4:30</b>	<b>Questions</b>	
<b>4:30</b>	<b>Adjournment</b>	

# Proton Working Group Agenda

## CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

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

### WORKSHOP AGENDA

7:00 – 7:05	Welcome/Introduction/ Moderator	Tom DeLaney, MD
7:05 - 7:15	Update on Proton Center Credentialing by IROC Houston	Paige Taylor, PhD
7:15 – 7:25	Protons in liver studies <u>RTOG 1112</u> - Ph III Sorafenib +/- SBRT for hepatocellular ca (L. Dawson) <u>NRG-GI003</u> - Ph III Protons vs Photons for Hepatocellular Carcinoma	Laura Dawson MD Ted Hong, MD
7:25 – 7:40	Brain Studies <u>NRG-BN001</u> : Randomized Phase II Trial of Hypofractionated Dose- Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation w/ Concomitant /Adjuvant Temozolomide in Glioblastoma <u>NRG BN003</u> - Phase III Trial of Observation versus Irradiation for a Gross Totally Resected Grade II Meningioma <u>NRG BN005</u> - A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas.	Minesh Mehta, MD
7:40—7:50	<u>RTOG 1308</u> : Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable Stage II-IIIB NSCLC	Zhong Xing Liao, MD Jeff Bradley, MD
7:50 – 7:55	<u>NRG-HN001</u> : Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA): Addition of Protons	Annie Chan, MD Tom DeLaney, MD
7:55-8:00	Phase II/III Randomized Study of IMPT vs IMRT for Oropharyngeal CA	Steven Frank, MD
8:00 – 8:10	<u>NRG-GI006</u> : Ph III Randomized Protons vs. IMRT Photon for Esophageal CA	Steven Lin, MD
8:10– 8:15	PCORI (Patient-Centered Outcomes Research Institute) RADCOMP Breast Randomized Trial of Photons versus Protons	Shannon Macdonald, MD
8:15– 8:20	COMPPARE (Comparative Study of Outcomes w/ Proton and Photon Radiation in Prostate Cancer) Prostate Ca Study	Nancy Mendenhall, MD
8:20-8:25	Trial Proposal: SHIPP: Stereotactic Heavy Particles vs Protons vs Photons for Unfavorable Intermediate Risk Prostate Cancer	Mack Roach, MD
8:25 – 8:30	Other Business/Questions	Tom DeLaney, M.D.

## Surgical Oncology Workshop

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

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

Following this activity, participant will be better able to:

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

### Workshop Agenda

- 7:00 – 7:05 Welcome/Introduction /Approval of Minutes
- 7:05 - 7:15 Medical Oncology Update
- 7:15 – 7:25 Radiation Oncology Committee Update
- 7:25 – 7:55 Disease Site Liaison Reports (brief discussion of status with no more than a single slide)
- a. Brain
  - b. Breast
  - c. GI
  - d. Gynecology
  - e. Head and Neck
  - f. Lung
  - g. Urology
- \*Liaison to provide a 5 minute update on latest surgical advancement
- 7:55 –8:00 Questions/Discussion

# Administrative Committees

## An Introduction to NRG Oncology New Investigator Educational Session Agenda

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

4:00pm – 4:05pm	Introductory Remarks	Committee Co-Chairs
4:05pm – 4:15pm	NRG Oncology Update	Kati Stoermer
4:15pm – 4:30pm	NRG-GY018	Ramez Eskander, MD
4:30pm – 4:45pm	NRG NCORP	Lisa Kachnic, MD
4:45pm – 5:00pm	NRG Biospecimen Bank	Jeff Simko, MD
4:45pm – 5:00pm	NRG Ancillary Projects	Steven Waggoner, MD
5:15pm – 6:00pm	New Investigator Reception	To follow in same room

## Canadian Members Meeting Workshop

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

### Learning Objectives:

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

- I. General  
Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest
- II. Status of NRG Oncology trials open to accrual
  - a. Accrual Update (June – December 2019)  
*Discussion lead - NRG Oncology Regulatory*
- III. Optimizing accrual in Canada
  - a. Discuss best practices for and barriers to optimizing accrual among Canadian sites  
*Discussion lead - Canadian Members Co-Chairs*
- IV. New concepts and protocols
  - a. CC008-A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [SOROC] (Douglas Levine)
- V. New Business, General Questions, Discussion, Next Meeting
  - a. NRG and CCTG Membership Points Discussion
- VI. Evaluation

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

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8:00 a.m.	Welcome	J. Walker, MD
8:05 a.m.	NCI NCORP Report	S. Russo, MD
8:15 a.m.	NCI CCDR Report	K. Castro, RN, MS
8:25 a.m. 15 min	Cancer Prevention and Control Committee/Overview of developing trials: NRG-CC005 and NRG-CC008	L. Kachnic, MD/D. Levine, MD
8:40 a.m. 10 min	Cancer Care Delivery Research Group	M. Cooley PhD, RN/M. Hudson, PhD, MPH
8:50 a.m. 10 min	Health Disparities Update	K. Yeager, RN, PhD/C. Hughes-Halbert, PhD
9:00 a.m. 10 min	Patient Centered Outcomes Research Committee	P. Ganz, MD
9:10 a.m. 20 min	Tips to increase interest and accrual	NCORP site representatives
9:30 10 min	NCORP Credits and subcontract updates	Kati Stoermer
9:40 a.m. 20 min	Discuss Research Priorities at NCORP sites Q&A – Open Discussion	

# Institutional Accrual

Accrual For Agenda Book from 12/1/2018 to 11/30/2019 Run Date: 12/13/2019				
NRG Main Member (Network)	CTEP ID	Accrued to NRG Studies and Credited to NRG	Accrued to Non-NRG NCTN Studies and Credited to NRG	Total
Allan Blair Cancer Centre	11076	13	0	13
Allegheny General Hospital	PA009	9	125	134
AMITA Health Alexian Brothers Medical Center	IL280	5	3	8
Arizona Center for Cancer Care-Peoria	AZ127	8	6	14
Aultman Health Foundation	OH100	1	31	32
Aurora NCI Community Oncology Research Program	AURORA	13	12	25
Avera Cancer Institute	SD021	3	15	18
Banner University Medical Center - Tucson	AZ017	8	6	14
Baptist Health Cancer Research Network	BHCRN	4	42	46
Bay Area Tumor Institute NCORP	BATI	1	0	1
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	TX041	0	6	6
Baystate Medical Center	MA004	19	5	24
Berkshire Medical Center - Cancer Center	MA125	0	2	2
Boston Medical Center	MA043	1	424	425
Cancer Research Consortium of West Michigan NCORP	CRCWM	20	5	25
Cancer Research for the Ozarks NCORP	OZARKS	19	0	19
Cancer Research of Wisconsin and Northern Michigan Consortium	CROWN	3	2	5
Cancer Trials Ireland	ICORG	12	0	12
Carle Cancer Center NCI Community Oncology Research Program	CARLE	21	4	25
Carolinas Medical Center/Levine Cancer Institute	NC042	16	2	18
Catholic Health Initiatives NCORP	CORA	23	21	44
Cedars-Sinai Medical Center	CA016	2	0	2
Centre Hospitalier Universitaire de Sherbrooke-Fleurimont	11065	17	0	17
Chinese University of Hong Kong-Prince of Wales Hospital	34003	8	0	8
CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)	11073	29	0	29
CHUM - Centre Hospitalier de l'Universite de Montreal	11062	12	0	12
City of Hope Comprehensive Cancer Center	CA043	6	6	12
CIUSSEMTL-Hopital Maisonneuve-Rosemont	11060	5	0	5
Columbia University Minority Underserved NCORP	COLUMBIA	6	16	22
Columbus NCI Community Oncology Research Program	COLUMBUS	10	4	14
Community Cancer Center North	IN006	2	20	22
Cooper Hospital University Medical Center	NJ036	2	10	12
Covenant Medical Center-Lakeside	TX054	0	1	1
Cross Cancer Institute	11132	4	0	4
CWRU Case Comprehensive Cancer Center LAPS	LAPS-OH029	87	40	127
Dana-Farber / Partners CancerCare LAPS	LAPS-MA036	31	5	36
Danbury Hospital	CT030	5	2	7
Dartmouth College - Norris Cotton Cancer Center LAPS	LAPS-NH012	12	10	22
Dayton NCI Community Oncology Research Program	DAYTON	5	13	18
Delaware/Christiana Care NCI Community Oncology Research Program	CHRISTIANA	36	6	42
Dell Seton Medical Center at The University of Texas	TX063	0	11	11
Duke University - Duke Cancer Institute LAPS	LAPS-NC010	13	0	13
Edward Hospital/Cancer Center	IL104	2	18	20
Einstein Medical Center Philadelphia	PA094	0	0	0

## Accrual from 12/1/2018 to 11/30/2019

Emory University - Winship Cancer Institute LAPS	LAPS-GA005	27	9	36
Essentia Health NCI Community Oncology Research Program	ESSENTIA	2	0	2
Fox Chase Cancer Center	PA086	13	13	26
Fred Hutchinson Cancer Research Center LAPS	LAPS-WA008	17	5	22
Froedtert and the Medical College of Wisconsin LAPS	LAPS-WI013	21	2	23
Geisinger Cancer Institute NCI Community Oncology Research Program	GEISINGER	8	47	55
Georgia Cares Minority Underserved NCORP	GACARES	22	18	40
Georgia NCI Community Oncology Research Program	GEORGIA	29	26	55
Greater Baltimore Medical Center	MD018	4	8	12
Gulf South Minority Underserved NCORP	GULFSOUTH	21	3	24
Hackensack University Medical Center	NJ022	4	11	15
Hartford Hospital	CT009	3	4	7
Hawaii Minority Underserved NCORP	HAWAII	9	62	71
Heartland Cancer Research NCORP	HEARTLAND	48	6	54
Henry Ford Hospital	MI026	8	6	14
Houston Methodist Hospital	TX036	7	9	16
Indiana University/Melvin and Bren Simon Cancer Center	IN007	14	1	15
Iowa-Wide Oncology Research Coalition NCORP	IWORC	10	22	32
James A. Haley Veterans Affairs Hospital	FL064	0	0	0
Jewish General Hospital	11116	8	1	9
JHU Sidney Kimmel Comprehensive Cancer Center LAPS	LAPS-MD017	13	7	20
Juravinski Cancer Centre at Hamilton Health Sciences	11183	4	0	4
Kaiser Permanente NCI Community Oncology Research Program	KAISER	51	94	145
Kaiser Permanente-Gaithersburg Medical Center	MD198	0	14	14
Kantonsspital Aarau	67029	8	0	8
Lahey Hospital and Medical Center	MA017	4	21	25
Lankenau Medical Center	PA125	13	1	14
Legacy Good Samaritan Hospital and Medical Center	OR013	14	1	15
Loyola University Medical Center	IL017	19	0	19
Maine-Health Cancer Care Network	MAINE	10	14	24
Mayo Clinic LAPS	LAPS-MN026	32	0	32
Medical University of South Carolina Minority Underserved NCORP	MUSC	12	0	12
MedStar Franklin Square Medical Center/Weinberg Cancer Institute	MD029	5	13	18
Memorial Sloan-Kettering Cancer Center LAPS	LAPS-NY016	45	8	53
Mercy Cancer Center - Sacramento	CA729	7	7	14
Metro Minnesota Community Oncology Research Consortium	METROMIN	40	14	54
Michigan Cancer Research Consortium NCORP	MCRC	24	0	24
Michigan State University Clinical Center	MI038	0	4	4
Midwestern Regional Medical Center	IL120	1	5	6
Moffitt Cancer Center	FL065	10	38	48
Montana Cancer Consortium NCORP	MONTANA	18	0	18
Montefiore Minority Underserved NCORP	MONTEFIORE	16	1	17
Mount Sinai Hospital	NY021	11	5	16
National Cancer Centre Singapore	47005	6	0	6
National Institutes of Health Clinical Center	MD004	0	0	0
NCORP of the Carolinas (Greenville Health System NCORP)	GREENVILLE	9	17	26
Nevada Cancer Research Foundation NCORP	NCRF	7	0	7
New Mexico Minority Underserved NCORP	NEWMEXICO	33	19	52
New York-Presbyterian/Brooklyn Methodist Hospital	NY075	14	1	15
NorthShore University HealthSystem-Evanston Hospital	IL018	7	10	17
Northwell Health NCORP	NORTHWELL	4	13	17
Northwestern Medicine Cancer Center Warrenville	IL387	16	26	42
Northwestern University LAPS	LAPS-IL036	20	21	41
Norton Hospital Pavilion and Medical Campus	KY049	7	1	8

Accrual from 12/1/2018 to 11/30/2019

NRG Oncology Foundation, Inc	NRG	0	0	0
Odette Cancer Centre- Sunnybrook Health Sciences Centre	11118	15	0	15
Ohio State University Comprehensive Cancer Center LAPS	LAPS-OH007	37	11	48
Ottawa Hospital and Cancer Center-General Campus	11025	5	0	5
Pacific Cancer Research Consortium NCORP	PCRC	30	0	30
Parkview Regional Medical Center	IN181	11	28	39
Peter MacCallum Cancer Centre	3003	2	0	2
Piedmont Hospital	GA027	4	7	11
ProMedica Flower Hospital	OH012	12	8	20
Puerto Rico Minority Underserved NCORP	PUERTORICO	7	1	8
Rabin Medical Center	40021	0	0	0
Reading Hospital	PA107	10	5	15
Rhode Island Hospital	RI005	2	7	9
Roswell Park Cancer Institute LAPS	LAPS-NY158	16	3	19
Rush University Medical Center	IL043	18	18	36
Rutgers Cancer Institute of New Jersey	NJ066	11	28	39
Saint Joseph Hospital - Orange	CA087	1	16	17
Saint Joseph's Hospital and Medical Center	AZ009	7	10	17
Saitama Medical University International Medical Center	42061	15	0	15
Sanford NCI Community Oncology Research Program of the North Central Plains	SANFORD	12	5	17
Saskatoon Cancer Centre	11120	12	0	12
Seoul National University Hospital	43002	51	0	51
Southeast Clinical Oncology Research Consortium NCORP	SCOR	46	24	70
Stanford Cancer Institute Palo Alto	CA141	16	1	17
Staten Island University Hospital	NY035	0	3	3
Stony Brook University Medical Center	NY184	4	17	21
Stroger Hospital of Cook County Minority Underserved NCORP	STROGER	11	0	11
Summa Health System - Akron Campus	OH055	7	8	15
Sun Yat-sen University Cancer Center	60021	36	0	36
Sutter Cancer Research Consortium	SUTTER	12	44	56
Technical Resources International	CTTRI	0	0	0
Tel Aviv Sourasky Medical Center	40019	0	0	0
The Community Hospital	IN044	0	7	7
The James Graham Brown Cancer Center at University of Louisville	KY002	5	6	11
The Research Institute of the McGill University Health Centre (MUHC)	11318	16	0	16
The US Oncology Network	USONC	22	0	22
Thomas Jefferson University Hospital LAPS	LAPS-PA121	49	9	58
Thompson Cancer Survival Center	TN038	2	0	2
Tibor Rubin VA Medical Center	CA041	0	0	0
Tom Baker Cancer Centre	11134	6	0	6
Trinity Cancer Care Center	ND026	0	3	3
Tulane University Health Sciences Center	LA001	0	3	3
UC Davis Comprehensive Cancer Center LAPS	LAPS-CA189	16	0	16
UC Irvine Health/Chao Family Comprehensive Cancer Center	CA088	10	22	32
UC San Diego Moores Cancer Center	CA249	23	13	36
UCLA / Jonsson Comprehensive Cancer Center	CA006	0	0	0
UCSF Medical Center-Mount Zion	CA136	19	70	89
UF Cancer Center at Orlando Health	FL020	6	8	14
UMass Memorial Medical Center - Memorial Division	MA009	0	0	0
UNC Lineberger Comprehensive Cancer Center LAPS	LAPS-NC007	10	193	203
University Health Network-Princess Margaret Hospital	11030	49	0	49
University of Alabama at Birmingham / Deep South Research Consortium	LAPS-AL002	12	1	13
University of Arkansas for Medical Sciences	AR006	14	3	17
University of Chicago Comprehensive Cancer Center LAPS	LAPS-IL057	11	3	14

Accrual from 12/1/2018 to 11/30/2019

University of Cincinnati/Barrett Cancer Center	OH070	23	373	396
University of Colorado Cancer Center LAPS	LAPS-CO070	17	65	82
University of Connecticut	CT002	0	1	1
University of Florida Health Science Center - Gainesville	FL015	10	61	71
University of Illinois	IL040	4	11	15
University of Iowa/Holden Comprehensive Cancer Center	IA018	25	12	37
University of Kansas Cancer Center - MCA Rural MU NCORP	KANSAS	26	0	26
University of Kentucky/Markey Cancer Center	KY010	5	6	11
University of Maryland/Greenebaum Cancer Center	MD015	25	8	33
University of Miami Miller School of Medicine-Sylvester Cancer Center	FL028	9	11	20
University of Michigan Comprehensive Cancer Center LAPS	LAPS-MI014	33	5	38
University of Minnesota/Masonic Cancer Center	MN022	1	0	1
University of Mississippi Medical Center	MS005	1	0	1
University of Nebraska Medical Center	NE003	6	7	13
University of Oklahoma Health Sciences Center LAPS	LAPS-OK003	87	85	172
University of Pennsylvania/Abramson Cancer Center	PA075	15	0	15
University of Pittsburgh Cancer Institute LAPS	LAPS-PA015	13	13	26
University of Rochester LAPS	LAPS-NY167	20	11	31
University of South Alabama Mitchell Cancer Institute	AL068	0	6	6
University of Tennessee - Knoxville	TN021	0	10	10
University of Tennessee Health Science Center	TN030	4	1	5
University of Texas Health Science Center at San Antonio	TX059	7	11	18
University of Texas MD Anderson Cancer Center LAPS	LAPS-TX035	49	32	81
University of Texas Medical Branch	TX045	2	9	11
University of Texas Southwestern Medical Center LAPS	LAPS-TX011	47	0	47
University of Utah - Huntsman Cancer Institute LAPS	LAPS-UT003	10	12	22
University of Vermont and State Agricultural College	VT004	7	13	20
University of Virginia Cancer Center	VA009	17	2	19
University of Wisconsin Carbone Cancer Center LAPS	LAPS-WI020	16	12	28
Upstate Carolina Consortium Community Oncology Research Program	UPSTATE	1	17	18
USC Norris Comprehensive Cancer Center LAPS	LAPS-CA011	14	78	92
Vanderbilt University - Ingram Cancer Center LAPS	LAPS-TN008	11	11	22
Vassar Brothers Medical Center	NY131	0	4	4
VCU Massey Cancer Center Minority Underserved NCORP	VCU	4	10	14
Wake Forest University Health Sciences	NC002	8	4	12
Walter Reed National Military Medical Center	MD001	0	0	0
Washington University - Siteman Cancer Center LAPS	LAPS-MO011	69	1	70
Wayne State University - Karmanos Cancer Institute LAPS	LAPS-MI020	53	32	85
WellSpan Health-York Hospital	PA047	9	12	21
West Virginia University Charleston Division	WV004	6	8	14
West Virginia University Healthcare	WV025	9	16	25
Western States Cancer Research NCORP	WESTERN	13	24	37
William Beaumont Hospital-Royal Oak	MI005	12	13	25
Wisconsin NCI Community Oncology Research Program	WINCORP	8	13	21
Women and Infants Hospital	RI012	26	10	36
Women's Cancer Center of Nevada	NV049	14	0	14
Yale University - Yale Cancer Center LAPS	LAPS-CT018	6	3	9
Yonsei University Health System-Severance Hospital	43027	12	0	12

# NRG Oncology Winter 2020 Exhibitor Companies

NRG Oncology wishes to acknowledge the following exhibitors:

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

Please take the time to visit the exhibit booths located in:  
**Texan Foyer - 4th Level**

## Exhibit hours are:

**Friday, Jan 10, 2020 - 7:00 am - 5:00 pm**

**Saturday, Jan 11, 2020 - 7:00 am - 2:00 pm**

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

## American College of Radiology

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

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## Caris Life Sciences

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

## Clovis Oncology, Inc.

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

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

## GSK

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

## Merck

For more than a century, Merck has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Today, Merck continues to

be at the forefront of research to deliver innovative health solutions and advance the prevention and treatment of diseases that threaten people and animals around the world.

## OVARCOME

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

## Prelude Dx™

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

## Seattle Genetics

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

## Xcision Medical Systems

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



*Advancing Research. Improving Lives.™*

## **NRG Oncology Commercial Supporters**

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

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## Notes

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# Future NRG Oncology Semiannual Meetings

SAVE THE DATES



**July 16-18, 2020**

Marriott Marquis  
Washington D.C



**January 28-30, 2021**

Hyatt Regency New Orleans  
New Orleans, LA



**July 22-24, 2021**

Philadelphia Marriott Downtown  
Philadelphia, PA



**February 10-12, 2022**

Phoenix Convention Center  
Phoenix, AZ



**July 21-23, 2022**

Hyatt Regency Chicago  
Chicago, IL