

# PROGRAM



## NRG ONCOLOGY SEMIANNUAL MEETING

February 7-9, 2019  
Phoenix, Arizona

**NRG**  
ONCOLOGY

*Advancing Research. Improving Lives.™*



*Celebrating 5 Years of Practice-Changing Research Through Collaboration*

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# Welcome

## to the 2019 Winter NRG Oncology Semiannual Meeting

It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Phoenix, AZ, February 7 - 9, 2019.

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

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

Meeting highlights include:

A day-long winter Symposium titled, "HPV related cancer: biology, treatment, and innovative approaches" with noted Oncologists and Scientists serving as speakers and moderators will take place on Thursday. 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. Speakers will focus their presentations on updates in HPV related malignancies. Special emphasis will be placed upon understanding molecular changes in these tumors and potential targeting of these changes, the role of immunotherapy in HPV related malignancies as well as a focus on patient outcomes and potential prognostic implications of current knowledge.

A Clinical Trial Nurse/Clinical Research Associate Workshop titled, "Introduction to Clinical Trials: Principles of Clinical Trial Management" will take place on Thursday.

A Social Media and Technology Workshop will take place on Friday. Social media is an increasingly important communication tool for health professionals. This session will help explain the continued value of social media presence for clinicians and investigators. It will also help to recognize and appreciate the value that social media can bring to professional development, and provide potential methods for utilizing social media as part of clinical trial outreach and awareness.

NRG Oncology research achievements will be featured during Friday's Scientific Session, "NRG Oncology Research Review," which will highlight the results of recently reported studies in breast, prostate, ovarian, lung, and pancreatic cancer.

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

We are very excited about 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 Phoenix!



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*

# 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 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 27 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.



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.

## NRG Oncology Semiannual Workshop CME Credits

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

## Evaluations/CME/Attendance Certificates

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

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

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

## How to submit your evaluation:

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

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

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

NO EVALUATIONS WILL BE ACCEPTED AFTER:  
March 1, 2019

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).

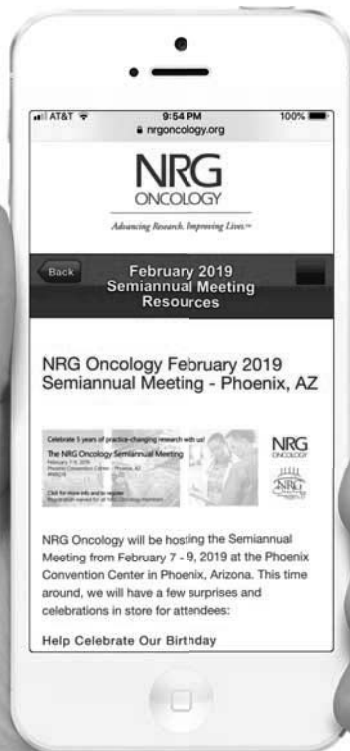
## FINAL LISTING OF APPROVED CME CREDITS

The following sessions/workshops have been approved to receive CME credits  
Accredited by the GOG Foundation, Inc. in Phoenix, AZ Feb 7-9, 2019  
AMA PRA Category 1 credits™

	THURSDAY	FRIDAY	SATURDAY
Symposium –“HPV Related Cancer: Biology, Treatment and Innovative Approaches” <b>CME Tickets</b>	5.25		
<b>WORKSHOP AGENDAS</b>			
Breast Cancer Workshop			3
Breast Cancer Rare Tumor Subcommittee Workshop		1	
Canadian Members Workshop			1
Cancer Prevention and Control Workshop		2	
Cervix Workshop		2	1
Gastrointestinal Cancer Workshop			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
Introduction to NRG Oncology: New Investigator Ed Session <b>CME Tickets</b>	1.25		
International Members Workshop		1	
Lung Cancer Workshop			2
Medical Oncology Workshop			1
NRG Clinical Trial HN004 Workshop		1	
NRG – LU003 Workshop			.5
NRG Oncology Protocol NRG-BR005 Workshop			1
NRG Protocol G1002 and Protocol G1004 Workshop		1	
NRG Protocol Workshop: NRG BR003 and BR004		1	
NRG Scientific Session - NRG Oncology Research Review <b>CME Tickets</b>		2	
Ovarian Workshop		2	1
Pathology Workshop		4	
Patient Centered Outcomes Research (PCOR)	2		
Pharmacy Subcommittee Workshop		1	
Radiation Development Therapeutics Workshop			2
Rare Tumor Workshop		2	
Social Media and Mobile Technology Workshop		1	
Surgical Oncology Workshop			1
Translational Science Workshop	1		
Translational Science GYN Workshop		1.5	
Translational Science Lung Cancer Workshop		2	
Uterine Corpus Workshop		2	1
<b>PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD's</b>			
Introduction to Clinical Trials: Principals of Clinical Trial Management <b>CME Tickets</b>	4		
PSC-Clinical Trial Nurse/Clinical Research Assoc Ed Session <b>CME Tickets</b>		3.75	
PSC Clinical Trial Nurse Subcommittee /Clinical Research Assoc Sub <b>CME Tickets</b>		2	
PSC Patient Screening & Enrollment	.75		
PSC Treatment Modalities	.75		
PSC Data Management	.75		
PSC Adverse Event Reporting	.75		
PSC Mentorship Working Group (Closed)	1.5		
PSC Protocol Review Working Group (Closed)	1		

# NRG Oncology Semi Annual Meeting

Stay up-to-date with updates and announcements from the NRG Oncology Semiannual Meeting 2019 on Twitter, Facebook and the Meeting App!



## NRG Oncology Meeting App

- Download EVENTSXD to your iOS, Android, Windows Phone or device to quickly access agendas, meeting room information and more!
- Sign up and login to select the NRG Oncology Semiannual Meeting from the list of meetings
- Access the Agenda and create your own personal agenda by tapping the green star to "favorite" specific sessions

## TWITTER

JOIN The Conversation On Twitter:  
@NRGONC #NRG19



## FACEBOOK

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



## WIFI

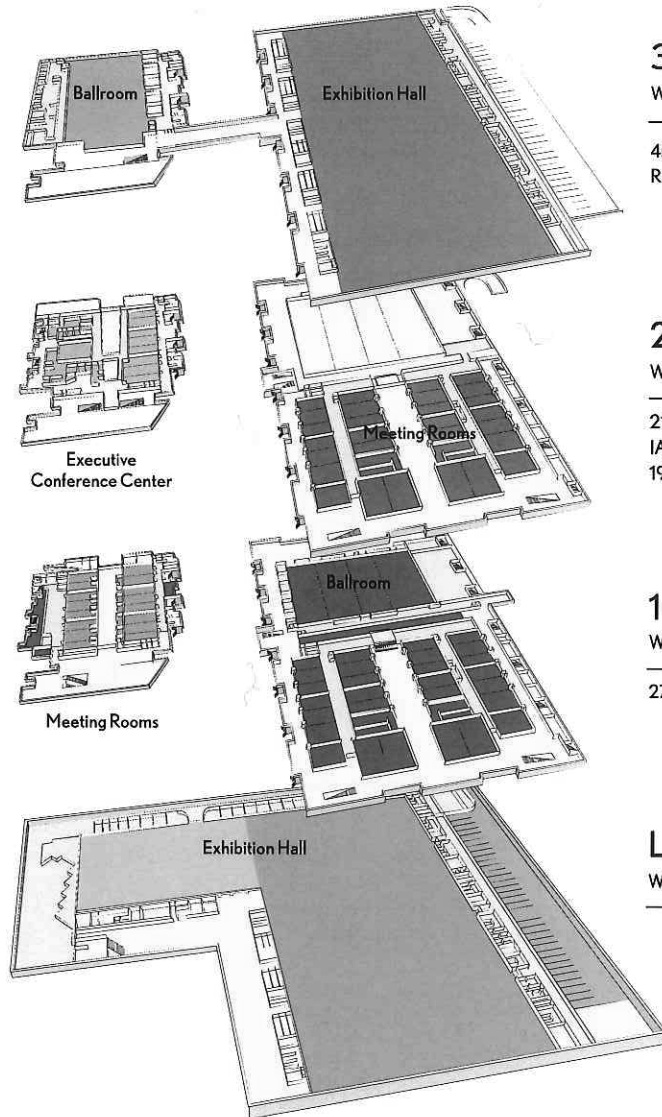
Complimentary wifi is available for meeting attendees:  
Network Login: nrgmeeting  
Passcode: n1r2g345

Stay **in-the-know** and join on Social Media

# PHOENIX CONVENTION CENTER

WEST BUILDING

NORTH BUILDING



## 300 LEVEL

WEST BUILDING

NORTH BUILDING

45,200 SF West Ballroom  
Riser seating for 1,200

190,000 SF Exhibition Hall

## 200 LEVEL

WEST BUILDING

NORTH BUILDING

21,000 SF Conference Center  
IACC Certified  
192-Seat Lecture Hall

43,000 SF Meeting Rooms

## 100 LEVEL

WEST BUILDING

NORTH BUILDING

27,200 SF Meeting Rooms

45,600 SF Ballroom  
43,000 SF Meeting Rooms

## LOWER LEVEL

WEST BUILDING

NORTH BUILDING

312,500 Total Combined SF Exhibition Hall

## NRG ONCOLOGY SEMIANNUAL MEETING FINAL AGENDA

Phoenix Convention Center  
Phoenix, Arizona  
February 7 – 9, 2019

Thursday, February 7, 2019		
6:30 am – 7:30 am	Introduction to Clinical Trials: Principles of Clinical Trial Management Breakfast	Convention-North 120A/1 <sup>st</sup> Level
7:00 am – 8:30 am	Symposium Breakfast	Convention-North 120CD/1 <sup>st</sup> Level
7:00 am – 6:00 pm	Registration/CME/Information Desk	Convention-North 120Lobby/1 <sup>st</sup> Level
9:30 am – 9:45 am	Introduction to Clinical Trials Coffee Break	Convention-North 120A/1 <sup>st</sup> Level
9:55 am – 10:10 am	Symposium Coffee Break	Convention-North 120CD/1 <sup>st</sup> Level
12:40 pm – 1:40 pm	Symposium Lunch	Convention-North 120CD/1 <sup>st</sup> Level
2:00 pm – 6:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Convention-West 104B/1 <sup>st</sup> Level
4:00 pm – 6:00 pm	Exhibit Setup	Convention-North 120Lobby/1 <sup>st</sup> Level
7:30 am – 12:00 pm	Introduction to Clinical Trials: Principles of Clinical Trial Management	Convention-North 120A/1 <sup>st</sup> Level
8:00 am – 12:00 pm	Imaging and Radiation Oncology Core (IROC) RT Focused Staff Meeting for NRG Oncology Protocols *	Convention-West 106B/1 <sup>st</sup> Level
8:00 am – 2:50 pm	Winter Symposium - “HPV Related Cancer: Biology, Treatment, and Innovative Approaches”	Convention-North 120CD/1 <sup>st</sup> Level
9:00 am – 12:00 pm	NRG DMC Panel A *	Convention-West 102B/1 <sup>st</sup> Level
1:00 pm – 2:00 pm	VisionTree Workshop	Convention-West 105BC/1 <sup>st</sup> Level
1:00 pm – 4:00 pm	NRG DMC Panel B *	Convention-West 102B/1 <sup>st</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Patient Screening & Enrollment	Convention-West 101A/1 <sup>st</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Treatment Modalities	Convention-West 101B/1 <sup>st</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Data Management	Convention-West 101C/1 <sup>st</sup> Level
1:15 pm – 4:30 pm	Introduction to Clinical Trials – Adverse Event Reporting	Convention-West 102C/1 <sup>st</sup> Level
2:00 pm – 4:00 pm	GYN Developmental Therapeutics/Phase 1/Translational Science Workshops	Convention-West 211AB/2 <sup>nd</sup> Level
2:00 pm – 4:00 pm	Immunotherapy and Immune Modulation Workshop	Convention-North 120B/1 <sup>st</sup> Level
2:30 pm – 4:00 pm	Comparative Effectiveness Research (CER) Committee *	*Hyatt Hotel-Remington A//2 <sup>nd</sup> Floor
3:00 pm – 5:00 pm	NRG-Harvard-Ohio State-Case Western R01 Grant Meeting*	Convention-West 106B/1 <sup>st</sup> Level
4:00 pm – 5:15 pm	An Introduction to NRG Oncology ( <i>Formerly known as Clinical Trials 101, is an educational, overview session of the process involved in NRG Oncology and clinical trials for new investigators.</i> )	Convention-North 120A/1 <sup>st</sup> Level
4:00 pm – 6:00 pm	Patient Centered Outcomes Research (PCOR) Workshop	Convention-North 120B/1 <sup>st</sup> Level
4:30 pm – 6:30 pm	PSC Education & Training Working Group *	*Hyatt Hotel-Russell AB//2 <sup>nd</sup> Floor
4:30 pm – 6:30 pm	PSC Mentorship Working Group *	*Hyatt Hotel-Remington A//2 <sup>nd</sup> Floor
4:30 pm – 6:30 pm	PSC Protocol Review Working Group *	Convention-West 213AB/2 <sup>nd</sup> Level

Revised 1/14/19

\*Sessions for Committee Member



*Advancing Research. Improving Lives.™*

## NRG ONCOLOGY SEMIANNUAL MEETING FINAL AGENDA

Phoenix Convention Center  
Phoenix, Arizona  
February 7 – 9, 2019

Thursday, February 7, 2019		
5:30 pm – 7:00 pm	PSC Quality Control Working Group *	*Hyatt Hotel-Borein A//2 <sup>nd</sup> Floor
6:00 pm – 7:00 pm	Early Phase Trial Oversight Committee *	Convention-West 106B/1 <sup>st</sup> Level
6:00 pm – 8:00 pm	NCORP Concept Review <i>(Invitation Only)</i>	Convention-West 106A/1 <sup>st</sup> Level
6:00 pm – 8:00 pm	NRG Oncology Japan Meeting	Convention-West 102B/1 <sup>st</sup> Level
6:30 pm – 8:00 pm	Translational Science Workshop	Convention-West 105BC/1 <sup>st</sup> Level
8:00 pm – 10:00 pm	Ancillary Projects Committee *	Convention-West 106B/1 <sup>st</sup> Level

Revised 1/14/19

**\*Sessions for Committee Member**

# NRG ONCOLOGY SEMIANNUAL MEETING FINAL AGENDA

Phoenix Convention Center  
Phoenix, Arizona  
February 7 – 9, 2019

## Friday, February 8, 2019

6:30 am – 8:30 am	Continental Breakfast	Convention-North 120Lobby/1 <sup>st</sup> Level
7:00 am – 5:00 pm	Exhibits	Convention-North 120Lobby/1 <sup>st</sup> Level
7:00 am – 5:30 pm	Registration/CME/Information Desk	Convention-North 120Lobby/1 <sup>st</sup> Level
7:00 am – 6:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Convention-West 104B/1 <sup>st</sup> Level
9:00 am – 1:00 pm	CTN/CRA Information Table	Convention-North 120Lobby/1 <sup>st</sup> Level
10:00 am – 11:00 am	General Coffee Break	Convention-North 120Lobby/1 <sup>st</sup> Level
2:00 pm – 3:30 pm	General Coffee Break	Convention-North 120Lobby/1 <sup>st</sup> Level
6:45 am – 9:00 am	Patient Advocates Meeting *	*Hyatt Hotel-Borein B//2 <sup>nd</sup> Floor
7:00 am – 8:00 am	Digital Health Working Group	Convention-North 125AB/1 <sup>st</sup> Level
7:00 am – 8:00 am	IROC DI Workshop Focused on NRG Oncology trials BR005, GI003, GI006, GU007, GY005, GY009	Convention-West 101A/1 <sup>st</sup> Level
7:00 am – 8:00 am	GYN Cancer Committee Executive Session *	Convention-West 102B/1 <sup>st</sup> Level
7:00 am – 8:00 am	Local Regional Breast Cancer Subcommittee *	Convention-West 105A/1 <sup>st</sup> Level
7:00 am – 9:00 am	Clinical Trials Nurse/Clinical Research Associate Subcommittees Combined Meeting * ( <i>Open for first hour</i> )	Convention-West 213AB/2 <sup>nd</sup> Level
7:00 am – 12:00 pm	GYN/RT Case Review	Convention-West 104B/1 <sup>st</sup> Level
8:00 am – 9:00 am	NRG SDMC Executive Committee *	Convention-West 105A/1 <sup>st</sup> Level
8:00 am – 9:00 am	Protocol 210 Subcommittee	Convention-West 106A/1 <sup>st</sup> Level
8:00 am – 9:30 am	Radiation Oncology GYN Working Group	Convention-North 124AB/1 <sup>st</sup> Level
8:00 am – 10:00 am	Ovarian Cancer Workshop	Convention-North 120B/1 <sup>st</sup> Level
8:00 am – 10:00 am	Scientific Session – <i>NRG Oncology Research Review</i>	Convention-North 120A/1 <sup>st</sup> Level
8:00 am – 10:30 am	Translational Science Brain Cancer Subcommittee/Low- Grade Glioma Working Group	Convention-West 105BC/1 <sup>st</sup> Level
8:00 am – 12:00 pm	Pathology Workshop & Review	*Sheraton Hotel-Ahwatukee AB/2 <sup>nd</sup> FI
9:00 am – 10:30 am	Cancer Prevention and Control Committee Meeting ( <i>Invitation Only</i> )	Convention-North 125AB/1 <sup>st</sup> Level
10:00 am – 10:30 am	Communications Committee *	Convention-North 223/2 <sup>nd</sup> Level
10:00 am – 11:00 am	International Members Meeting	Convention-North 126AB/1 <sup>st</sup> Level
10:00 am – 11:00 am	NRG BR003 and NRG BR004 Workshops	Convention-North 127AB/1 <sup>st</sup> Level
10:00 am – 11:30 am	GYN GTN Subcommittee	Convention-West 213AB/2 <sup>nd</sup> Level
10:00 am – 12:00 pm	Health Disparities Committee	Convention-North 124AB/1 <sup>st</sup> Level
10:00 am – 12:00 pm	Cervix Cancer Workshop	Convention-North 120B/1 <sup>st</sup> Level
10:00 am – 12:00 pm	Sarcoma Working Group	Convention-West 101C/1 <sup>st</sup> Level
10:00 am – 12:00 pm	Imaging Committee	Convention-West 102C/1 <sup>st</sup> Level
10:30 am – 11:30 am	Social Media and Mobile Technology Workshop	Convention-North 223/2 <sup>nd</sup> Level
11:00 am – 12:00 pm	Protocol 225 Information Session	Convention-West 102A/1 <sup>st</sup> Level

Revised 1/14/19

\*Sessions for Committee Member

# NRG ONCOLOGY SEMIANNUAL MEETING FINAL AGENDA

Phoenix Convention Center  
Phoenix, Arizona  
February 7 – 9, 2019

<b>Friday, February 8, 2019</b>		
11:00 am – 12:00 pm	New Investigators Committee *	Convention-West 101B/1 <sup>st</sup> Level
11:00 am – 12:00 pm	NRG HN004 Update and Training Session	Convention-West 101A/1 <sup>st</sup> Level
11:00 am – 12:30 pm	Immunotherapy and Immune Modulation Workshop	Convention-West 212ABC/2 <sup>nd</sup> Level
11:00 am – 1:00 pm	Neurosurgical Subcommittee	Convention-West 105BC/1 <sup>st</sup> Level
11:00 am – 1:00 pm	Older Adult Working Group	Convention-North 126AB/1 <sup>st</sup> Level
11:00 am – 1:00 pm	NRG Oncology Foundation Board of Directors *	Convention-West 106A/1 <sup>st</sup> Level
11:00 am – 1:00 pm	Breast Cancer Rare & Genetically-Linked Subcommittee Workshop	Convention-North 129AB/1 <sup>st</sup> Level
11:30 am – 12:30 pm	NRG GI004 and NRG GI002 Workshops	Convention-North 127AB/1 <sup>st</sup> Level
11:30 am – 1:00 pm	Cancer Care Delivery Research Session Workshop	Convention-North 132AB/1 <sup>st</sup> Level
12:00 pm – 1:00 pm	NRG Pharmacy Subcommittee	Convention-West 105A/1 <sup>st</sup> Level
12:00 pm – 1:00 pm	Pathology Committee *	*Sheraton Hotel-Ahwatukee AB/2 <sup>nd</sup> FI
1:00 pm – 2:00 pm	NRG Oncology General Session	Convention-North 120A/1 <sup>st</sup> Level
2:00 pm – 3:00 pm	Translational Science Head & Neck Cancer Subcommittee	Convention-West 105BC/1 <sup>st</sup> Level
2:00 pm – 3:30 pm	Publications Committee *	Convention-West 105A/1 <sup>st</sup> Level
2:00 pm – 3:30 pm	Translational Science Breast Cancer Subcommittee	Convention-West 211AB/2 <sup>nd</sup> Level
2:00 pm – 4:00 pm	Translational Science GU Cancer Subcommittee	Convention-North 126AB/1 <sup>st</sup> Level
2:00 pm – 4:00 pm	Rare Tumor Workshop	Convention-West 212ABC/2 <sup>nd</sup> Level
2:00 pm – 4:00 pm	Radiation Oncology Committee Meeting	Convention-North 131ABC/1 <sup>st</sup> Level
2:00 pm – 5:00 pm	Brain Tumor Core Committee *	Convention-North 132AB/1 <sup>st</sup> Level
2:00 pm – 6:00 pm	Clinical Trial Nurse/Clinical Research Associate Workshop - Educational Session	Convention-North 120CD/1 <sup>st</sup> Level
2:30 pm – 4:30 pm	Uterine Corpus Cancer Workshop	Convention-North 120B/1 <sup>st</sup> Level
2:30 pm – 4:30 pm	Cancer Prevention and Control Workshop	Convention-North 129AB/1 <sup>st</sup> Level
3:00 pm – 6:00 pm	Head & Neck Cancer Core Committee *	Convention-North 125AB/1 <sup>st</sup> Level
3:30 pm – 6:30 pm	Breast Cancer Working Group *	Convention-North 124AB/1 <sup>st</sup> Level
4:00 pm – 5:00 pm	NRG Oncology Human Research Committee *	Convention-West 105A/1 <sup>st</sup> Level
4:00 pm – 5:30 pm	Translational Science GYN Workshop	Convention-West 211AB/2 <sup>nd</sup> Level
4:00 pm – 6:00 pm	Medical Physics Subcommittee Meeting	Convention-West 101B/1 <sup>st</sup> Level
4:00 pm – 6:00 pm	Translational Science Lung Cancer Workshop	Convention-West 105BC/1 <sup>st</sup> Level
4:00 pm – 6:00 pm	Genitourinary Cancer Core Committee *	Convention-North 126AB/1 <sup>st</sup> Level
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group Meeting	Convention-West 106A/1 <sup>st</sup> Level
5:00 pm – 7:00 pm	Brain Tumor Workshop	Convention-North 132AB/1 <sup>st</sup> Level
6:00 pm – 8:00 pm	NRG Oncology Welcome Reception	Convention-North 221ABC&222ABC/2 <sup>nd</sup> Level

Revised 1/14/19

\*Sessions for Committee Member



# NRG ONCOLOGY SEMIANNUAL MEETING FINAL AGENDA

Phoenix Convention Center  
Phoenix, Arizona  
February 7 – 9, 2019

## Saturday, February 9, 2019

6:30 am – 8:30 am	Continental Breakfast	Convention-North 120Lobby/1 <sup>st</sup> Level
7:00 am – 1:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Convention-West 104B/1 <sup>st</sup> Level
7:00 am – 2:00 pm	Exhibits	Convention-North 120Lobby/1 <sup>st</sup> Level
7:00 am – 3:00 pm	Registration/CME/Information Desk	Convention-North 120Lobby/1 <sup>st</sup> Level
10:00 am – 12:00 pm	General Coffee Break	Convention-North 120Lobby/1 <sup>st</sup> Level
6:45 am – 8:30 am	Proton Working Group Meeting	Convention-North 223/2 <sup>nd</sup> Level
7:00 am – 8:00 am	Surgical Oncology Workshop	Convention-North 124AB/1 <sup>st</sup> Level
7:00 am – 8:00 am	Canadian Members Meeting	Convention-West 101A/1 <sup>st</sup> Level
7:00 am – 8:00 am	NRG SDMC Data Management Working Group *	Convention-West 106B/1 <sup>st</sup> Level
7:00 am – 8:00 am	NRG SDMC IT Working Group *	Convention-West 208B/2 <sup>nd</sup> Level
7:00 am – 8:00 am	NRG SDMC Statistical Working Group *	Convention-West 105A/1 <sup>st</sup> Level
7:00 am – 8:00 am	Medical Oncology Workshop	Convention-North 127AB/1 <sup>st</sup> Level
7:00 am – 9:00 am	Translational Science GI Cancer Subcommittee	Convention-North 231ABC/2 <sup>nd</sup> Level
7:00 am – 9:30 am	Protocol Support Committee Business Meeting *	Convention-North 125AB/1 <sup>st</sup> Level
8:00 am – 9:00 am	NRG BR005 Workshop	Convention-North 124AB/1 <sup>st</sup> Level
8:00 am – 9:00 am	GYN Developmental Therapeutics/Phase I Workshops	Convention-North 120B/1 <sup>st</sup> Level
8:00 am – 9:30 am	Safety Review Committee *	Convention-West 105A/1 <sup>st</sup> Level
8:00 am – 10:00 am	NCORP PI & Administrators Meeting	Convention-North 127AB/1 <sup>st</sup> Level
8:00 am – 10:00 am	Genitourinary Cancer Workshop	Convention-West 105BC/1 <sup>st</sup> Level
8:00 am – 10:00 am	Head & Neck Surgical Subcommittee	Convention-West 211AB/2 <sup>nd</sup> Level
8:00 am – 10:00 am	Lung Cancer Core Committee *	Convention-North 126AB/1 <sup>st</sup> Level
9:00 am – 10:00 am	Ovarian Cancer Workshop	Convention-North 120B/1 <sup>st</sup> Level
9:00 am – 10:00 am	Cervix Cancer Workshop	Convention-North 232ABC/2 <sup>nd</sup> Level
9:00 am – 10:00 am	Uterine Corpus Cancer Workshop	Convention-West 212ABC/2 <sup>nd</sup> Level
9:00 am – 10:00 am	Quality Assurance Audit Meeting *	Convention-West 208B/2 <sup>nd</sup> Level
9:00 am – 11:00 am	GI Colorectal Cancer Subcommittee *	Convention-North 231ABC/2 <sup>nd</sup> Level
9:00 am – 1:00 pm	Breast Cancer Workshop	Convention-North 120CD/1 <sup>st</sup> Level
10:00 am – 10:30 am	NRG LU005 Information Session	Convention-North 223/2 <sup>nd</sup> Level
10:00 am – 11:30 am	Membership Committee *	Convention-West 105A/1 <sup>st</sup> Level
10:00 am – 12:00 pm	Gynecologic Cancer Workshop	Convention-North 120B/1 <sup>st</sup> Level
10:00 am – 12:00 pm	Radiation-Developmental Therapeutics Workshop	Convention-North 124AB/1 <sup>st</sup> Level
10:00 am – 12:00 pm	Head & Neck Cancer Workshop	Convention-West 105BC/1 <sup>st</sup> Level
10:30 am – 11:00 am	NRG-LU003 Kick-Off Meeting	Convention-North 223/2 <sup>nd</sup> Level
11:00 am – 1:00 pm	GI Non-Colorectal Cancer Subcommittee *	Convention-North 231ABC/2 <sup>nd</sup> Level

Revised 1/14/19

*\*Sessions for Committee Member*



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## NRG ONCOLOGY SEMIANNUAL MEETING FINAL AGENDA

Phoenix Convention Center  
Phoenix, Arizona  
February 7 – 9, 2019

Saturday, February 9, 2019		
12:00 pm – 1:00 pm	Voting Members PI Meeting *	Convention-North 129AB/1 <sup>st</sup> Level
1:00 pm – 3:00 pm	Gastrointestinal Cancer Workshop	Convention-North 127AB/1 <sup>st</sup> Level
1:00 pm – 3:00 pm	Lung Cancer Workshop	Convention-West 105BC/1 <sup>st</sup> Level
2:00 pm – 3:00 pm	VA/MTF Meeting	Convention-North 126AB/1 <sup>st</sup> Level
3:00 pm – 6:00 pm	Research Strategy Meeting *	Convention-West 102ABC/1 <sup>st</sup> Level

Revised 1/14/19

**\*Sessions for Committee Member**

# Information Technology Resource Center

**NRG Semi-Annual  
Meeting**

**Phoenix, AZ**

**February 7 - 9, 2019**

**Phoenix Convention Center**

**West 104 B**

**First Level**

**Open**

**Thur. Feb 7: 2PM -6PM**

**Fri. Feb 8: 7AM-6PM**

**Sat. Feb 9: 7AM-1PM**



<http://www.nrgoncology.org>



## **The Resource Center will feature:**

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

- ❑ Medidata RAVE
- ❑ CTSU OPEN
- ❑ User Accounts

Available services include:

- ❑ Internet Access
- ❑ Email
- ❑ Printing

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



## Special Events/Sessions Workshops

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

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**Date:** Thursday, February 7, 2019  
**Start and End Time:** 4:00 pm - 5:15 pm

**Chairs:** Elizabeth Gore, MD  
Priya Rastogi, MD  
Angeles Secord, MD, MHSc

### Learning Objectives:

Following this activity, participants will be better able to:

1. Define the different processes within NRG Oncology at each phase in the lifespan of a clinical trial.
2. Utilize the NCI Cancer Therapy Evaluation Program (CTEP) Project Team Member Applications (PTMA)
3. To develop a strategy to use NRG Oncology study data for ancillary projects

### WORKSHOP AGENDA

An Introduction to NRG Oncology: New Investigator Educational Session

- |    |   |                               |
|----|---|-------------------------------|
| A. | Introduction from the Session Chair   | Speaker: Angeles Secord, MD   |
| B. | 4:05-4:20PM – NRG Oncology Protocol Development Process                             | Speaker: Nancy Soto           |
| C. | 4:20-4:35PM - The Role of the Statistician in Protocol Development and Study Design | Speaker: Mike Sill, PhD       |
| D. | 4:35-4:50PM – Project Team Member Applications: Understanding PTMA                  | Speaker: Carol Aghajanian, MD |
| E. | 4:50-5:05 – NRG Oncology Study Data for Ancillary Projects                          | Speaker: Steven Waggoner, MD  |

### QUESTIONS / DISCUSSION

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

# NRG Oncology Scientific Session

Research Review Hosted by the Publications Committee

Friday, February 8, 2019

8:00-10:00 am

NRG Oncology February 2019 Semiannual Meeting

Phoenix Convention Center

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## PRESENTATIONS



NRG Oncology Phase II Randomized Trial of nivolumab with or without Ipilimumab in patients with persistent or recurrent ovarian cancer.

**Presenter:** Robert Burger, MD

**Discussant:** Sarah Temkin, MD



Preservation of neurocognitive function (NCF) with hippocampal avoidance during whole-brain radiotherapy (WBRT) for brain metastases: preliminary results of phase III trial NRG Oncology CC001.

**Presenter:** Vinai Gondi, MD

**Discussant:** Paul Sperduto, MD



Short term androgen deprivation therapy without or with pelvic lymph node treatment added to prostate bed only salvage radiotherapy: the NRG Oncology/ROG 0534 SPPORT Trial.

**Presenter:** Alan Pollack, MD

**Discussant:** William Hall, MD



Post-resection CA19-9 and margin status as predictors of recurrence after adjuvant treatment for pancreatic carcinoma: analysis of NRG Oncology RTOG trial 9704

**Presenter:** William Regine, MD

**Discussant:** Richard Tuli, MD



NRG-RTOG 1016: phase III trial comparing radiation/cetuximab to radiation/cisplatin in HPV-related cancer of the oropharynx.

**Presenter:** Andy Trotti, MD, PhD

**Discussant:** Stuart Wong, MD



Primary results of NSABP B-39/RTOG 0413 (NRG Oncology): A randomized phase III study of conventional whole breast irradiation versus partial breast irradiation for women with stage 0, I, or II breast cancer.

**Presenter:** Frank, Vicini, MD

**Discussant:** Atif Khan, MD

## NRG Scientific Session NRG Oncology Research Review

**Date:** Friday, February 8, 2019  
**Start and End Time:** 8:00 am – 10:00 am  
**Chair:** Harry Bear, MD  
**Co-Chair:** Elizabeth M Gore, MD; Thomas B Julian, MD; and Krishnansu S Tewari, MD (Moderator)

### Learning Objectives:

Following this activity, participants will be better able to:

1. Educate members regarding ipilimumab (IPI) plus nivolumab (NIVO) compared with NIVO alone in women with persistent or recurrent epithelial ovarian cancer.
2. Discuss the neuro-protective effects of avoiding the hippocampus using intensity-modulated radiotherapy.
3. Examine whether there are incremental gains in freedom from progression (FFP) from the addition of 4-6 months of short term androgen deprivation therapy (STADT) using antiandrogen plus an LHRH agonist, without or with pelvic lymph node treatment (PLNRT), to prostate bed salvage radiotherapy (PBRT).
4. Describe how the secondary analysis assessed the prognostic value of post-resection CA19-9 and surgical margin status (SMS) in predicting patterns of disease recurrence.
5. Understand whether radiation with cetuximab has non-inferior overall survival compared to radiation with cisplatin in patients with local regionally advanced human papillomavirus (HPV)–related oropharynx cancer.
6. Determine whether partial breast irradiation PBI limited to the region of the tumor bed following lumpectomy provides equivalent local tumor control in the breast compared to whole breast irradiation WBI in pts with early-stage breast cancer.

### WORKSHOP AGENDA

8:00 – 8:05 am	Welcome	Krishnansu S Tewari, MD
8:05 – 8:17 am	NRG Oncology Phase II Randomized Trial of nivolumab with or without Ipilimumab in patients with persistent or recurrent ovarian cancer.	Robert Burger, MD
8:17 – 8:22 am	Discussant	Sarah Temkin, MD
8:22 – 8:34 am	Preservation of neurocognitive function (NCF) with hippocampal avoidance during whole-brain radiotherapy (WBRT) for brain metastases: preliminary results of phase III trial NRG Oncology CC001.	Vinai Gondi, MD
8:34 – 8:39 am	Discussant	Paul Sperduto, MD
8:39 – 8:51 am	Short term androgen deprivation therapy without or with pelvic lymph node treatment added to prostate bed only salvage radiotherapy: the NRG Oncology/RTOG 0534 SPPORT Trial.	Alan Pollack, MD
8:51 – 8:56 am	Discussant	William Hall, MD
8:56 – 9:08 am	Post-resection CA19-9 and margin status as predictors of recurrence after adjuvant treatment for pancreatic carcinoma: analysis of NRG Oncology RTOG trial 9704.	William Regine, MD
9:08 – 9:13 am	Discussant	Richard Tuli-invited
9:13 – 9:25 am	NRG-RTOG 1016: phase III trial comparing radiation/cetuximab to radiation/cisplatin in HPV-related cancer of the oropharynx.	Andy Trotti, MD, PhD
9:25 – 9:30 am	Discussant	Stuart Wong, MD
9:30 – 9:42 am	Primary results of NSABP B-39/RTOG 0413 (NRG Oncology): A randomized phase III study of conventional whole breast irradiation versus partial breast irradiation for women with stage 0, I, or II breast cancer.	Frank Vicini, MD
9:42 – 9:47 am	Discussant	Atif Khan, MD

# NRG Oncology Social Media Workshop

Presented by the NRG Oncology Communications Committee

Friday, February 8, 2019

10:30-11:30 am

NRG Oncology February 2019 Semiannual Meeting  
Phoenix Convention Center

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## SPEAKERS



**Michael Cowher, MD**  
*West Virginia University*  
Session Chair

@MikeCowher

Welcome and Introductions



**Hannah Hazard-Jenkins, MD**  
*West Virginia University*

@HannahHazard

"Embedding PROs in the EMR:  
The Potential of Smart Devices to  
Impact Cancer Outcomes - SIM-  
PRO Research Center"



**Jame Abraham, MD**  
*Cleveland Clinic*

@JameCancerDoc

"Why I am on Social Media or  
What is Wrong with Me?"



**Rebecca Previs, MD**  
*Duke University*

@BeccaPrevisMD

Twitter 101 - How to Sign Up and  
Create

Use the NRG Oncology Semiannual Meeting hashtag to be a part of the conversation:

# #NRG19



## Social Media and Mobile Technology Workshop Agenda

**Session Title:** Social Media and Mobile Technology Workshop  
**Date:** Friday, February 8, 2019  
**Start and End Time:** 10:30 am to 11:30 am (EST) (tentative)  
**Chair:** Michael S. Cowher, MD

### Learning Objectives:

Following this activity, participants will be better able to:

1. Explain the continued value of social media presence for clinicians and investigators.
2. Understand the emerging role of patient-reported outcomes in medical records, clinical trials, and practice.
3. Recognize and appreciate the value that social media can bring to professional development.
4. Understand how to create, set up, and effectively use your Twitter account.

### WORKSHOP AGENDA

A.	10:30 – 10:35	Welcome and Introduction	Michael S. Cowher, MD
B.	10:35 – 10:50	Embedding PROs in the EMR: The Potential of Smart Devices to Impact Cancer Outcomes – SIMPRO Research Center”	Hannah Hazard-Jenkins, MD
C.	10:50 – 11:05	“Why I am on Social Media or What is Wrong with Me?”	Jame Abraham, MD
D.	11:05 – 11:20	Twitter 101 – How to Sign Up and Create	Rebecca Previs, MD

### QUESTIONS / DISCUSSION

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

# NRG Oncology General Session

Friday, February 8, 2019  
1:00 pm - 2:00 pm  
Room





*Join the Celebration!*

## **NRG Oncology Welcome Reception**

Friday, February 8, 2019 - 6 pm to 8 pm  
North 221ABC & North 222ABC on the 2nd level

This meeting's Welcome Reception isn't just a place to catch up with your NRG friends and colleagues! Birthday cake is on the menu, as well as informal remarks in honor of our success!



## Workshop Agendas (CME/Non-CME)

# NRG Scientific Committees

## Brain Tumor Workshop

**Date:** February 8, 2019  
**Start and End Time:** 5:00 pm – 7:00 pm  
**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	1071	NCCTG N0577/Endorsed Study: Phase III CODEL PFS endpoint. RT/PCV vs RT/TMZ, NI P3 study	G2/3 Glios	9/09	138/360	Vogelbaum; 48 from NRG
2	1470 A071101	Randomized Phase II Trial of Bevacizumab +/- HSP vaccine in Patients with rGBM	rGBM	5/13	90/165	Raizer; 17 from NRG
3	BN 001	Hypofractionated Dose escalated Photon IMRT or PBT vs Conventional Photon Irradiation with Concomittant and Adjuvant Temozolomide	nGBM	10/14	Photon: 302/288; 41/30 for advanced imaging Proton: 130/288	IIR: Mehta/Gondi; photon arm accrued; advanced imaging issues to be discussed by Dr. Tsien

	STUDY	NAME	DX	START	N	COMMENTS
4	NRG 1119	Phase IIR RT+/- Lapatinib	BM Breast		130/143	Kim
5	CC 003	Phase II/III PCI WBRT +/- HA	SCLC PCI	12/15	176/172 and 304	Gondi: P2 accrued
6	Alliance A071401	Meningioma targeted agents, 3 arms (SMO, AKT, NF2)	Menin	8/15	40/56	Brastianos
7	BN 003	Meningioma RT vs Obs	Menin	6/17	31/133	Rogers
8	BN 005	LGG Photons vs Protons	LGG	8/17	3/120	Grosshans

## 2. Closed Studies:

	STUDY	NAME	DX	START	N	COMMENTS
1	A071102	Phase II/III Rt/TMZ +/- ABT 888	GBM		Accrued 447/440	Sarkaria; accrued
2	RTOGf 3508	IIR/III RT/TMZ +/- ABT 414 for nGBM	nGBM		Accrued	Lassman
3	RTOGf 3503	Bev-refractory rec GBM PIIR	rGBM	5/16	Closed	Ahluwalia

## 3. Studies Activating soon:

	STUDY	NAME	DX	START	N	COMMENTS
1	BN 006	Phase II/III Toca511	GBM			Ahluwalia

## Brain Steering

**Date:** February 8, 2019  
**Start and End time:** 2:00 pm – 5:00 pm  
**Chair:** Minesh P. Mehta, MD  
**Co-Chairs:** Mark Gilbert, MD; Michael Vogelbaum, MD, PhD; Arnab Chakravarti, MD

### AGENDA:

#### Developing/Approved concepts for discussion:

1. GBM:
  - a. Yazmin Odia: ONC 201
  - b. Manmeet Ahluwalia: Toca 511
  - c. Andy Lassman: Ipi+Nivo
  - d. Vinai Gondi: Radiomics-guided resection
  - e. Rimas Lukas: IDO inhibition
  - f. Jay Huang: Large vs small field lymphocyte depletion
2. Brain Mets
  - a. Paul Sperduto: Ipi/Nivo melanoma brain mets
  - b. Vinai Gondi: BM velocity concept
  - c. David Roberge: NCIC p3 randomized brain met trial
3. PCNSL:
  - a. Christian Grommes: Ibrutinib concept



## Breast Cancer Workshop Agenda

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 9:00 am – 12:00 pm  
**Chair:** Eleftherios Mamounas, MD  
**Co-Chairs:** Julia White, MD

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

<b>9:00 – 9:15</b>	<b>Welcome/Update</b>	Norman Wolmark, MD
<b>9:15 – 9:45</b>	<b>Report from the Breast Working Group Meeting</b>	Eleftherios Mamounas, MD Julia White, MD
<b>9:45 – 10:00</b>	<b>NRG BR-003</b> 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
<b>10:00 – 10:15</b>	<b>NRG BR-005</b> -A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy	Mark Basik, MD Jennifer Delossantos, MD
<b>10:15 – 10:45</b>	<b>Immunotherapy Trials</b>	
	<b>NRG BR-004</b> 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
	<b>NSABP-59/GBG 96</b> 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	
	<b>NRG BR-006</b> 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
<b>10:45 – 10:55</b>	<b>FB-12</b> -Neoadjuvant Chemotherapy plus Anti-HER2 Therapy in HER2 Negative Patients with Increased HER2 Signaling Activity	Eleftherios Mamounas, MD

<b>10:55 – 11:10</b>	<b>Olympia (NSABP B-55/BIG 6-13)</b> A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multicenter Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High-Risk HER2-Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy	Charles Geyer, Jr., MD
<b>11:10 – 11:25</b>	<b>NRG BR-002</b> A Phase IIR/III Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer	Steve Chmura, MD, PhD
<b>11:25 – 11:35</b>	<b>NSABP B-58:</b> Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy Compared to Standard Endocrine Therapy Alone in Patients with High Risk, Node Positive, Hormone Receptor Positive, HER2-Negative, Breast Cancer	Priya Rastogi, MD
<b>11:35 – 11:45</b>	<b>NSABP B-51/RTOG 1304:</b> A Randomized Phase III Clinical Trial Evaluating the Role of Post-mastectomy Chest Wall and Regional Nodal XRT and Post-lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy	Julia White, MD Eleftherios Mamounas, MD
<b>11:45 – 12:00</b>	<b>EA1131:</b> A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy	Bill Sikov, MD

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## Breast Cancer Rare Tumor Subcommittee Workshop

**Date:** Friday, February 8, 2019  
**Start and End Time:** 11:00 am – 12:00 pm  
**Chair:** Alexandra Thomas

### Learning Objectives:

Following this activity, participants will be better able to:

1. Identify and describe opportunities for trial concept development in metaplastic breast cancer
2. Identify and describe opportunities to study and treat phyllodes tumors
3. Identify and describe opportunities to develop clinical trials in rare breast tumors and how to capitalize on existing expertise in this area from other tumor types
4. Identify and describe mechanisms by which to assess trial proposals on rare breast cancers

## WORKSHOP AGENDA

<b>11:00- 11:10</b>	Committee Updates <ul style="list-style-type: none"><li>▪ Introductions</li><li>▪ Update from the Working Group</li><li>▪ Speakers for future meetings</li><li>▪ BR1703 Metaplastic Concept Update</li></ul>	<b>Alexandra Thomas, MD</b>
<b>11:10– 11:30</b>	Phyllodes Tumors – <ul style="list-style-type: none"><li>▪ Previous work and future opportunities</li></ul>	<b>Richard J. Barth, Jr, MD</b>
<b>11:30 – 11:40</b>	<i>Trial Concept (Tentative)</i> <ul style="list-style-type: none"><li>▪ <i>RAD51 Concept</i></li></ul>	<b>Simona Shaitelman, MD</b>
<b>11:40 – 11:55</b>	Inflammatory Breast Cancer <ul style="list-style-type: none"><li>▪ Background and early discussion on concepts</li><li>▪ Mechanism for concept proposals</li></ul>	<b>Stan Lipkowitz, MD, PhD</b>
<b>11:55- 12:00</b>	Organization for 2019-2022 <ul style="list-style-type: none"><li>• Mechanisms to Develop Trial Concepts</li><li>• Technology/Big Data</li><li>• GOG Experience</li><li>• Future directions</li></ul>	<b>Committee</b>

## Local Regional Breast Cancer Subcommittee

**Date:** Friday, February 8, 2019

**Start and End Time:** 7-8 am

**Chair:** Thomas Julian, M.D.

**Co-Chair:** Doug Arthur, M.D.

### Learning Objectives:

Following this activity, participant will be better able to:

1. Provide information on committee mission and format.
2. Discuss local regional questions related to breast cancer.
3. Acquire insight to evolve LR clinical trials.

**Educational Needs:** This committee was designed by the NRG Breast Committee Chairs to help answer questions related to local regional breast disease and design local regional concepts related to breast cancer.

### Workshop Agenda:

7:00	Welcome/Introduction	Thomas Julian, MD & Doug Arthur, MD
7:05 – 7:20	Ideal monotherapy in the elderly, hormone sensitive, Stage 1 breast cancer	Manjeet Chadra, MD
7:20 – 7:35	RSI/GARD radiosensitivity assays – dose determination based on the radiosensitivity profile.	Eleanor Harris, MD
7:35 – 7:50	TBA	Jose Bazan, MD
7:50 – 8:00	Closing comments	Lead by Thomas Julian, MD & Doug Arthur, MD

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

**Date:** Friday, February 8, 2019  
**Start and End Time:** 10:00 am – 11:00 am

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

<b>10:00-10:25</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>10:25-10:35</b>	Clinical Logistics	Lynne Suhayda, RN, MEd
<b>10:35-10:45</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>10:45-10:50</b>	Clinical Logistics	Kristen Kotsko RN, BSN
<b>10:50-10:55</b>	Questions/Discussion	
<b>10:55-11:00</b>	Evaluation	

## NRG Oncology Protocol NRG-BR005 Workshop

Date: Saturday, February 9, 2019 Start and End

Time: 8:00 am- 9:00 am

### Learning Objectives

Following this activity, participants will be better able to:

1. Explain the rationale for the BR005 trial.
2. Understand eligibility/biopsy factors for BR005 trial.

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

### WORKSHOP AGENDA

8:00-8:10 am	Background and Scientific	Mark Basik, MD
8:10-8:20 am	Eligibility Criteria	Jennifer F. De Los Santos, MD
8:20-8:40 am	Radiologic Considerations including Stereotactic Biopsy of the Tumor Bed	Heidi Umphrey, MD
8:40 -8:55 am	Moderated Panel Discussion	Thomas Julian, MD
8:55 -9:00 am	Questions and Answers	

## Cancer Prevention and Control Workshop

Chair: Lisa Kachnic, MD

Session I: Friday, February 8, 2019 11:00 am – 12:00 pm GOG-225 Informational Session

Session II: Friday, February 8, 2019 2:30 pm – 4:30 pm CPC Workshop

### **SESSION I – GOG-0225, Information Session**

Friday, February 8, 2019 11:00 am – 12:00 pm CME's are not provided

#### **GOG-225: The Lifestyle Intervention for ovarian cancer Enhanced Survival (LIVES) Study**

Presentations with a question and answer session

**Cynthia Thomson, PhD, RD, CSO**, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona

**Tracy Crane, MS, RD**, Research Specialist, Sr.LIVES Study Coordinator -Study co-chair and coordinator will be available to answer questions regarding ongoing study

### **SESSION II – NRG CPC Committee Workshop**

Friday, February 8, 2019 2:30 pm – 4:30 pm

#### **Learning Objectives**

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

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

#### **A. Introduction**

#### **B. Review of Open Studies:**

- **GOG-0237:** Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papillomavirus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC) (S-Y. Liao)
- **GOG 0278:** Before/after Non-radical Surgery Physical function and QOL (A. Covens)
- **NRG-CC003:** Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC (V. Gondi), *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)

#### **C. Review of Concepts & Protocols in Development:**

- **NRG-CC005:** FORTE – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (R. Schoen)
- **NRG-CC1860:** A Randomized Trial of IADL-Based Dose-Adjusted Pegylated Liposomal Doxorubicin Every 28 Days with Bevacizumab 10 mg/kg Every 2 Weeks versus Standard of Care Dosing of Chemotherapy in Elderly Recurrent Ovarian Cancer Patients (D. Chase)
- **NRG-CC1742:** Adaptive Intervention for Smoking Cessation in Women with Breast, Cervical, Endometrial and Vaginal Cancer prior to Radiation Therapy (T. Crane)
- Utility of gonadotropin-releasing Hormone Agonists (GnRHA) to Protect Ovarian Reserve for Women Undergoing Chemotherapy (H. Burks, L. Landrum, J. Walker)
- Prevention of Falls among older Multiethnic breast cancer patients receiving taxane chemotherapy (**PERFORM ANEW**) (J. Bea)
- Salpingectomy concept (D. Levine)

#### **D. Other Updates**

- Lymphedema update – state of the science meeting with NCI to discuss the endpoints for two concepts (J. Walker)
- GOG 0225 update (T. Crane, C. Thomson)
- New Pilot Project Awardees
- C. Xiao and K. Sturgeon – Pilot project update
- K. Hutchinson – pilot project update



# Cancer Care Delivery Research (CCDR) Workshop Agenda

**Date:** Friday, February 8, 2019  
**Start and End Time:** 11:30 am – 1:00 pm  
**Co-Chair:** Debra Ritzwoller, PhD  
**Co-Chair:** Matthew F. Hudson, PhD, MPH

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

## WORKSHOP AGENDA

## SPEAKERS

### Session I

- |    |   |  |
|----|---|--|
| A. | Welcome and information   | Matt Hudson, PhD, MPH                  |
| B. | Update on CCDR Committee  | Deb Ritzwoller, PhD                    |
| C. | NCI CCDR updates  |  |
| a. | Building a Foundation for CCDR Studies  | Kate Castro, RN & Ann Geiger, MPH, PhD |
| D. | Update on CCDR Pilot Awards   |  |
| a. | PROTECT: Patient Reported Outcomes to Enhance Care on Treatment   | Alexi Wright, MD                       |
| b. | Breast Cancer Screening Decisions in Younger Women: A Hybrid Effectiveness-Implementation Study   | Erin Hahn, MD                          |
| c. | Physical Activity Monitoring to Predict Hospitalization in Advanced Cancer Patients   | Nitin Ohri, MD                         |
| E. | NRG-CC007CD: “Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy” Protocol update    | Ron Chen, MD, MPH                      |
| F. | U01 Grant: The Implementation of Families Accelerating Cascade Testing Toolkit to Improve Cascade Genetic Testing through the NCORP/CCDR                  | Andrea Hagemann, MD                    |
| G. | NRG CCDR Concept Review-Evaluating Patients’ Perception of Care Coordination to Improve Cancer Care Delivery<br>Review Facilitator: Matt Hudson, PhD, MPH | Randall F. Holcombe, MD, MBA           |

## QUESTIONS / DISCUSSION

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

**Date:** Thursday, February 7, 2019  
**Start and End Time:** 2:00 PM – 4:00 PM  
**Chairs:** Roisin O’Cearbhaill, MD (Developmental Therapeutics) and Michael Birrer, MD, PhD (Translational Science)  
**Translational Research Chair:** Panagiotis Konstantinopoulos, MD, PhD (Developmental Therapeutics)  
**Co-Chairs:** Floor Backes, MD (Phase II), Russell Schilder, MD (Phase I), Stephanie Gaillard, MD, PhD (Phase I)

### Learning Objectives

Following this activity, participants will be better able to:

1. Participants will become familiar with current mechanisms for development of clinical and translational research within National Clinical Trials Network (NCTN).
2. Participants will become familiar with current status of translational research projects involving phase I and II studies that are under development or activated for accrual.
3. New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.
4. Participants will become familiar with the challenges in relation to study biospecimen acquisition and storage
5. Recommendations for action by the GYN Developmental Therapeutics committee will be summarized.

### WORKSHOP AGENDA

**Thursday, February 7, 2019**

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

2:00 PM – 2:10 PM	Introduction, Drs. O’Cearbhaill and Birrer. Welcome new members and opportunities for young investigators.
2:10 PM – 2:30 PM	CTEP Early Drug Development Update, Charles Kunos, MD, PhD, Medical Officer and Coordinator, Investigational Therapeutics & Radiation, Investigational Drug Branch, CTEP
2:30 PM – 2:50 PM	Translational research opportunities in early phase trials, Panagiotis Konstantinopoulos, MD, PhD, Director of Translational Research and attending oncologist in the Gynecologic Oncology Program at Dana-Farber Cancer Institute
2:50 PM – 3:05 PM	Proposal to develop taskforce to address challenges encountered with study biospecimen procurement, Jyoti Mayadev, MD, University of California, San Diego, and Roisin O’Cearbhaill, MD, Memorial Sloan Kettering Cancer Center
3:05 PM – 4:00 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>

#### New Concepts:

- **DT1907:** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer- Floor Backes
- **DT1910:** Phase II single arm trial of Visudyne in platinum resistant recurrent ovarian cancer- Radhika Gogoi
- **OV1911:** 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.(Dmitriy Zamarin)
- **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)

### Follow up on submitted concepts from the July 2018 Meeting:

1. **DT1831:** A Phase II study of combination pegylated liposomal doxorubicin (PLD) with durvalumab in women with microsatellite stable recurrent endometrial cancer. (B Corr) **(disapproved, unsuccessful attempt through CTEP/DART mechanism)**
2. **DT1833/NRG- GY022:** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Sarah Taylor/ Jan Beumer) **(under development)**
3. **PI1845** Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi) **(tabled, call with CTEP; required additional preclinical data. Plan to submit as new concept)**
4. **DT1846** A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with neoadjuvant and postsurgical chemotherapy in patients with newly-diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (D Zamarin) **(Disapproved by Gyn Steering Committee)**

### Open 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**

### Studies under development

#### Endometrial

- **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) **(currently closed, working with CTEP to replace/add additional arms)**
- **NRG-GY013** A window of opportunity pharmacodynamic trial of triapine in uterine corpus serous adenocarcinoma (Sarah Temkin) **(awaiting additional preclinical work prior to resubmitting)**
- **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)**

#### Ovary

- **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)**

#### Miscellaneous

- **NRG-GY022** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Sarah Taylor/ Jan Beumer) **(Supported by CTPEP, approved for development of protocol)**

## **GYN Developmental Therapeutics/Phase I Workshop**

**Date:** Saturday, February 9, 2019  
**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. Immuno-oncology toxicity management and Immune Modulation workshop will present an update from Thursday, February 7, 2019 (2:00 – 4:00 PM) and plan for integration and prioritization.
3. Integration and prioritization of studies will be reviewed and reference to Cervix/Vulva Cancer, Ovarian Cancer and Uterine Corpus Cancer workshops and the Translational Science workshop.
4. New phase I concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.

### **Saturday, February 9, 2019**

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

**8:00 AM - 9:00 AM**      **Russell Schilder, MD**

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

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

**8:45 AM – 9:00 AM**

##### **Cervical Cancer (Dmitriy Zamarin, MD, PhD)**

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

##### **Endometrial Cancer (Floor Backes)**

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

##### **Ovarian Cancer (Roisin O’Cearbhaill, MD)**

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

##### **Sarcomas (Roisin O’Cearbhaill, MD)**

- Active
- Studies under development
- Closed studies

## List of Studies

### New Concepts

- **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)
- **DT1916**: Randomized phase II trial with safety lead in evaluating dual checkpoint immunotherapy with nivolumab and low dose ipilimumab with or without anetumab ravtansine in recurrent ovarian cancer with moderate-strong mesothelin expression (Haider Mahdi)

### 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**

#### Prior safety lead-ins:

- **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** Active for accrual

#### 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)
- **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
- **NRG-GY002** A phase II evaluation of nivolumab, a fully human antibody against PD-1, in the treatment of persistent or recurrent cervical cancer (A Santin) Both stages of accrual complete
- **265** A phase II evaluation of ADXS11-001 in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix (W Huh) Safety lead in performed by Phase I subcommittee - completed. ASCO 2016 (Stage 1 of Phase II). SGO 2017

#### Endometrial Cancer 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
- **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 in preparation

#### Ovarian Cancer

- **9923** A phase I study of intravenous carboplatin/paclitaxel or intravenous and intraperitoneal paclitaxel/cisplatin in combination with continuous or intermittent, CTEP supplied agent ABT-888 and CTEP supplied agent bevacizumab, in newly diagnosed patients with previously untreated epithelial ovarian, fallopian tube or primary peritoneal cancer (K Moore) CTEP/CRDL. ASCO 2015
- **170R** A phase II evaluation of dalantercept, a novel soluble recombinant activin receptor-like kinase 1 (ALK-1) inhibitor receptor-fusion protein, in the treatment of persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (R Burger)

- **186G** A phase II randomized, double-blinded evaluation of oral everolimus (RAD001) plus bevacizumab vs. oral placebo plus bevacizumab in the treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (W Tew). No TR specimens collected. ASCO 2014
- **186K** A randomized phase II study of cabozantinib versus weekly paclitaxel in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (U Matulonis). TR: BIQSFP, MET IHC – Center for Molecular Oncologic Pathology (CMOP) DFCI. SGO 2016
- **255** A phase II randomized, double-blind trial of a polyvalent vaccine-KLH conjugate + OPT-821 versus OPT-821 in patients with epithelial ovarian, fallopian tube, or peritoneal cancer who are in second or third complete remission (P Sabbatini). TR completed. ASCO 2016. SGO 2017. ESGO 2017
- **260** A phase II evaluation of elesclomol sodium and weekly paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (B Monk)
- **NRG-GY003** Phase II randomized trial of nivolumab with or without ipilimumab in patients with persistent or recurrent ovarian, primary peritoneal or fallopian tube cancer (B Burger)

#### QUESTIONS/DISCUSSION/EVALUATION

## Gastrointestinal Cancer Committee Workshop Agenda

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 1:00 pm – 3:00 pm  
**Colorectal Chair:** Thomas George, MD, FACP  
**Colorectal Co-Chair:** Scott Kopetz, MD, PhD  
**Non-colorectal Chair:** Christopher Crane, MD  
**Non-colorectal Co-Chair:** David Ilson, MD

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

<b>1:00 – 1:05</b>	Introduction and Opening Remarks	Christopher Crane, MD Thomas George, MD
<b>1:05 – 1:15</b>	<b>CRC SUBCOMMITTEE - Review of Upcoming Trials</b> <b>NRG-GI005:</b> Use of cfDNA as a decision tool for stage II colon cancer treatment <b>SOLARIS:</b> Vitamin D supplementation in untreated mCRC	Van Karlyle Morris, MD Christina Wu, MD
<b>1:15 – 2:00</b>	<b>Active Studies</b> <b>N1048 (PROSPECT):</b> Intergroup Selective Radiotherapy Elimination Trial <b>NRG-GI002:</b> TNT Trial <b>S0820 (PACES):</b> Eflornithine & Sulindac for polyp prevention after CRC <b>A021502 (ATOMIC):</b> MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab <b>NRG-GI004 / S1610 (COMMIT):</b> Metastatic MSI-H CRC Immunotherapy Study <b>S1613:</b> A Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan in Advanced/mCRC with HER2 Amplification	Thomas George, MD Thomas George, MD Jenny Dorth, MD Asha Dhanarajan, MD James Lee, MD, PhD Marwan Fakih, MD
<b>2:00 – 2:20</b>	<b>NON-CRC SUBCOMMITTEE</b>  <b>Active Studies</b> <b>RT0G 1112:</b> Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma  <b>NRG GI003:</b> Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma	Laura Dawson, MD   Ted Hong, MD
<b>2:20 – 3:00</b>	<b>Review of Developing Trials</b> <b>NRG GI 1426:</b> Phase III Randomized Trial of Protons vs. Photons for Esophageal Carcinoma  <b>NRG 1824</b> Phase I trial of chemoradiation and telomolysin for inoperable esophageal and GEJ ACA  <b>NRG GI1802</b> A Randomized Phase II of Local Treatment Targeted Sensitization Wee1 vs PARPi in Locally Advanced Pancreatic cancer  <b>NRG 1862 Randomized phII</b> Nivolumab vs SOC post local therapy for non-responding localized SCCa Esophagus  <b>NRG XXX</b> Ablative RT +/- checkpoint inhibition in IHCC	Steven Lin, MD  Geoff Ku, MD  Rich TuliMD/Kyle CuneoMD  Geoff Ku  Ted Hong

## NRG Oncology Protocol GI004 and Protocol GI002 Workshop

**Date:** Friday, February 8, 2019  
**Start and End Time:** 11:30 am – 12:30 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 common eligibility and treatment questions.

### WORKSHOP AGENDA

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

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

11:30 am - 11:50 am	Overview of GI004	James Lee, MD, PhD
11:50 am - 12:00 pm	Discussion Questions & Answers	James Lee, MD, PhD
12:00 pm - 12:20 pm	Overview of GI002	Thomas George, MD
12:20 pm - 12:25 pm	Frequently Asked Questions	Lynne Suhayda RN, BSN, MSED
12:25 pm - 12:30 pm	Questions & Answers	Thomas George, MD Lynne Suhayda, RN, BSN, MSED



## **Translational Science GI Cancer Subcommittee Agenda**

**Date:** Saturday, February 9, 2019

**Time:** 7:00 am - 9:00 am

**Chair:** Chandan Guha, MD, PhD

- |                    |   |
|--------------------|---|
| <b>7:00 – 7:10</b> | <b>Introduction/Overview</b><br>Chandan Guha, MD, PhD / Christopher Crane, MD   |
| <b>7:10 – 7:30</b> | <b>Intestinal Radioprotection as a Strategy to Enable Dose-Escalated Radiotherapy for Unresectable Pancreatic Cancer</b><br>Cullen Taniguchi, MD, PhD (MD Anderson Cancer Center) |
| <b>7:30 – 7:50</b> | <b>Analyses of the Peripheral Immunome in Cancer Immunotherapy Trials</b><br>Renee Donahue, PhD (NIH NCI Center for Cancer Research)  |
| <b>7:50 – 8:10</b> | <b>RT Dose and Fractionation for Immunomodulation</b><br>Marka Crittenden, MD, PhD (Providence Health & Services)   |
| <b>8:10 – 8:30</b> | <b>Pitfalls of Clinical Trial Design and Calm Suggestions</b><br>David Raben, MD (University of Colorado)   |
| <b>8:30 – 8:50</b> | <b>Safety &amp; Efficacy of PD-1/CTLA-4 &amp; 8 Gy x 3 in Metastatic GI Cancers</b><br>Theodore Hong, MD (University of Colorado)   |
| <b>8:50 – 9:00</b> | <b>Closing Remarks and Discussion</b><br>Chandan Guha, MD, PhD / Christopher Crane, MD  |

## Genitourinary Cancer Workshop Agenda

**Date:** Saturday, February 9, 2019  
**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**

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

**8:45 – 9:35**      **Review of Pending Studies**

NRG GU007	Phase I/IIR of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer	Zachary Zumsteg, MD
NRG 1817	Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial	Ronald Chen, MD, MPH

NRG Foundation 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 Felix Feng, MD
SWOG 1802	Local therapy for M1 prostate cancer, a SWOG study	Richard Valicenti, MD
SWOG/NRG 1806	Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer	Jason Efstathiou, MD
NRG 1826	Randomized trial of molecular imaging for high-risk prostate cancer patients	Ashesh Jani, MD
NRG 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
<b>9:35 – 9:55</b>	<b>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</b>	<b>Closing Remarks</b>	

## Cervix Workshop Agenda

**Date:** Friday, February 8, 2019  
**Start and End Time:** 10:00am – 12:00 (Session I)

**Date:** Saturday, February 9, 2019  
**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, February 8, 2019 (Scientific Developmental Focus) 10:00 am – 12:00 pm

- A. Introduction (10:00 – 10:10)
  - a. Welcome, introduction of new members and chairs, committee membership and rotation plan and review of July 2018 minutes
- B. Scientific updates (10:10 – 10:45)
  - a. Report of the cervical cancer trials planning meeting – objectives, methods, collaborations (Ritu Salani, M.D.)
  - b. Vision of the CTEP portfolio and future plans from the clinical trials planning meeting (Elise Kohn, M.D.)
  - c. Chromosomal instability as a target for clinical trials (**Samuel F. Bakhoun, M.D., Ph.D**)
  - d. Previously committee approved/reviewed concepts – current updates and future directions
    - a. NRG CV1735: Practice changing evaluation of lymphedema and quality of life after sentinel lymph node biopsy only in women with early stage cervical cancer. (Al Covens)
    - b. CV1649: A randomized phase II trial of cisplatin, paclitaxel and bevacizumab vs. cisplatin, paclitaxel, bevacizumab, and anti-PD1 ligand in patients with Stage IVB recurrent or persistent carcinoma of the cervix. (Katherine Moxley, Scott Richard)
      - Transitioned to GCIG
    - c. SWOG DART (Dual anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors) – Ipilimumab and Nivolumab (Gyn Champion – Lilian Gien)
    - d. Other

C. **New proposed concepts**

- a. **CV1908:** Incorporation of HPV Status and Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva- Scott Glaser
- b. **DT1912:** Phase II study of nelfinavir and chemoradiotherapy for locally advanced vulvar cancer – Lilie Lin
- c. **CV1914:** ctHPVDNA surveillance – Randomized trial for HPV associated cervical, oropharyngeal and anal cancers (Bhishamjit Chera) (PP Slides only)
- d. **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)
- e. **CV1920:** Maintenance. *To be developed as result of CV CTPM*
- f. **CV1921:** RT Platform. *To be developed as result of CV CTPM*
- g. **CV1922:** GOG-0240R Switch maintenance. *To be developed as result of CV CTPM*

Session II: Saturday, February 9, 2019 (Operational management of on-going NRG trials) 9:00 am – 10:00 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
  - Amendment to add 3 sites approved by CTEP and CIRB on 11/20/2018

#### 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 –**July 18 - 20, 2019** Philadelphia Marriott Downtown Philadelphia, PA

## QUESTIONS / DISCUSSION

## Gynecologic Cancer Workshop Committee

**Date:** Saturday, February 9, 2019  
**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 2018
- 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**

**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

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



### III. Cervix/Vulvar Cancer Subcommittee

#### New Concepts

- a. **CV1908**, Incorporation of HPV Status and Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (Scott Glaser)
- b. **CV1912**, Phase II study of nelfinavir and chemoradiotherapy for locally advanced vulvar cancer (Lilie Lin)
- c. **CV1914**, ctHPVDNA surveillance – Randomized trial for HPV associated cervical, oropharyngeal and anal cancers (Bhishamjit Chera)
- d. **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)
- e. **CV1920**, Cervical cancer CTPM (maintenance)
- f. **CV1921**, Cervical cancer CTPM (RT platform)
- g. **CV1922**, Cervical cancer CTPM (240R)

#### *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)

#### GYN Developmental Therapeutics Committee - Cervical Cancer

##### *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

- a. **GOG-0237**, Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papilloma Virus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC)
- b. **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), 9929, 265, GY002

*Terminations:* 9926

#### IV. Ovarian Cancer Subcommittee

##### New Concepts

- a. **DT1907**, Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer (Floor Backes)
- b. **DT1910**, Phase II single arm trial of Visudyne in platinum resistant recurrent ovarian cancer (Radhika Gogoi)
- c. **DT1916**, Randomized phase II trial with safety lead in evaluating dual checkpoint immunotherapy with nivolumab and low dose ipilimumab with or without anetumab ravtansine in recurrent ovarian cancer with moderate-strong mesothelin expression (Haider Mahdi)
- d. **OV1911**, 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 (Dmitriy Zamarin)
- e. **OV1913**, A randomized phase II trial of triplet therapy (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 (Jung-Min Lee)
- f. **RT1905**, A phase II trial evaluation of sapanisertib (TAK-228) in combination with paclitaxel/carboplatin, and followed by sapanisertib (TAK-228) maintenance in the treatment of advanced ovarian, peritoneal or fallopian tube clear cell carcinoma (John Farley). Sapanisertib – mTORC 1/2 inhibitor
- g. **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)

##### Studies Under Development

- a. **NRG-GY021**, A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Sarah Adams)
- b. **OV1741**, Surgery and chemotherapy vs chemotherapy alone as primary treatment of elderly women with advanced stage ovarian, fallopian tube or primary peritoneal serous carcinomas. (Amina Ahmed/Amy Bregar) - Elderly & Special Populations Working Group and Cancer Care Delivery (Health Disparities Committee)
- c. **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 (Rebecca Arend)
- d. **OV1838**, Randomized Phase 2 trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (Panagiotis Konstantinopoulos)
- e. **OV1839**, Randomized Phase 2 trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary

Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (Panagiotis Konstantinopoulos)

*Active Studies:*

- a. **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. (Robert Burger). Closed to accrual 8.28.17
- b. **NRG-GY004**, A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. (Joyce Liu). Closed to non-Japanese sites 11.10.17. Closed to accrual 7.24.18
- c. **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). Temporarily closed to accrual 6/16/17
- d. **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)
- e. **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)

Rare Tumor Subcommittee

Studies Under Development

- a. **NRG-GY019**, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum. (Amanda Fader)
- b. **RT1849**, A phase II trial of durvalumab and cediranib in recurrent ovarian sex cord stromal tumors (Danielle Vicus)
- c. **RT1841**, A phase II evaluation of bevacizumab and bortezomib for recurrent sex-cord stromal ovarian tumors. (L Gien)

*Active Studies:*

- a. **GOG-0281**, A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (GSK 1120212) in Patients with Recurrent or Progressive Low-Grade Serous Ovarian Cancer or Peritoneal Cancer. (David Gershenson). Closed to accrual 4.10.18
- b. **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)
- c. **NRG-GY016**, Randomized phase II evaluation pembrolizumab + epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)

GYN Developmental Therapeutics Committee - Ovarian Cancer

Studies Under Development

- 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)

#### NCORP

- a. **CC1860**, A Randomized Trial of IADL-adjusted Dosing- versus Standard of Care of Dosing of Pegylated Liposomal Doxorubicin (PLD) every 28 Days with Bevacizumab 10 mg/kg Every 2 Weeks in Elderly Women with Recurrent Ovarian Cancer. (Dana Chase)

*Closed Studies (Primary manuscript NOT published):* 9923, 212, 241, 252, 255, 268, 281, 283, GY003, GY004

*Closed Studies (Primary manuscript published):* 186H\*, 213, 218, 239\*, 262

*\*patient on active treatment*

*Terminations:* 170R, 186K, 254, 260, GY001

### V. Uterine Corpus Cancer Subcommittee

#### New Concepts

- a. **UC1904**, A phase III trial of gemcitabine/docetaxel vs. doxorubicin/olaratumab for first line treatment of metastatic uterine leiomyosarcoma (Martee Hensley)
- b. **UC1909**, A randomized controlled trial of long term prophylactic oral apixaban versus placebo for prevention of venous thromboembolism in women with uterine serous carcinoma (Gregory Gressel)

#### Studies Under Development

- a. **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)
- b. **NRG-GY020**, Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer. (Floor Backes)
- c. **UC1731**, Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study. (Katarzyna Jerzak/Helen Mackay/Linda Duska)
- d. **UC1814**, A phase II/III randomized study of carboplatin, paclitaxel, atezolizumab, and bevacizumab plus atezolizumab and bevacizumab maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer. (Debra Richardson)

#### *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. **GOG-261**, A Randomized Phase III Trial of Paclitaxel + Carboplatin vs Ifosfamide + Paclitaxel in Chemotherapy-Naïve Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (MMT) of the Uterus, Fallopian Tube, Peritoneum or Ovary (Matthew Powell). Close to accrual 3.24.14

- c. **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)

GYN Developmental Therapeutics Committee - Endometrial Cancer Studies Under Development

a.

*Active Studies:*

- a. **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)

NCORP

- a. **UC1744**, Randomized Phase II Study of Conventional versus Hypofractionated Pelvic RT for adjuvant treatment of endometrial cancer. (Camille Gunderson/Mark Bernard)
- b. **UC1815**, A phase II randomized study of standard IMRT versus scanning beam proton radiation therapy for post-operative treatment of endometrial and cervical cancer. (Ann Klopp, Lilie Lin)

*Closed Studies (Primary manuscript NOT published):* 209, 229O, 249, 258, 261, 275, 286B, GY008

*Closed Studies (TS):* 210

*Closed Studies (Primary manuscript published):* 184, 188\*

\*patient on active treatment

*Terminations:* 277

- VI. **Developmental Therapeutics Committee** (O’Cearbhaill, Backes, Konstantinopoulos)
- 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)
- 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)
- Active Studies:* 8015, 8016, 8020, 8025
- Terminations:* 8031, 8034, 8039
- X. **Cancer Prevention and Control Committee Report** (Walker)
- Active Studies:* 237, 278
- Closed Studies:* 199, 214, 225, 244, 8199
- Terminations:*

**QUESTIONS / DISCUSSION**

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

**Date:** Thursday, February 7, 2019  
**Start and End Time:** 2:00 PM – 4:00 PM  
**Chairs:** Roisin O’Cearbhaill, MD (Developmental Therapeutics) and Michael Birrer, MD, PhD (Translational Science)  
**Translational Research Chair:** Panagiotis Konstantinopoulos, MD, PhD (Developmental Therapeutics)  
**Co-Chairs:** Floor Backes, MD (Phase II), Russell Schilder, MD (Phase I), Stephanie Gaillard, MD, PhD (Phase I)

### Learning Objectives

Following this activity, participants will be better able to:

1. Participants will become familiar with current mechanisms for development of clinical and translational research within National Clinical Trials Network (NCTN).
2. Participants will become familiar with current status of translational research projects involving phase I and II studies that are under development or activated for accrual.
3. New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.
4. Participants will become familiar with the challenges in relation to study biospecimen acquisition and storage
5. Recommendations for action by the GYN Developmental Therapeutics committee will be summarized.

### WORKSHOP AGENDA

**Thursday, February 7, 2019**

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

2:00 PM – 2:10 PM	Introduction, Drs. O’Cearbhaill and Birrer. Welcome new members and opportunities for young investigators.
2:10 PM – 2:30 PM	CTEP Early Drug Development Update, Charles Kunos, MD, PhD, Medical Officer and Coordinator, Investigational Therapeutics & Radiation, Investigational Drug Branch, CTEP
2:30 PM – 2:50 PM	Translational research opportunities in early phase trials, Panagiotis Konstantinopoulos, MD, PhD, Director of Translational Research and attending oncologist in the Gynecologic Oncology Program at Dana-Farber Cancer Institute
2:50 PM – 3:05 PM	Proposal to develop taskforce to address challenges encountered with study biospecimen procurement, Jyoti Mayadev, MD, University of California, San Diego, and Roisin O’Cearbhaill, MD, Memorial Sloan Kettering Cancer Center
3:05 PM – 4:00 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>

#### New Concepts:

- **DT1907:** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer- Floor Backes
- **DT1910:** Phase II single arm trial of Visudyne in platinum resistant recurrent ovarian cancer- Radhika Gogoi
- **OV1911:** 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.(Dmitriy Zamarin)
- **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)

### Follow up on submitted concepts from the July 2018 Meeting:

1. **DT1831:** A Phase II study of combination pegylated liposomal doxorubicin (PLD) with durvalumab in women with microsatellite stable recurrent endometrial cancer. (B Corr) **(disapproved, unsuccessful attempt through CTEP/DART mechanism)**
2. **DT1833/NRG- GY022:** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Sarah Taylor/ Jan Beumer) **(under development)**
3. **PI1845** Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi) **(tabled, call with CTEP; required additional preclinical data. Plan to submit as new concept)**
4. **DT1846** A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with neoadjuvant and postsurgical chemotherapy in patients with newly-diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (D Zamarin) **(Disapproved by Gyn Steering Committee)**

### Open 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**

### Studies under development

#### Endometrial

- **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) **(currently closed, working with CTEP to replace/add additional arms)**
- **NRG-GY013** A window of opportunity pharmacodynamic trial of triapine in uterine corpus serous adenocarcinoma (Sarah Temkin) **(awaiting additional preclinical work prior to resubmitting)**
- **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)**

#### Ovary

- **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)**

#### Miscellaneous

- **NRG-GY022** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Sarah Taylor/ Jan Beumer) **(Supported by CTPEP, approved for development of protocol)**

## **GYN Developmental Therapeutics/Phase I Workshop**

**Date:** Saturday, February 9, 2019  
**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. Immuno-oncology toxicity management and Immune Modulation workshop will present an update from Thursday, February 7, 2019 (2:00 – 4:00 PM) and plan for integration and prioritization.
3. Integration and prioritization of studies will be reviewed and reference to Cervix/Vulva Cancer, Ovarian Cancer and Uterine Corpus Cancer workshops and the Translational Science workshop.
4. New phase I concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents.

### **Saturday, February 9, 2019**

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

**8:00 AM - 9:00 AM**      **Russell Schilder, MD**

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

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

**8:45 AM – 9:00 AM**

**Cervical Cancer (Dmitriy Zamarin, MD, PhD)**

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

**Endometrial Cancer (Floor Backes)**

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

**Ovarian Cancer (Roisin O’Cearbhaill, MD)**

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

**Sarcomas (Roisin O’Cearbhaill, MD)**

- Active
- Studies under development
- Closed studies



## List of Studies

### New Concepts

- **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)
- **DT1916**: Randomized phase II trial with safety lead in evaluating dual checkpoint immunotherapy with nivolumab and low dose ipilimumab with or without anetumab ravtansine in recurrent ovarian cancer with moderate-strong mesothelin expression (Haider Mahdi)

### 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**

#### Prior safety lead-ins:

- **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** Active for accrual

#### 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)
- **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
- **NRG-GY002** A phase II evaluation of nivolumab, a fully human antibody against PD-1, in the treatment of persistent or recurrent cervical cancer (A Santin) Both stages of accrual complete
- **265** A phase II evaluation of ADXS11-001 in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix (W Huh) Safety lead in performed by Phase I subcommittee - completed. ASCO 2016 (Stage 1 of Phase II). SGO 2017

#### Endometrial Cancer 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
- **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 in preparation

#### Ovarian Cancer

- **9923** A phase I study of intravenous carboplatin/paclitaxel or intravenous and intraperitoneal paclitaxel/cisplatin in combination with continuous or intermittent, CTEP supplied agent ABT-888 and CTEP supplied agent bevacizumab, in newly diagnosed patients with previously untreated epithelial ovarian, fallopian tube or primary peritoneal cancer (K Moore) CTEP/CRDL. ASCO 2015
- **170R** A phase II evaluation of dalantercept, a novel soluble recombinant activin receptor-like kinase 1 (ALK-1) inhibitor receptor-fusion protein, in the treatment of persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (R Burger)

- **186G** A phase II randomized, double-blinded evaluation of oral everolimus (RAD001) plus bevacizumab vs. oral placebo plus bevacizumab in the treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (W Tew). No TR specimens collected. ASCO 2014
- **186K** A randomized phase II study of cabozantinib versus weekly paclitaxel in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (U Matulonis). TR: BIQSFP, MET IHC – Center for Molecular Oncologic Pathology (CMOP) DFCI. SGO 2016
- **255** A phase II randomized, double-blind trial of a polyvalent vaccine-KLH conjugate + OPT-821 versus OPT-821 in patients with epithelial ovarian, fallopian tube, or peritoneal cancer who are in second or third complete remission (P Sabbatini). TR completed. ASCO 2016. SGO 2017. ESGO 2017
- **260** A phase II evaluation of elesclomol sodium and weekly paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (B Monk)
- **NRG-GY003** Phase II randomized trial of nivolumab with or without ipilimumab in patients with persistent or recurrent ovarian, primary peritoneal or fallopian tube cancer (B Burger)

#### QUESTIONS/DISCUSSION/EVALUATION

## Ovarian Workshop Agenda

<b>Date:</b>	<b>Friday, February 8, 2019</b>	<b>Saturday, February 9, 2019</b>
<b>Start and End Time:</b>	<b>8:00 am - 10:00 am</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 promising translational research objectives and priorities for future clinical trials
4. Apply standards and review procedures required to design, submit, and conduct a research protocol within NRG, including ancillary data proposals
5. Assure strict quality control of GOG/NRG clinical trials

### WORKSHOP AGENDA

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

#### A. Introduction

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

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

- Update regarding international studies from GCIG Oct 2018 (Kathleen Moore)
  - Discussion of EAE161: Perfusion CT to predict progression free survival and response rate in bevacizumab and paclitaxel treatment of platinum resistant, persistent or recurrent epithelial ovarian cancer (Russ Schilder).
  - Discussion of 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 -
  - Discussion about PARP resistance: How do we design trials in a post SOLO-1 (maybe PRIMA/VELIA/PAOLA era) (Swisher)
  - Discussion of Platinum resistance: What is the best clinical trial design, control arms etc. (Landen)
- 

#### C. Review of Closed Studies (non-terminated)

- GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
- GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman). Accrual to surgical component completed and study closed JUN2017, awaiting events for primary analysis
- GOG0218 A Phase III trial of carboplatin and paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent bevacizumab (NSC #704865, IND #7921) followed by placebo, versus carboplatin and paclitaxel plus concurrent and extended bevacizumab, in women with newly diagnosed, previously untreated, stage III and IV epithelial ovarian, primary peritoneal or fallopian tube cancer (Robert A Burger).
- GOG0252 Phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma (Joan L Walker) Awaiting publication

- 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 not yet presented/published.
- 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). Results Anticipated 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
- 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
- GOG0281 RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson)
  - Activated 27FEB2014, closed to US sites 01MAY2017 with 178 enrolled, ongoing accrual in UK (slow), amendment approved to re-open for 20 additional patients at US sites

#### D. Review of Active Studies

- GOG0264 RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Carol Brown)
  - Activated 08FEB2010
- 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 12/2018
  - Reminder to sites regarding completion of scheduled QOL assessments
- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer. Activated for Phase I accrual. (Robert A Burger)
- 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
- 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
- GY016 - phase 2 pembrolizumab + epacadostat (IDO inhibitor) in recurrent clear cell of the ovary (L Gien)
  - Activated Oct 2018

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

- 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)
  - Approved PDC 2/17 RSC 2/17. CPAC 3/6/17. CRDL LOI submitted 3/15/17. Review call 4/27/17 was positive with responses provided by Study Team. Revised LOI submitted 05/02/2017. LOI provisionally approved 5/30 and sent by CTEP to Epizyme for review and approval to supply Tazemetostat. LOI fully approved, protocol docs sent to team. Eskander circulated first draft 8/8/17 BRC consensus review rec'd 8/14/17. Protocol to CTEP 9/22/17. PRC review on 10/19/17. CR received 11/7/17. OEWG conference call on 11/15 to review Major Issues on CR.
  - Consensus Review response to CTEP 11/30/17. Possible Canadian participation. 3/14/18: CIRB Approved and CTEP Approval-on-Hold (awaiting IND approval, 30-days since submission is 5/10/18). Submitted Pre-activation amendment 4/19/18.
  - FDA hold removed 11/2018 – activation pending as of 11/2018
- 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). GCSC review 21SEP2017, anticipate revision of study design using 2 arms. International interest from GCIG (AGO, AGO-Austria, GINECO, MRC-UK, NSGO) GCSC approved 5/7/2018. Activation pending
- TS1514 Immunoscore determination as predictive biomarkers for clinical outcomes in GOG-0262. Awaiting amendment of data sharing plan (Samir Khleif).
- GY021 Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams). Approved by GCSC
- OV1741 Randomized evaluation of interval cytoreductive surgery in elderly patients receiving neoadjuvant chemotherapy. Coordinated development with Elderly Working Group, plan for initial OTF GCSC submission after JAN2018 (Amina Ahmed, Amy Breggar, Helen Huang, et al.)
- NC1427 (CPC1206) Risk reducing salpingectomy in premenopausal BRCA1/2 carriers (Doug Levine). To be submitted for NCORP review
- DT1846 A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with neoadjuvant and postsurgical chemotherapy in patients with newly-diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (D Zamarin)
  - GCSC review 11/15/2018- disapproved – will be redesigned and resubmitted
- 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
- OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos) LOI submitted 10/2018
  - RSC 2/2019
- OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos) LOI submitted 10/2018
  - RSC 2/2019
- 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) RSC 11/1/2018, LOI to PIO 10/12/18

- PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)
  - GYN approved provisionally with instructions to further develop in combo approach with chemo or immuno. Call conducted 11/6/18 with J Moscow to determine rx commitment for anetumab ravtansine
- RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus) LOI. Needs RSC review Feb '19

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

Front line:

- **HIPEC Working Group to have been created following disapproval 07/2018** :OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins).

Platinum Sensitive:

Platinum Resistant

- **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) in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung Min Lee)
- **OV1911:** 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. (Dmitriy Zamarin)

Rare Tumors/Other

- RT1841 A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien) #2 in queue behind RT1849
- **RT1905:** A Phase II trial Evaluation of sapanisertib (TAK-228) in combination with carboplatin, paclitaxel, and followed by sapanisertib (TAK-228) consolidation in the treatment of Advanced Ovarian, Peritoneal or Fallopian tube Clear Cell Carcinoma (John Farley)
- **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)
- **DT1907:** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer- (Floor Backes)
- **DT1910:** Phase II single arm trial of Visudyne in platinum resistant recurrent ovarian cancer- Radhika Gogoi

#### QUESTIONS / DISCUSSION

## Rare Tumor Workshop

**Date:** Friday, February 8, 2019  
**Start and End Time:** 2:00 pm - 4:00 pm  
**Chair:** Allan Covens, MD  
**Co-Chair:** Jubilee Brown, MD

### Learning Objectives

Following this activity, participants will be better able to:

1. Discuss emerging and ongoing NRG clinical trials on rare gynecologic cancers
2. Discuss promising translational research objectives and priorities for future clinical trials
3. Discuss rationale for triaging women with specific rare tumors to separate clinical trials including a “match” type trial.
4. Develop a strategy to study mucosal melanoma in a group-wide NRG protocol

### WORKSHOP AGENDA

#### 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:

Statistical considerations for “match” rare tumours- Austin Miller

#### 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)

**NRG-GY016:** A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epcadostat (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. Priority 1.

**RT1841:** A Phase II Evaluation of Bevacizumab and Bortezomib for Recurrent Sex Cord Stromal Ovarian Tumours (Gien). Approved for development. Priority 2

A randomized phase II trial in patients with mucosal melanoma (Vicus)

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

**RT1829:** A Randomized Single Blind, Phase II Study of Pegylated Liposomal Doxorubicin in Combination with M3814 or Placebo in Patients with Recurrent Low Grade Serous Ovarian Cancer (Grisham) *rejected by CTEP, but will open in ETCTN*

#### **E. New proposals:**

**RT1905:** A Phase II evaluation of sapanisertib (TAK-228) in combination with carboplatin, paclitaxel, and followed by sapanisertib (TAK-228) consolidation in the treatment of advanced Ovarian, Peritoneal or Fallopian Tube Clear Cell Carcinoma (John Farley)

**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)

#### **F. Discussion Topics:**

- a) "Match" trial for rare tumours
- b) RFA: low grade endometrioid ovarian cancer. Both Adjuvant (stages II-IV), and for recurrent disease
- c) RFA: Clear Cell Ovarian Cancer. Adjuvant therapy for stages I-IV
- d) Ovarian - Stromal Tumors- hormonal targets
- e) improve accrual to AGCT 1531

#### **Questions /Discussion**



## Uterine Corpus Agenda

**Date:** Friday, February 8, 2019  
**Start and End time:** 2:30 pm – 4:30 pm (Session I)

**Date:** Saturday, February 9, 2019  
**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 10:00-11:30 (Lead Neil Horowitz, MD)

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

### Workshop Agenda

**A. Introduction (Powell): Molecular predictors of therapeutic interventions in early stage endometrial cancer (30 Min):**  
Larry Maxwell, MD, Kathleen Darcy, MD

### B. Review of Closed Studies

1. **GOG0184:** Tumor Volume-Directed Pelvic Plus or Minus Para-Aortic Irradiation followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for advanced Endometrial Carcinoma (Spirtos) [*Gynecol Oncol* 112: 543-52, 2009; *Gynecol Oncol* 119: 538-42, 2010]
2. **GOG0188:** Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [*Gynecol Oncol* 120(2): 185-8, 2011]:
3. **GOG0209:** A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer (**David Scott Miller**) [*Gynecol Oncol* 125: 771-3, 2012]
4. **GOG0210:** A Molecular Staging study of Endometrial Carcinoma (William T Creasman) : **Reviewed by Mutch**
5. **GOG0249:** Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy (Randall) doi:10.1016/j.ygyno.2014.07.078:
6. **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)
7. **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 (Powell)

8. **GOG0275** A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia (Schink)
9. **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 (Bae-Jump)
10. **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)
11. **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)

#### C. Review of Active Studies

##### 1. Endometrial Protocols:

- a. **GOG0238**: A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus (Jonathan Feddock):
- b. **S1609, DART**: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Schink)
- 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)

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

1. **UC0905**: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (**Mutch**)
2. **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):
3. **GOG-8040 (UC1107)**: An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino):
4. **UC1506** Translational Science for Uterine Carcinosarcoma Trials [Amendment to GOG0261] (Douglas Levine):
5. **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)
6. **NC1603**: Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (Tanner)
7. **GY013 (DT1620)**: A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Temkin)
8. **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)
9. **GY014** (DT1718): A phase II study of tazemetostat (EPZ-64438) an EZH2 inhibitor in select gynecologic cancers (Eskander)
10. **NC1744**: A Randomized Phase II Trial of Conventional versus Hypofractionated Pelvic Radiotherapy for Adjuvant Treatment of Endometrial Cancer (Gunderson/Bernard)

#### E. Proposed studies :

1. **UC1904**: A phase III trial of gemcitabine-docetaxel vs. doxorubicin-olaparumab for first-line treatment of metastatic uterine leiomyosarcoma. (Martee Hensley)
2. **UC1909**: A randomized controlled trial of long-term prophylactic oral apixaban versus placebo for prevention of venous thromboembolism in women with uterine serous carcinoma. (Gregory Gressel)

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

1. **DT1907:** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer. (Floor Backes)

**G. New Business**

1. Report from GOG Foundation
2. Report from Subcommittee on Gestational Trophoblastic Disease (Horowitz)
3. Report from GOG0210 Scientific Advisory Board (Mutch)

**See 210 Subcommittee Report below**

4. Report from RTOG (Klopp)

## Head and Neck Cancer Workshop Agenda

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 10:00 am – 12:00 pm  
**Chair:** Quynh-Thu Le, MD  
**Co-Chairs:** Erich Sturgis, MD-MPH; Stuart Wong, MD, Andy Trotti, MD

### Learning Objectives

Following this activity, participants will be better able to:

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

### WORKSHOP AGENDA

<b>10:00 – 10:10</b>	<b>Report on publications and protocol closed to active accrual</b>	Quynh-Thu Le, MD
<b>10:10 – 10:30</b>	<b>Review of Active Studies</b>	
RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR)	Cristina Rodriguez, MD
RTOG 1216	RT-cisplatin vs. RT-Docetaxel + Cetuximab for “high risk” resected HNSCC (Phase IIR-III)	David Rosenthal, MD
NRG HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III)	Dimitrios Colevas, MD
NRG HN004	Phase IIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC	Loren Mell, MD
NRG HN005	Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer	Sue Yom, MD
RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong, MD
<b>10:30-10:40</b>	<b>Review of recently completed study</b>	
NRG HN003	Phase I of Adjuvant Chemoradiotherapy +/- Pembrolizumab in High Risk, HPV(-) HNSCC	Julie Bauman, MD, MPH
RTOG 3504	Phase I/IIIR of CRT +/- Nivolumab in intermediate/high risk HNSCC	Maura Gillison, MD, PhD
NRG HN002	Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good-Prognosis Advanced-Stage Oropharyngeal Cancer	Sue Yom, MD

RTOG 0912	Concurrent radiation + chemotherapy + pazopanib for Anaplastic Thyroid Cancer (Phase II-R)	Eric Sherman, MD
RTOG 3501	Phase II R study of CRT +/- Lapatinib in high risk HNSCC	Stuart Wong, MD
RTOG 0920	IMRT/IGRT + cetuximab for “intermediate risk” resected HNSCC (Phase III)	Mitchell Machtay, MD
<b>10:40 – 11:30      Review of developing studies and ECOG studies</b>		
NRG 1706	Clinically N0 Oral cavity cancer: ND vs. sentinel node biopsy	Stephen Lai, MD, PhD
NRG 1865	RT-cisplatin vs. RT-Avelumab for “high risk” resected HNSCC (Phase IIR-III) (to be merged with RTOG 1216)	Julie Bauman, MD
NRG 1801	Phase I of M3814 (DNA-PK inhibitor) + Avelumab vs. cisplatin + Avelumab in patients who cannot tolerate cisplatin with locally advanced high risk HNSCC	Maura Gillison, MD, PhD/ Michael Samuels
NRG 1854	Phase III trial of cisplatin/gemcitabine chemo +/- anti PD1/PDL1 for first line recurrent/metastatic NPC	Brigette Ma, MD
ECOG trials	E3132 PORT +/- Cisplatin in intermediate risk pts with disruptive P53 mutation E3163 Sinonasal carcinoma	Christine Chung, MD, PhD Nabil Saba, MD
<b>11:30 – 11:50      Presentations &amp; Updates</b>		
Translational Research Program update		Neil Hayes, MD, MPH
Surgical subcommittee update		Erich Sturgis, MD
HN Committee Membership update		Stuart Wong, MD
HNSC update		Robert Ferris, MD
<b>11:50 – 12:00      New Business</b>		
HNC retreat update		Quynh Le, MD

## Lung Cancer Workshop

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 1:00 pm – 3:00 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 clinical trials at your home institution.

### WORKSHOP AGENDA

#### 1. Active Studies:

- |   |   |
|---|---|
| a.) Lung-MAP SWOG S-1400  | Saiana Waqar, MD<br>Jeffrey Bradley, MD   |
| b.) ALCHEMIST Trial   | Martin Edelman, MD                        |
| c.) RTOG 1308: Protons vs photons for St III NSCLC  | Zhongxing Liao, MD<br>Jeffrey Bradley, MD |
| e.) NRG CC001 and 003: Hippocampal avoidance brain  | Vinai Gondi, MD                           |
| f.) LU002: Phase III chemo +/- SBRT for Stage IV  | Puneeth Iyengar, MD, PhD                  |
| g.) NRG-LU003: NCI NRG ALK Master Protocol<br>-CIRB approved. Please open at your center! | Alice Shaw, MD, PhD<br>Shakun Malik, MD   |
| h.) NRG/Alliance LU1804 Limited-stage SCLC  | Kristin Higgins, MD                       |
| i.) NRG LU1705 Phase I/II anti-PD1 concurrent with RT<br>-CIRB approved.                  | Steven Lin, MD, PhD<br>Anne Tsao, MD      |
| j.) Phase IIR; Dose-painting IMRT for mesothelioma  | Andreas Rimner, MD<br>Anne Tsao, MD       |

#### 2. Pending Concepts

- |   |                       |
|---|-----------------------|
| a.) SBRT +/- durva for medically-inoperable Stage I<br>-RTOG Foundation Trial with AZ | Clifford Robinson, MD |
| b.) SWOG S1914/NRG LU – SBRT +/- neoadjuvant atezo for Stage I                        | Charles Simone, MD    |

### QUESTIONS / DISCUSSION

NRG Principal Investigators and Research Associates are cordially invited to a workshop to discuss:

***NRG-LU003: A Biomarker-Driven Protocol for Previously Treated ALK-Positive  
NSCLC Patients: The NCI-NRG ALK Master Protocol***

**Date: Saturday, February 9, 2019**

**Start and End Time: 10:30 am – 11:00 am**

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss the significance of the study.
2. Apply standards and procedures required to participate in the trial.
3. Overview of statistical design and treatment assignment.

Agenda

Welcome and Introductions – *Erica Field, NRG Oncology*

Protocol Overview – *Alice Shaw, MD and Shakun Malik, MD, NRG-LU003 Co-Chairs*

Statistical Design – *Chen Hu, PhD, Statistician, NRG Oncology*

Question and Answer Session

## Translational Science Lung Cancer Workshop Agenda

**Date:** Friday, February 8, 2019  
**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. Biomarker Development for Immunotherapy and Radiotherapy and its Implications in Lung Cancer Trials
2. Planned Translational Studies for NRG-LU001
3. New Therapeutics

### WORKSHOP AGENDA

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

**Speaker:** Naresh Menon, PhD (ChromoLogic, LLC)  
**Presentation Title:** "Long Term Care: Biomarkers for Predicting Delayed Chronic Effects following Treatment"

**Speaker:** Sarah Moseley, PhD (AstraZeneca, LP)  
**Presentation Title:** "Biomarker Approaches to Development of Lung Cancer Therapeutics"

**Speaker:** Terence Williams, MD, PhD (Ohio State University)  
**Presentation Title:** "The Current and Evolving Landscape of Biomarkers for Immunotherapy in Lung Cancer"

**Speaker:** Theodoros Tsakiridis, MD, PhD, FRCPC (Juravinski Cancer Centre)  
**Presentation Title:** "NRG-LU001: Biomarker Analysis Concepts"

**Speaker:** Heath Skinner, MD, PhD (University of Pittsburgh)  
**Presentation Title:** "Metformin as a Radiation and Immune Modulator: What We Can Learn from NRG-LU001"

**Speaker:** Tithi Biswas, MD (Case Western Reserve University)  
**Presentation Title:** "Inhibiting Base Excision Repair with Methoxyamine to Enhance Radiosensitization by Pemetrexed in Non-Small-Cell Lung Cancer"

**Speaker:** Javier Torres-Roca, MD (Moffitt Cancer Center)  
**Presentation Title:** "A Precision Radiotherapy Dosing Model for Lung Cancer"

### QUESTIONS / DISCUSSION



## Patient Centered Outcomes Research (PCOR) Workshop Agenda

**Date:** Thursday, February 7, 2019  
**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

4:00 – 4:30	<b>Use and Capabilities of ePRO for PRO-CTCAE Data Collection</b> Comments/Audience Q & A	Lori Minasian, MD Deputy Director, NCI Division of Cancer Prevention
4:30 – 4:40	<b>Differences between PRO-CTCAE versus PROs on NRG-RT0G 0232</b>	Deb Bruner, PhD
4:40 – 4:55	<b>PCOR Compliance Update</b> Comments/Audience Q & A	Ron Chen, MD
4:55 – 5:05	<b>Digital Health Update</b>	Adam Dicker, MD
5:05 – 5:40	<b>Concepts in Development</b>  <b>Protocols in Development</b>	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD
5:40 – 5:50	<b>NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates</b>	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD
5:50 – 6:00	<b>Other Business</b>	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD

### Activated Studies with PCOR/CER Endpoints

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

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

**NRG-BN005:** A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas (activated 8/17)

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

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

**NRG-GI004:** 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 (activated 11/17)

**NRG-GU005:** Phase III IGRT and SBRT vs IGRT and Hypofractionated IMRT for Localized Intermediate Risk Prostate Cancer (activated 11/17)

**NRG-GY005:** A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent/Persistent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS) (activated 2/16)

**NRG-GY009:** A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and CTEP-Supplied Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (activated 5/17)

**NRG-HN001:** Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA) (activated 4/14)

**NRG-HN004:** Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin (activated 12/17)

**NRG-LU002:** Maintenance Systemic Therapy Versus Consolidative Stereotactic Body Radiation Therapy (SBRT) Plus Maintenance Systemic Therapy for Limited Metastatic Non-Small Cell Lung Cancer (NSCLC): A Randomized Phase II/III Trial (activated 4/17)

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

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

New GYN concepts for review

**UC1904:** A phase III trial of gemcitabine-docetaxel vs. doxorubicin-olaparatumab for first-line treatment of metastatic uterine leiomyosarcoma- Martee Hensley

## SARCOMA WORKING GROUP AGENDA

**DIAN WANG, M.D, PH.D., CHAIR**  
**Peter Houghton, Ph.D., TRP Liaison**  
**Friday, Feb 08 2019**  
**10:00AM – 12:00PM**

### 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. Developing Concepts: **Oral Update only**

1. Phase IIR Trial of Radiotherapy versus Surgery and Radiotherapy for Soft Tissue Sarcomas of the Extremities and Chestwall Following an Unplanned Excision (Wolfson)
2. Phase II trial to investigate the role of peri-operative RT in desmoid tumors harboring CTNNB1 S45 mutation (Pollock/Welliver)
3. Phase IIR Trial of Immunotherapy and SBRT for Metastatic Soft Tissue Sarcoma (Wong): update only (submitted to Alliance)

### C. Sarcoma TRP

1. Exploiting BRAF – preventing resistance and enhancing radiation (Peter Houghton)
2. Effect of BMN 673 in combination with RT and immunotherapy on sarcoma cells (George Iliakis)
3. Exploiting the biological context of radiotherapy in sarcoma (Phil Wong)

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

### E. New Business

## Translational Science Workshop Agenda

**Date:** Thursday, February 7, 2019  
**Start/End Time:** 6:30 - 8:00 pm  
**Chair:** Michael Birrer, MD, PhD  
**Co-Chairs:** Adam Dicker, MD, PhD  
Matthew Ellis, MB, BCHIR, PhD

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

- 1 To understand the translational research being conducted in NRG GU
- 2 To understand the status of the CPTAC grants
- 3 To identify, describe, and discuss the DP1 analysis
- 4 To understanding the present translational research to be conducted by the NRG UG1.

### WORKSHOP AGENDA

6:30 – 6:45	Opening Remarks and Introduction	M. Birrer, MD, PhD A. Dicker, MD, PhD M. Ellis, MB, BCHIR, PhD
6:45 – 7:00	NRG GU Translational Research	P. Tran, MD (Johns Hopkins)
7:00 – 7:30	Microscaled Proteogenomic Analysis of HER2+ BC	M. Ellis, MB, BCHIR, PhD
7:30 – 7:45	New Insights into Endometrial Cancer from CPTAC	B. Zhang, PhD (Baylor)
7:45 – 8:00	CPTAC/UG1 Update	M. Birrer, MD, PhD M. Ellis, MB, BCHIR, PhD D. Mutch, MD

## Translational Science GYN Workshop

**Date:** Friday, February 8, 2019  
**Start and End Time:** 4:00 pm – 5:30 pm  
**Chair:** Michael Birrer, MD, PhD  
**Co-Chair:** Heather Lankes, PhD, MPH

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

- 1 Understand the translational research being conducted by NRG and discuss translational research projects.
- 2 Understand the design and status of the NCTN Biobanks reorganization and specimen access process.
- 3 Discuss the developing research priorities of NRG GYN studies.
- 4 Assure strict quality control of NRG clinical trials.

### WORKSHOP AGENDA

4:00-4:10	Opening Remarks Biospecimen Bank/Translational Science Update	Michael Birrer, MD, PhD Heather Lankes, PhD, MPH
	TS-GYN Disease Site Updates	
4:10-4:33	Ovary	Rebecca Arend, MD Elizabeth Swisher, MD
4:30-4:50	Uterine Corpus 210 Subcommittee	Doug Levine, MD David Mutch, MD
4:50-5:10	Cervix	Dmitriy Zamarin, MD
5:10-5:30	GOG 8025 EZH2 in uterine tumors	Lauren Krill, MD

### Concept Review

1. **UC1904:** A phase III trial of gemcitabine-docetaxel vs. doxorubicin-olaparib for first-line treatment of metastatic uterine leiomyosarcoma. (Martee Hensley)
2. **RT1905:** A Phase II evaluation of sapanisertib (TAK-228) in combination with carboplatin, paclitaxel, and followed by sapanisertib (TAK-228) consolidation in the treatment of advanced Ovarian, Peritoneal or Fallopian Tube Clear Cell Carcinoma. (John Farley)
3. **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)
4. **UC1909:** A randomized controlled trial of long-term prophylactic oral apixaban versus placebo for prevention of venous thromboembolism in women with uterine serous carcinoma. (Gregory Gressel )
5. **OV1911:** 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. (Dmitriy Zamarin)
6. **CV1912:** Phase II study of nelfinavir and chemoradiotherapy for locally advanced vulvar cancer. (Lilie Lin)
7. **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) in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab. (Jung- Min Lee)
8. **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)
9. **DT1916:** Randomized phase II trial with safety lead in evaluating dual checkpoint immunotherapy with nivolumab and low dose ipilimumab with or without anetumab ravtansine in recurrent ovarian cancer with moderate-strong mesothelin expression (Haider Mahdi)

### Other Business

### Questions/Discussion

## Translational Science Lung Cancer Workshop Agenda

**Date:** Friday, February 8, 2019  
**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. Biomarker Development for Immunotherapy and Radiotherapy and its Implications in Lung Cancer Trials
2. Planned Translational Studies for NRG-LU001
3. New Therapeutics

### WORKSHOP AGENDA

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

**Speaker:** Naresh Menon, PhD (ChromoLogic, LLC)  
**Presentation Title:** "Long Term Care: Biomarkers for Predicting Delayed Chronic Effects following Treatment"

**Speaker:** Sarah Moseley, PhD (AstraZeneca, LP)  
**Presentation Title:** "Biomarker Approaches to Development of Lung Cancer Therapeutics"

**Speaker:** Terence Williams, MD, PhD (Ohio State University)  
**Presentation Title:** "The Current and Evolving Landscape of Biomarkers for Immunotherapy in Lung Cancer"

**Speaker:** Theodoros Tsakiridis, MD, PhD, FRCPC (Juravinski Cancer Centre)  
**Presentation Title:** "NRG-LU001: Biomarker Analysis Concepts"

**Speaker:** Heath Skinner, MD, PhD (University of Pittsburgh)  
**Presentation Title:** "Metformin as a Radiation and Immune Modulator: What We Can Learn from NRG-LU001"

**Speaker:** Tithi Biswas, MD (Case Western Reserve University)  
**Presentation Title:** "Inhibiting Base Excision Repair with Methoxyamine to Enhance Radiosensitization by Pemetrexed in Non-Small-Cell Lung Cancer"

**Speaker:** Javier Torres-Roca, MD (Moffitt Cancer Center)  
**Presentation Title:** "A Precision Radiotherapy Dosing Model for Lung Cancer"

### QUESTIONS / DISCUSSION

## **Translational Science GI Cancer Subcommittee Agenda**

**Date:** Saturday, February 9, 2019

**Time:** 7:00 am - 9:00 am

**Chair:** Chandan Guha, MD, PhD

- |                    |   |
|--------------------|---|
| <b>7:00 – 7:10</b> | <b>Introduction/Overview</b><br>Chandan Guha, MD, PhD / Christopher Crane, MD   |
| <b>7:10 – 7:30</b> | <b>Intestinal Radioprotection as a Strategy to Enable Dose-Escalated Radiotherapy for Unresectable Pancreatic Cancer</b><br>Cullen Taniguchi, MD, PhD (MD Anderson Cancer Center) |
| <b>7:30 – 7:50</b> | <b>Analyses of the Peripheral Immunome in Cancer Immunotherapy Trials</b><br>Renee Donahue, PhD (NIH NCI Center for Cancer Research)  |
| <b>7:50 – 8:10</b> | <b>RT Dose and Fractionation for Immunomodulation</b><br>Marka Crittenden, MD, PhD (Providence Health & Services)   |
| <b>8:10 – 8:30</b> | <b>Pitfalls of Clinical Trial Design and Calm Suggestions</b><br>David Raben, MD (University of Colorado)   |
| <b>8:30 – 8:50</b> | <b>Safety &amp; Efficacy of PD-1/CTLA-4 &amp; 8 Gy x 3 in Metastatic GI Cancers</b><br>Theodore Hong, MD (University of Colorado)   |
| <b>8:50 – 9:00</b> | <b>Closing Remarks and Discussion</b><br>Chandan Guha, MD, PhD / Christopher Crane, MD  |

# Scientific Core Committees



## Health Disparities Committee

**Date:** Friday, February 8, 2019  
**Start and End Time:** 10:00 am - 12:00 pm  
**Chairs:** Elise Cook, MD, MS; Kate Yeager, PhD, RN, MS

**10:00-10:05 am**      **Welcome/Announcements**

**10:05-10:25 am**      **HDC Disease Site Liaisons-Committee-Tri Chairs**  
*- HDC Disease Site Liaisons awareness presentations to disease site/other committees*  
*-Disease Site Committee Updates-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: Eleanor Walker)
<u>Gyn-Ovarian</u>	Melissa Simon	(Alternate: Dana Chase)
<u>Gyn-Cervix</u>	Wendy Brewster	
<u>Gyn-Uterine</u>	Anuja Jhingran	(Alternate: Marianne Matzo)
<u>Head &amp; Neck</u>	Steven Chang*	
<u>Rare Tumors</u>	Mary Scroggins	
<u>Lung (Thoracic)</u>	Tom Simon	

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|                                                  |                |
|--------------------------------------------------|----------------|
| <u>Older Adult Working Group</u>                 | William Tew    |
| <u>Cancer Prevention &amp; Control (CPC)</u>     | Rusty Robinson |
| <u>Patient Centered Outcomes Research (PCOR)</u> | Dana Chase     |
| <u>NCORP</u>                                     | HDC Chairs     |

Communications Committee/Patient Engagement Working Group  
 Anuja Jhingran, Kate Yeager

Protocol Support Committee (PSC)      Tiffany Elsea\*, Donna White\*

\*Committee Liaison to HDC

**10:25-11:35 am**      **HDC Research Vice Chair Candidate Presentation**  
*-Introduction*  
*-Applicant presentation*  
*-Discussion*

**11:35-11:50 am**      **Working Groups Updates- Chairs**  
 -Naming of Co Leaders

- **Clinical trial enrollment-** William (Rusty) Robinson
- **Education/training/mentorship-Kathie Ann Joseph**  
*-HDC Workshop - July 2019*  
*-HDC Mentor Program*

- **Health disparities research**-*Electra Paskett*  
- *Alliance Pilot Study Update*
- **Statistics/metrics**-*Reena Cecchini*  
- *SDMC Reports*

**11:50-11:55 am Future Plans: NCTN and NCORP grant updates - Chairs**

**Other Business / Discussion**

**12:00 pm Adjournment**

***Future Meetings***

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

**July 18 - 20, 2019**

Philadelphia Marriott -Downtown \*\*HDC Workshop-TBA  
Philadelphia, PA

**January 9 - 11, 2020**

Marriott Marquis  
Houston, TX

**July 16 - 18, 2020**

Marriott Marquis \*\*HDC Workshop - TBA  
Washington, DC

## Imaging Committee Meeting Agenda

|                            |                                                                         |
|----------------------------|-------------------------------------------------------------------------|
| <b>Date:</b>               | <b>Friday, February 8, 2019</b>                                         |
| <b>Start and End Time:</b> | <b>10:00 am – 12:00 pm</b>                                              |
| <b>Chair</b>               | <b>Daniel Pryma, MD</b>                                                 |
| <b>Co-Chairs</b>           | <b>James Fink, MD, Amy Fowler, MD, PhD, Rathan Subramaniam, MD, PhD</b> |
| <b>Members</b>             | <b>Mark Rosen, MD, Ying Xiao, PhD, Feng-Ming (Spring) Kong, PhD, MD</b> |

### MEETING AGENDA

|                    |                                                                                                                                                                                     |                           |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>10:00-10:10</b> | <b>Committee introduction and charge</b>                                                                                                                                            | <b>Dan Pryma</b>          |
| <b>10:10-10:20</b> | <b>Committee workflow and resources</b>                                                                                                                                             | <b>Dan Pryma</b>          |
| <b>10:20-10:30</b> | <b>Report from IROC on Imaging QA in NRG trials</b>                                                                                                                                 | <b>Mark Rosen</b>         |
| <b>10:30-10:45</b> | <b>Lessons learned and issues to address</b>                                                                                                                                        | <b>Mark Rosen</b>         |
| <b>10:45-11:00</b> | <b>GI002 A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer</b>                                                   | <b>Mark Rosen</b>         |
| <b>11:00-11:20</b> | <b>HN005 (1707) Randomized Phase II/III Trial of Reduced-Field Radiation Therapy (RFRT for Patients with Early-Stage, p16-Positive, Non-Smoking-Associated Oropharyngeal Cancer</b> | <b>Rathan Subramaniam</b> |
| <b>11:20-11:35</b> | <b>Brief overview of future trials &amp; role of liaisons</b>                                                                                                                       | <b>Dan Pryma</b>          |
| <b>11:35-12:00</b> | <b>Questions, comments, concerns &amp; suggestions</b>                                                                                                                              | <b>Dan Pryma</b>          |

## Medical Oncology Workshop Agenda

**Date:** Saturday February 9, 2018  
**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. Update clinical trial outcomes in major disease entities from ASCO 2018
2. Provide updates on NRG clinical trial developments

### WORKSHOP AGENDA

- |      |                                                       |                                           |
|------|-------------------------------------------------------|-------------------------------------------|
| I.   | Introductions                                         | Corey Langer, MD                          |
| II.  | Pharmacy Subcommittee                                 | Judith Smith Pharm MD                     |
|      | A. Update on Protocol Drug Information Database/Forms |                                           |
| III. | Critical post-ASCO updates                            | Corey Langer, MD<br>Deborah Armstrong, MD |
| IV.  | Other business                                        | Corey Langer, MD<br>Deborah Armstrong, MD |

### QUESTIONS / DISCUSSION

## Pharmacy Subcommittee Workshop

**Date:** Friday, February 8, 2019  
**Start and End Time:** 12:00 pm – 1:00 pm  
**Chair:** Judith Smith, Pharm.D.

### Learning Objectives:

Following this activity, participants will be better able to:

1. Compare and contrast the toxicity profiles and pharmacology parameters for selection of PARP Inhibitors for maintenance chemotherapy in ovarian cancer patients.
2. Understand the rationale and benefits of standardizing drug information for research protocols.
3. Explain the primary aspects for standardizing patient variables for dosing carboplatin.
4. Discuss the role of standardization of pre-medication components.

### WORKSHOP AGENDA

- I. Introduction **(2 min)**
  - a. Committee purpose and goals
- II. CE Presentation: “Factors to Consider in the Selection of PARP Inhibitors for Maintenance Chemotherapy” **Judith A. Smith, Pharm.D., BCOP, CPHQ**
- III. Update on Protocol Review Process for Pharmacy Subcommittee **(3 min)**
- IV. Protocol Drug Information Update **(15 min)**
  - a. To be reviewed/approved at this meeting:
  - b.

|                                     |
|-------------------------------------|
| Ado-Trastuzumab                     |
| Cetuximab                           |
| Ramucirumab                         |
| Doxorubicin Liposomal               |
| Etoposide                           |
| Gemcitabine                         |
| Paclitaxel Albumin Bound (Abraxane) |
| Paclitaxel IP                       |
| Temozolomide                        |
| Topotecan                           |
  - c. Approval of standardized pre-medications for chemotherapy templates
- V. Carboplatin Position Paper Update **(5 min)**
- VI. Updates/Discussion of any Pharmacy Related Issues Identified in Other NRG Committee Meetings **(5 min)**
  - a. Any issues that the Pharmacy Subcommittee should follow up on regarding new protocol proposals presented at the other committee meetings.
- VII. Evaluation

**Immunotherapy and Immune Modulation Workshop**  
**11 am -12:30 pm**  
**February 8, 2019**

**NRG ONCOLOGY SEMIANNUAL MEETING**  
**Phoenix Convention Center, Phoenix, AZ, February 7–9, 2019**

**"New Analyses of the Peripheral Immunome in Cancer Immunotherapy Trials"**

Dr. Renee Donahue, Head, Molecular Immunology Group, Laboratory of Tumor Immunology and Biology, National Cancer Institute, NIH, Bethesda, MD.

If you would like to read more about this research, please see:

J Immunother Cancer. 2017 Feb 21;5:20. doi: 10.1186/s40425-017-0220-y. eCollection 2017.

Eur Urol Focus. 2018 Sep;4(5):636-638. doi: 10.1016/j.euf.2018.08.016. Epub 2018 Sep 7.

**"Molecular Classification of Lymph Node Metastases in Head and Neck Cancers"**

Dr. Michael Spiotto, Department of Radiation and Cellular Oncology, University of Chicago, Chicago, IL.

If you would like to read more about this research, please see:

Clin Cancer Res December 20 2018 DOI: 10.1158/1078-0432.CCR-18-1884

Continuation of Thursday, February 7, 2pm-4pm (**Immunotherapy and Immune Modulation Workshop; Protocol Review**); (if needed).

## **Pathology Workshop**

**Date:** Friday, February 8, 2019  
**Start and End Time:** 8:00 am – 12:00 pm  
**Chair:** William H Rodgers PhD MD  
**Co-Chairs:** Jeff Simko MD, PhD  
Peter Lucas MD, PhD

### **Learning Objectives:**

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

1. Apply standardized criteria for classification of neoplasms
2. Discuss and apply specialized criteria for clinical trial eligibility
3. Utilize staging criteria as cited in the Pathology Manual
4. Improve quality assurance for case selection for NRG protocols
5. Discuss active and proposed NRG protocols

### **WORKSHOP AGENDA**

#### Session I

- A. Current priorities and organization of the Committee; Background, status, and significance of major projects
- B. Membership and Role of Committee
- C. Reports of organ site representatives
- D. Review of cases

### **QUESTIONS / DISCUSSION**

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

**Date:** Thursday, February 7, 2019  
**Start and End Time:** 7:30 am – 4:30 pm  
**Facilitators:** Sharon Stockman BA, CCRP and Cindy Licavoli RN, BSN, MA

**Learning Objectives**

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

1. Discuss NRG Oncology membership requirements
2. Describe the events leading up to the development of IRB's
3. Describe the roles and responsibilities of the IRB relative to the performance of clinical research involving human subjects
4. Describe the roles and responsibilities of clinical research sites in following IRB regulatory and ethical requirements
5. Describe the processes to be followed by clinical research sites in adhering to IRB requirements
6. Describe the standard drug accountability procedures for NCTN trials
7. List resources for additional information regarding investigational drug
8. Describe the basic methodology of RECIST 1.1 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. Discuss NRG Oncology Mentorship Program.
22. Discuss protocol requirements for administration of chemotherapy, immunotherapy, radiation therapy and surgery
23. Discuss the nature of and preparation for NCI-mandated Quality Assurance Audits.
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                               | Sharon Stockman, BA, C-CRP & Cindy Licavoli RN, MA |
| 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                                               | Heather Lankes, BS, MS, MPH                    |
| 11:10 am - 11:30 am | RECIST                                                                          | Mark Shahin, MD                                |
| 11:30 am - 11:40 am | QOL                                                                             | Sharon Stockman, BA, C-CCRP                    |
| 11:40am - 11:50am   | Mentorship Program                                                              | Nancy Fusco, RN, BSN                           |
| 11:50 am - 12:00 pm | Morning Closing Remarks                                                         | Cindy Licavoli, RN & Sharon Stockman, BA, CCRP |
| 12:00 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<br>Room:            | <i>Lead Facilitator-</i> Cindy Licavoli, RN, BSN, MA<br>Joni Shortt, RN, BSN, CCRC<br>Tiffany Elsea, BA, CCRP       |
| Treatment Modalities in Clinical Trial<br>Management | <i>Lead Facilitator-</i> Joyce Neading, RHIT, CTR<br>Kathy Phipps, CCRP<br>Karen Holeva, BS                         |
| Data Management<br>Room:                             | <i>Lead Facilitator-</i> Lynne Lippmann, BA, CCRP<br>Sue Eaton, CCRP<br>Whitney Jacobson, RN, BSN, CCRP             |
| Adverse Event Reporting<br>Room:                     | <i>Lead Facilitator-</i> Mary Smrekar, RN, MSN, CNP<br>Donna White, RN, BSN, OCN<br>Alison Ivey, RN, BSN, OCN, CCRP |

4:10pm – 4:30pm Evaluation

QUESTIONS/DISCUSSION  
EVALUATION

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

**Date:** Thursday, February 7, 2019  
**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** 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  
Education & Training Working Group (CLOSED)**

**Date:** Thursday, February 7, 2019  
**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** Sally Brown RN, BSN, MGA, Melinda Weiblen, BS

**Learning Objectives**

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

- 1) Discuss alternative methods of education
- 2) Provide the PSC with potential topics and speakers for July 2019 and winter 2020 meeting

**WORKSHOP AGENDA**

- 1) Welcome
- 2) Announcements of open positions
- 3) Discuss plans for July 2019 meeting
  - a. Lunch time session
  - b. Sub group
  - c. Round tables
  - d. Format for morning
    - i. 4 hours lecture
    - ii. 2 hours lecture
    - iii. 2 hours concurrent sessions
- 4) Suggestions for winter 2020 meeting
  - a. Sub working group

QUESTIONS/DISCUSSION  
EVALUATION

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

**Date:** Thursday, February 7, 2019  
**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** Nancy Fusco RN, BSN, Sue Eaton CCRP

### **Learning Objectives**

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

1. Identify potential new topics for the Mentorship Introductory Materials
2. Discuss the development of mentor program tools
3. Identify topics for the mentor orientation 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 meet and greet/orientation items/questions and answers

#### **\*\*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. Review ongoing projects for the working group:
  - a. Introductory Materials For NRG Oncology Research Clinical Trials Coordinators:
    - i. Annual review of material contents
    - ii. Discuss new topics to include
    - iii. Quality Assurance and Audit Team & Quality Control Working Group: recommendation of materials for institutions in need
  - b. Mentor Program:
    - i. Development of Mentorship Program tools:
      1. Mentor Evaluation tool
      2. Mentee Evaluation tool
      3. New tools as needed
8. Meeting Plan: Monthly conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

QUESTIONS/DISCUSSION  
EVALUATION

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

**Date:** Thursday, February 7, 2019  
**Start and End Time:** 5:30 pm – 7:00 pm  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Working Group Facilitators** Joyce Neading CTR (retired), Michele Lacy RN, BSN, OCN

### **Learning Objectives**

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

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

### **Workshop Agenda**

1. Review and approval of minutes from July 12, 2018 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/ First hour open, Second hour closed)**

**Date:** Friday, February 8, 2019  
**Start and End Time:** 7:00 am – 9:00 am  
**PSC Chair:** Susan Nolte, PhD, CRNP  
**PSC Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**CTN Chair:** Cindy Licavoli RN, BSN, MA,  
**CTN Co Chairs:** Nancy Fusco RN, BSN, HeeSun Kim-Suh RN  
**CRA Chair:** Sharon Stockman BA, CCRP  
**CRA Co-Chairs:** Sally Brown RN, BSN, MGA, Joyce Neading RHIT, CTR

**Learning Objectives:**

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

1. Identify, describe and discuss roles and responsibilities for Health Disparities Committee
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. Health Disparities Committee Representative Presentation - **Kate Yeager**
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, February 8, 2019  
**Start and End Time:** 2:00 pm - 6:00 pm  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Program Facilitators:** Sally Brown RN, BSN, MGA, Melinda Weiblen, BS

**Learning Objectives**

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

- 1) Describe tools on the CTSU website
- 2) Discuss the purpose of Institutional performance reports
- 3) Summarize the impact of USP 800
- 4) Discuss the methods to support the family caregiver

**AGENDA**

| <u>Time</u> | <u>Topic</u>                                                                           | <u>Speakers</u>                                          |
|-------------|----------------------------------------------------------------------------------------|----------------------------------------------------------|
| 2:00-2:10   | Introduction/Welcome                                                                   | Sally Brown, RN, BSN, MGA, CCRP                          |
| 2:10-2:20   | Welcome                                                                                | Katie Stoermer, MSBA<br>Executive Director, NRG Oncology |
| 2:20-3:00   | Updates and information from CTSU                                                      | Ginger Riley                                             |
| 3:00-3:25   | Update on NRG Oncology QA<br>Audits, monitoring and Institution<br>Performance reports | Mimi Passarello, MBA                                     |
| 3:25-3:35   | break                                                                                  |                                                          |
| 3:35 -4:20  | What is USP 800 and its impact                                                         | Jeffrey Burmeister, PharmD, CCRP                         |
| 4:20-5:05   | Understanding and supporting the<br>family caregiver                                   | Norissa Honea, PhD RN, AOCN, CCRP                        |
| 5:05-5:50   | An overview of ovarian cancer and<br>what is new on the horizon                        | Mark Shahin, MD                                          |
| 5:50-6:00   | Questions and evaluation                                                               |                                                          |

**QUESTIONS/DISCUSSION  
EVALUATION**

## **Protocol Support Committee Workshop (Closed)**

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 7:00 – 9:30 am  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Room:**

### **AGENDA**

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

QUESTIONS/DISCUSSION  
EVALUATION



## Radiation Oncology Committee Workshop Agenda

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

**Date:** Friday, February 8, 2018  
**Start and End Time:** 2:00 pm – 4:00 pm  
**Chair:** Jeff Michalski, MD  
**Co-Chairs:** Ivy Petersen, MD and Evan Wuthrick, MD

### WORKSHOP AGENDA

|                    |                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                         |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>2:00 – 2:05</b> | <b>Welcome / Introduction</b>                                                                                                                                                                                                                                                                                                                                                                                                            | Ivy Petersen, MD                                                                                                                                                                                                        |
| <b>2:05 – 2:40</b> | <b><u>Adaptive Radiotherapy Sessions – Introduction</u></b><br>a. Thoracic and Abdomen (8min)<br>i. Cooperative Groups Adaptive Trials – what we’ve learned?<br>ii. Q & A (2min)<br>a. Abdominal / Pancreas tumors adaptive treatment<br>i. MR Linac for Pancreatic cancer (8 min)<br>ii. Q & A (3min)<br>b. Where things are going? Innovative? (10 min)<br>i. For abdominal malignancies / Innovations in Imaging<br>ii. Q & A (4 min) | Evan Wuthrick, MD<br>Michael Roach , MD<br><br>Michael Bassetti, MD<br>Carri Glide-Hurst, PhD<br>Stan Benedict, MD                                                                                                      |
| <b>2:40 – 2:50</b> | <b><u>Update on NCTN Cooperative Cores</u></b><br>a. Imaging and Radiation Oncology Core (IROC) RT Update<br>b. Imaging and Radiation Oncology Core (IROC) Imaging Update                                                                                                                                                                                                                                                                | David Followill, PhD<br>Denise Manfredi, RT(T)<br>Mark Rosen, MD                                                                                                                                                        |
| <b>2:50– 2:55</b>  | <b>Overview of Medical Physics</b>                                                                                                                                                                                                                                                                                                                                                                                                       | Ying Xiao, PhD                                                                                                                                                                                                          |
| <b>2:55 – 3:55</b> | <b><u>Disease Site Liaisons Reports</u></b><br>a. H&N (8 min.)<br>b. Brain (8min.)<br>c. Breast (8 min.)<br>d. Gyn (8 min.)<br>e. GI (8 min.)<br>f. GU (8 min.)<br>g. Lung (8 min.)<br>h. Sarcoma (4 min.)                                                                                                                                                                                                                               | Sue Yom, MD<br>Christina Tsien, MD<br>Steven Chmura, MD / Simona Shaitelman, MD<br>Sushil Beriwal, MD<br>Evan Wuthrick, MD / Eugene Koay, MD<br>Dan Krauss, MD / Hiram Gay, MD<br>Charles Simone, MD<br>Philip Wong, MD |
| <b>3:55 – 4:00</b> | <b>Other Business / Q &amp; A Discussion</b>                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                         |

## Radiation Development Therapeutics Workshop Agenda

**Date:** Saturday February 9, 2019  
**Start and End Time:** 10:00 am - 12:00 pm  
**Chairs:** David Raben, MD; Steven Lin, MD PhD

### Learning Objectives

Following this activity, participants will be better able to:

1. To understand the processes within industry and the FDA to lead to drug approvals in combination with radiation
2. To apply innovative statistical approaches toward phase I/II clinical trial designs
3. To critically appraise the clinical trials under development at the NRG

### WORKSHOP AGENDA

- I. Introduction
  - A. General Business David Raben, M.D.
    - a. Dealing with Pharma and FDA
- II. Scientific Talk: Innovative Statistical Approaches Toward Ph I/II Trial Designs
- III. Disease Site Committee Updates
  - a. **Head & Neck**
    - i. NRG-HN1868: Ph I M3814 + Avelumab
    - ii. NRG-HN004: Phase I safety run in followed by RP2-3 of RT+Cetuximab vs RT+ Durvalumab for Cis ineligible patients
  - b. **Sarcoma**
    - i. NRG-DT001: Phase Ib Trial of Neoadjuvant AMG-232 Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma
  - c. **Lung**
    - i. NRG-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)
  - d. **GI-non colorectal**
    - i. GI1802: A randomized multi-arm phase II trial of gemcitabine and hypofractionated radiotherapy with or without olaparib or AZD1775 in patients with locally advanced pancreatic cancer—Richard Tuli, MD, PhD
  - e. **GI-colorectal**
    - i. NRG-GI002: A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer (safety lead in)
  - f. **GYN**
    - i. NRG-GY017: Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer.
    - ii. LNRG-PI727: Revised Phase I concept for CRT+ Anti-PDL1 in locally advanced cervical cancer

### QUESTIONS / DISCUSSION

**NRG Medical Physics Subcommittee Meeting Agenda  
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)**

**Date:** Friday, Feb, 2019  
**Start and End Time:** 4:00 pm – 6:00 pm  
**Chair:** Ying Xiao, PhD  
**Co-Chairs** Jason Sohn, PhD and Stanley Benedict, PhD

**WORKSHOP AGENDA**

|                    |                                                                                                                                                                                                                                           |                                                                                                                                            |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| <b>4:00 – 4:05</b> | <b>Introductions / Subcommittee Updates</b>                                                                                                                                                                                               | Ying Xiao/Jason Sohn -                                                                                                                     |
| <b>4:05 – 4:10</b> | <b>NCI Communications/NCTN Medical Physics</b>                                                                                                                                                                                            | Ceferino Obcemea                                                                                                                           |
| <b>4:10 – 4:20</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<br>Ying Xiao, PhD<br>Mark Rosen, MD                                                                                       |
| <b>4:20 – 4:50</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>                                                     | Yunfeng Cui<br>X Allen Li<br>Adam Yock / William Parker<br>Robert Wallace<br>Hayeon Kim<br>Nataliya Kovalchuk/ Ping Xia<br>Martha Matuszak |
| <b>4:50 – 5:15</b> | <b>Modality Technology Reports</b> <ul style="list-style-type: none"> <li>• Imaging <ul style="list-style-type: none"> <li>○ Fluciclovine PET</li> <li>○ MR guided GI boost for GI</li> </ul> </li> <li>• Notable technologies</li> </ul> | Kristy Brock/Hania Hallaq<br><br>Zoufeng Li                                                                                                |
| <b>5:15 – 5:40</b> | <b>Working Group and Other Updates</b> <ul style="list-style-type: none"> <li>• Adaptive QA</li> <li>• Deformable QA</li> <li>• Mesothelioma IMRT</li> <li>• SBRT Practice Survey</li> </ul>                                              | Carrie Glide-Hurst<br>Stan Benedict<br>Chair/Co-Chair on behalf of Dr. Yorke<br>Jason Sohn                                                 |
| <b>5:40 – 5:50</b> | <b>Other Business</b>                                                                                                                                                                                                                     |                                                                                                                                            |
| <b>5:50 – 6:00</b> | <b>Questions/Discussions</b>                                                                                                                                                                                                              |                                                                                                                                            |

## NRG Oncology Proton Working Group Agenda

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

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 6:45 am – 8:30 am  
**Chair:** Tom DeLaney, MD  
**Co-Chair:** Ted Hong, MD  
**WG Coordinator/Staff:** Betty O'Meara / Theresa Powell

#### WORKSHOP AGENDA

|             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                   |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| 6:45 – 6:50 | Welcome/Introduction                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Tom DeLaney, MD                   |
| 6:50 – 7:00 | Update on Proton Center Credentialing by IROC Houston<br>Protocols/ Concepts                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Paige Taylor, PhD                 |
| 7:00 – 7:15 | Protons in liver studies<br><u>RTOG 1112</u> - Ph III Sorafenib +/- SBRT for hepatocellular ca (L. Dawson)<br><u>NRG-GI003</u> - Ph III Protons vs Photons for Hepatocellular Carcinoma                                                                                                                                                                                                                                                                                                                                                                 | Laura Dawson MD<br>Ted Hong, MD   |
| 7:15 – 7:25 | Brain Studies<br><u>NRG-BN001</u> : Randomized Phase II Trial of Hypofractionated Dose-<br>Escalated Photon IMRT or Proton Beam Therapy Versus Conventional<br>Photon Irradiation w/ Concomitant /Adjuvant Temozolomide in Glioblastoma<br><u>NRG BN003</u> - Phase III Trial of Observation Versus Irradiation for a Gross Totally<br>Resected Grade II Meningioma<br><u>NRG BN005</u> - A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive<br>Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas. | Minesh Mehta, MD                  |
| 7:25 – 7:35 | <u>NRG-BN005</u> : Ph II Randomized Proton vs IMRT for Cognitive<br>Preservation in Pts with IDH Mutant, Low to Intermediate Grade Gliomas                                                                                                                                                                                                                                                                                                                                                                                                              | David Grosshans, MD               |
| 7:35--7:45  | <u>RTOG 1308</u> : Phase III Randomized Trial Comparing Overall Survival after<br>Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable<br>Stage II-IIIB NSCLC                                                                                                                                                                                                                                                                                                                                                                              | Jeffrey Bradley, MD               |
| 7:45 – 7:55 | <u>NRG-HN001</u> : Randomized Phase II and Phase III Studies of Individualized<br>Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr<br>Virus (EBV) Deoxyribonucleic Acid (DNA): Addition of Protons                                                                                                                                                                                                                                                                                                                                | Annie Chan, MD<br>Tom DeLaney, MD |
| 7:55 – 8:05 | <u>GI 006</u> : Ph III Randomized Protons vs. IMRT Photon for Esophageal CA                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Steven Lin, MD                    |
| 8:05– 8:15  | PCORI (Patient-Centered Outcomes Research Institute) RADCOMP Breast<br>Randomized Trial of Photons versus Protons                                                                                                                                                                                                                                                                                                                                                                                                                                       | Shannon Macdonald, MD             |
| 8:15– 8:25  | COMPPARE (Comparative Study of Outcomes w/ Proton and Photon<br>Radiation in Prostate Cancer) Prostate Ca Study                                                                                                                                                                                                                                                                                                                                                                                                                                         | Nancy Mendenhall, MD              |
| 8:25 – 8:30 | Other Business/Questions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Tom DeLaney, M.D.                 |

## Surgical Oncology Committee Agenda

Date: Saturday, February 9, 2019

Start and End Time: 7:00 – 8:00 AM

Chair: Thomas Julian, M.D.

Co-Chairs: Drew Ridge, M.D., Nick Spirtos, M.D.

### Learning Objectives:

Following this activity, participant will be better able to:

1. Provide information on the latest developments related to the NCTN and NRG Oncology
2. Describe different aspects of the field of surgical oncology such as QA/QC and integration into trials
3. Discuss the most recent findings and technological advances in surgical oncology for multiple NRG clinical disease sites.

### Workshop Agenda

|             |                                                                                                                                                                                              |                                                                                        |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 7:00 – 7:05 | Welcome/Introduction<br>-Minutes approval                                                                                                                                                    | Thomas Julian, M.D.                                                                    |
| 7:05 - 7:15 | Medical Oncology Update                                                                                                                                                                      | Corey Langer, M.D.                                                                     |
| 7:15 – 7:25 | Radiation Oncology Committee Update                                                                                                                                                          | Evan Wuthrick, M.D.                                                                    |
| 7:25 – 7:45 | Disease Site Liaisons Reports (very brief update on developments)* <ol style="list-style-type: none"><li>a. Brain</li><li>b. Breast</li><li>c. Gynecology</li><li>d. Head and Neck</li></ol> | Michael Vogelbaum, MD<br>Irene Wapnir, M.D.<br>Nick Spirtos, M.D.<br>Erich Sturgis, MD |
|             | *Liaison to provide a 5 minute update on latest surgical advancement                                                                                                                         |                                                                                        |
| 7:45 -7:55  | HN1903                                                                                                                                                                                       | Stephen Lai, MD                                                                        |
| 7:55 –8:00  | Questions/Discussion                                                                                                                                                                         |                                                                                        |

# Administrative Committees

## **An Introduction to NRG Oncology: New Investigator Educational Session**

**Date:** Thursday, February 7, 2019  
**Start and End Time:** 4:00 pm -5:15 pm

**Chairs:** Elizabeth Gore, MD  
Priya Rastogi, MD  
Angeles Secord, MD, MHSc

### **Learning Objectives:**

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

1. Define the different processes within NRG Oncology at each phase in the lifespan of a clinical trial.
2. Utilize the NCI Cancer Therapy Evaluation Program (CTEP) Project Team Member Applications (PTMA)
3. To develop a strategy to use NRG Oncology study data for ancillary projects

### **WORKSHOP AGENDA**

An Introduction to NRG Oncology: New Investigator Educational Session

- |    |                                                                                     |                               |
|----|-------------------------------------------------------------------------------------|-------------------------------|
| A. | Introduction from the Session Chair                                                 | Speaker: Angeles Secord, MD   |
| B. | 4:05-4:20PM – NRG Oncology Protocol Development Process                             | Speaker: Nancy Soto           |
| C. | 4:20-4:35PM - The Role of the Statistician in Protocol Development and Study Design | Speaker: Mike Sill, PhD       |
| D. | 4:35-4:50PM – Project Team Member Applications: Understanding PTMA                  | Speaker: Carol Aghajanian, MD |
| E. | 4:50-5:05 – NRG Oncology Study Data for Ancillary Projects                          | Speaker: Steven Waggoner, MD  |

### **QUESTIONS / DISCUSSION**

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

## Canadian Members Workshop

**Date:** Saturday, February 9, 2019  
**Start and End Time:** 7:00 am – 8:00 am Eastern Time  
**Chair:** Jean-Paul Bahary, MD  
**Co-Chairs:** Andre Robidoux, MD; Al Covens, MD  
**NRG Oncology Operations:** Judy Langer (back-up representatives: Erica Field and Kate Wiser)

### Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing NRG Oncology clinical trials available in Canada
2. 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 (July 2018-December 2018 and Totals for 2018)  
*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. NRG-LU005: Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation vs. Chemoradiation plus Atezolizumab  
*Discussion lead by PI: Kristin Higgins, MD*
  - b. NRG-HN004: Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin  
*Discussion lead by PI: Loren Mell, MD*
- V. New Business, General Questions, Discussion, Next Meeting
  - a. Reminders from Membership (e.g. Renewals of State Department Clearance)
  - b. Reminders from the SDMC and Regulatory (e.g submit all data in English, consent form do/don't)

*Discussion lead by NRG Oncology Staff TBD*
- VI. Evaluation



## International Members Workshop

**Date:** Friday, February 8, 2019  
**Start and End Time:** 10:00 am – 11:00 am  
**Chairs:** Ben Corn, MD; Stephan Bodis, MD  
**NRG Operations:** Erica Field

### Learning Objectives:

Following this activity, participants will be better able to:

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

#### I. General

- a. Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest

#### II. Status of NRG trials open to accrual –

**Erica Field**

#### III. Optimizing accrual - Discuss best practices for optimizing accrual among International sites –

**Ben Corn, MD and Stephan Bodis, MD**

- a. Disease Sites of interest
- b. RT only protocols (overview)
- c. Study protocols with RT and systemic chemotherapy, targeted, immunotherapy: involvement of pharmaceutical sponsor upfront early during protocol development if trial opened for international members
- d. Site discussion/presentation – best practices for ethics committee approval

#### IV. New concepts and protocols

- a. Development of International concept/proposal –

**Ben Corn, MD and Stephan Bodis, MD**

- *Regional Hyperthermia combined with RT*

#### V. New Business, General Questions, Discussion - *discussion lead* **Ben Corn, MD and Stephan Bodis, MD**

- a. Goals and milestones
- b. International membership and obligations
- c. Input from international members

#### VI. Evaluation

**AGENDA**  
**NCORP PI & ADMINISTRATORS MEETING**

**SATURDAY, February 9, 2019**

**8:00 – 10:00 AM**

**Phoenix, AZ**

|           |                                         |                                            |
|-----------|-----------------------------------------|--------------------------------------------|
| 8:00 a.m. | Welcome                                 | D. Bruner, PhD, RN; J. Walker, MD          |
| 8:05 a.m. | NCI NCORP Report                        | W. McCaskill-Stevens, MD; S. Russo, MD     |
| 8:15 a.m. | NCI CCDR Report                         | K. Castro, R.N., M.S.; A. Geiger, PhD, PMH |
| 8:25 a.m. | Executive Leadership update             | K. Stroemer; D. Bruner, PhD, RN            |
| 8:35 a.m. | Cancer Prevention and Control Committee | L. Kachnic, MD                             |
| 8:45 a.m. | Cancer Care Delivery Research Group     | D. Ritzwoller, PhD; M. Hudson, PhD, MPH    |
| 8:55 a.m. | Health Disparities Update               | Kate Yeager, MD; Elise Cook, MD            |
| 9:05 a.m. | PCOR Committee<br>a. PRO Report Cards   | P. Ganz, MD                                |
| 9:20 a.m. | NRG-CC007CD Training                    | Ron Chen, MD                               |

## NRG Scientific Session NRG Oncology Research Review

**Date:** Friday, February 8, 2019  
**Start and End Time:** 8:00 am – 10:00 am  
**Chair:** Harry Bear, MD  
**Co-Chair:** Elizabeth M Gore, MD; Thomas B Julian, MD; and Krishnansu S Tewari, MD (Moderator)

### Learning Objectives:

Following this activity, participants will be better able to:

1. Educate members regarding ipilimumab (IPI) plus nivolumab (NIVO) compared with NIVO alone in women with persistent or recurrent epithelial ovarian cancer.
2. Discuss the neuro-protective effects of avoiding the hippocampus using intensity-modulated radiotherapy.
3. Examine whether there are incremental gains in freedom from progression (FFP) from the addition of 4-6 months of short term androgen deprivation therapy (STADT) using antiandrogen plus an LHRH agonist, without or with pelvic lymph node treatment (PLNRT), to prostate bed salvage radiotherapy (PBRT).
4. Describe how the secondary analysis assessed the prognostic value of post-resection CA19-9 and surgical margin status (SMS) in predicting patterns of disease recurrence.
5. Understand whether radiation with cetuximab has non-inferior overall survival compared to radiation with cisplatin in patients with local regionally advanced human papillomavirus (HPV)–related oropharynx cancer.
6. Determine whether partial breast irradiation PBI limited to the region of the tumor bed following lumpectomy provides equivalent local tumor control in the breast compared to whole breast irradiation WBI in pts with early-stage breast cancer.

### WORKSHOP AGENDA

|                |                                                                                                                                                                                                                 |                         |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| 8:00 – 8:05 am | Welcome                                                                                                                                                                                                         | Krishnansu S Tewari, MD |
| 8:05 – 8:17 am | NRG Oncology Phase II Randomized Trial of nivolumab with or without Ipilimumab in patients with persistent or recurrent ovarian cancer.                                                                         | Robert Burger, MD       |
| 8:17 – 8:22 am | Discussant                                                                                                                                                                                                      | Sarah Temkin, MD        |
| 8:22 – 8:34 am | Preservation of neurocognitive function (NCF) with hippocampal avoidance during whole-brain radiotherapy (WBRT) for brain metastases: preliminary results of phase III trial NRG Oncology CC001.                | Vinai Gondi, MD         |
| 8:34 – 8:39 am | Discussant                                                                                                                                                                                                      | Paul Sperduto, MD       |
| 8:39 – 8:51 am | Short term androgen deprivation therapy without or with pelvic lymph node treatment added to prostate bed only salvage radiotherapy: the NRG Oncology/RTOG 0534 SPPORT Trial.                                   | Alan Pollack, MD        |
| 8:51 – 8:56 am | Discussant                                                                                                                                                                                                      | William Hall, MD        |
| 8:56 – 9:08 am | Post-resection CA19-9 and margin status as predictors of recurrence after adjuvant treatment for pancreatic carcinoma: analysis of NRG Oncology RTOG trial 9704.                                                | William Regine, MD      |
| 9:08 – 9:13 am | Discussant                                                                                                                                                                                                      | Richard Tuli-invited    |
| 9:13 – 9:25 am | NRG-RTOG 1016: phase III trial comparing radiation/cetuximab to radiation/cisplatin in HPV-related cancer of the oropharynx.                                                                                    | Andy Trotti, MD, PhD    |
| 9:25 – 9:30 am | Discussant                                                                                                                                                                                                      | Stuart Wong, MD         |
| 9:30 – 9:42 am | Primary results of NSABP B-39/RTOG 0413 (NRG Oncology): A randomized phase III study of conventional whole breast irradiation versus partial breast irradiation for women with stage 0, I, or II breast cancer. | Frank Vicini, MD        |
| 9:42 – 9:47 am | Discussant                                                                                                                                                                                                      | Atif Khan, MD           |

# Institutional Accrual

| Accrual For Agenda Book from 1/1/2018 to 12/31/2018 Run Date: 1/04/2019 |          |                                            |                                                     |       |
|-------------------------------------------------------------------------|----------|--------------------------------------------|-----------------------------------------------------|-------|
| 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 |
| Abington Memorial Hospital-Asplundh Cancer Pavilion                     | PA501    | 9                                          | 5                                                   | 14    |
| Advocate Lutheran General Hospital                                      | IL010    | 0                                          | 8                                                   | 8     |
| Allan Blair Cancer Centre                                               | 11076    | 17                                         | 0                                                   | 17    |
| Allegheny General Hospital                                              | PA009    | 13                                         | 21                                                  | 34    |
| AMITA Health Alexian Brothers Medical Center                            | IL280    | 6                                          | 6                                                   | 12    |
| Arizona Center for Cancer Care-Peoria                                   | AZ127    | 19                                         | 6                                                   | 25    |
| Aultman Health Foundation                                               | OH100    | 4                                          | 139                                                 | 143   |
| Aurora NCI Community Oncology Research Program                          | AURORA   | 20                                         | 21                                                  | 41    |
| Avera Cancer Institute                                                  | SD021    | 2                                          | 28                                                  | 30    |
| Baptist Health Cancer Research Network                                  | BHCRN    | 3                                          | 39                                                  | 42    |
| Bay Area Tumor Institute NCORP                                          | BATI     | 3                                          | 2                                                   | 5     |
| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center     | TX041    | 0                                          | 11                                                  | 11    |
| Baystate Medical Center                                                 | MA004    | 13                                         | 3                                                   | 16    |
| Beaumont NCI Community Oncology Research Program                        | BEAUMONT | 10                                         | 7                                                   | 17    |
| Berkshire Hematology Oncology PC                                        | MA125    | 1                                          | 1                                                   | 2     |
| Boston Medical Center                                                   | MA043    | 4                                          | 1                                                   | 5     |
| Cancer Alliance of Nebraska                                             | MVCC     | 0                                          | 0                                                   | 0     |
| Cancer Research Consortium of West Michigan NCORP                       | CRCWM    | 25                                         | 1                                                   | 26    |
| Cancer Research for the Ozarks NCORP                                    | OZARKS   | 16                                         | 2                                                   | 18    |
| Cancer Trials Ireland                                                   | ICORG    | 4                                          | 0                                                   | 4     |
| Carle Cancer Center NCI Community Oncology Research Program             | CARLE    | 11                                         | 40                                                  | 51    |
| Carolinas Medical Center/Levine Cancer Institute                        | NC042    | 17                                         | 3                                                   | 20    |
| Catholic Health Initiatives NCORP                                       | CORA     | 19                                         | 76                                                  | 95    |
| Cedars-Sinai Medical Center                                             | CA016    | 8                                          | 0                                                   | 8     |
| Centre Hospitalier Universitaire de Sherbrooke-Fleurimont               | 11065    | 13                                         | 0                                                   | 13    |
| Chinese University of Hong Kong-Prince of Wales Hospital                | 34003    | 12                                         | 0                                                   | 12    |
| CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)                              | 11073    | 28                                         | 0                                                   | 28    |
| CHUM - Centre Hospitalier de l'Universite de Montreal                   | 11062    | 38                                         | 0                                                   | 38    |
| City of Hope Comprehensive Cancer Center                                | CA043    | 7                                          | 5                                                   | 12    |
| CIUSSSEMTL-Hopital Maisonneuve-Rosemont                                 | 11060    | 4                                          | 0                                                   | 4     |
| Colorado Cancer Research Program NCORP                                  | CCRP     | 8                                          | 37                                                  | 45    |
| Columbia Saint Mary's Water Tower Medical Commons                       | WI161    | 4                                          | 9                                                   | 13    |
| Columbia University Minority Underserved NCORP                          | COLUMBIA | 8                                          | 26                                                  | 34    |
| Columbus NCI Community Oncology Research Program                        | COLUMBUS | 9                                          | 7                                                   | 16    |
| Community Cancer Center North                                           | IN006    | 3                                          | 14                                                  | 17    |
| Cooper Hospital University Medical Center                               | NJ036    | 8                                          | 9                                                   | 17    |
| Covenant Medical Center-Lakeside                                        | TX054    | 0                                          | 10                                                  | 10    |
| Cross Cancer Institute                                                  | 11132    | 5                                          | 0                                                   | 5     |

Accrual from 1/1/2018 to 12/31/2018

|                                                                    |            |    |     |     |
|--------------------------------------------------------------------|------------|----|-----|-----|
| CWRU Case Comprehensive Cancer Center LAPS                         | LAPS-OH029 | 98 | 29  | 127 |
| Dana-Farber / Partners CancerCare LAPS                             | LAPS-MA036 | 25 | 12  | 37  |
| Dartmouth College - Norris Cotton Cancer Center LAPS               | LAPS-NH012 | 20 | 7   | 27  |
| Dayton NCI Community Oncology Research Program                     | DAYTON     | 3  | 16  | 19  |
| Delaware/Christiana Care NCI Community Oncology Research Program   | CHRISTIANA | 38 | 6   | 44  |
| Dell Seton Medical Center at The University of Texas               | TX063      | 1  | 17  | 18  |
| Duke University - Duke Cancer Institute LAPS                       | LAPS-NC010 | 16 | 3   | 19  |
| Edward Hospital/Cancer Center                                      | IL104      | 4  | 18  | 22  |
| Einstein Medical Center Philadelphia                               | PA094      | 0  | 1   | 1   |
| Emory University - Winship Cancer Institute LAPS                   | LAPS-GA005 | 36 | 18  | 54  |
| Essentia Health NCI Community Oncology Research Program            | ESSENTIA   | 1  | 15  | 16  |
| Florida Hospital Orlando                                           | FL086      | 0  | 1   | 1   |
| Fox Chase Cancer Center                                            | PA086      | 8  | 39  | 47  |
| Franciscan Health Indianapolis                                     | IN087      | 0  | 0   | 0   |
| Fred Hutchinson Cancer Research Center LAPS                        | LAPS-WA008 | 10 | 11  | 21  |
| Froedtert and the Medical College of Wisconsin                     | WI013      | 21 | 19  | 40  |
| Geisinger Cancer Institute NCI Community Oncology Research Program | GEISINGER  | 6  | 18  | 24  |
| Georgia Cares Minority Underserved NCORP                           | GRU        | 10 | 14  | 24  |
| Georgia NCI Community Oncology Research Program                    | GEORGIA    | 17 | 18  | 35  |
| Greater Baltimore Medical Center                                   | MD018      | 3  | 7   | 10  |
| Gulf South Minority Underserved NCORP                              | GULFSOUTH  | 9  | 9   | 18  |
| Hartford Hospital                                                  | CT009      | 1  | 6   | 7   |
| Hawaii Minority Underserved NCORP                                  | HAWAII     | 10 | 11  | 21  |
| Heartland Cancer Research NCORP                                    | HEARTLAND  | 33 | 5   | 38  |
| Henry Ford Hospital                                                | MI026      | 16 | 2   | 18  |
| Indiana University - Melvin and Bren Simon Cancer Center LAPS      | LAPS-IN007 | 12 | 0   | 12  |
| Iowa-Wide Oncology Research Coalition NCORP                        | IWORC      | 7  | 12  | 19  |
| James A. Haley Veterans Affairs Hospital                           | FL064      | 0  | 0   | 0   |
| Jewish General Hospital                                            | 11116      | 2  | 0   | 2   |
| JHU Sidney Kimmel Comprehensive Cancer Center LAPS                 | LAPS-MD017 | 8  | 0   | 8   |
| Juravinski Cancer Centre at Hamilton Health Sciences               | 11183      | 2  | 0   | 2   |
| Kaiser Permanente NCI Community Oncology Research Program          | KAISER     | 78 | 127 | 205 |
| Kaiser Permanente-Gaithersburg Medical Center                      | MD198      | 0  | 19  | 19  |
| Kansas City NCI Community Oncology Research Program                | KANSASCITY | 2  | 0   | 2   |
| Kantonsspital Aarau                                                | 67029      | 15 | 0   | 15  |
| Kingston Health Sciences Centre                                    | 11021      | 0  | 0   | 0   |
| Lahey Hospital and Medical Center                                  | MA017      | 3  | 14  | 17  |
| Lakeland Regional Health Hollis Cancer Center                      | FL071      | 0  | 0   | 0   |
| Legacy Good Samaritan Hospital and Medical Center                  | OR013      | 5  | 2   | 7   |
| London Regional Cancer Program                                     | 11137      | 3  | 0   | 3   |
| Loyola University Medical Center                                   | IL017      | 14 | 2   | 16  |
| Main Line Health NCORP                                             | MAINLINE   | 9  | 5   | 14  |
| Maine Medical Center- Scarborough Campus                           | ME018      | 16 | 11  | 27  |
| Mayo Clinic LAPS                                                   | LAPS-MN026 | 20 | 4   | 24  |
| Medical University of South Carolina Minority Underserved NCORP    | MUSC       | 18 | 4   | 22  |
| MedStar Franklin Square Medical Center/Weinberg Cancer Institute   | MD029      | 1  | 13  | 14  |
| Memorial Sloan-Kettering Cancer Center LAPS                        | LAPS-NY016 | 51 | 5   | 56  |

Accrual from 1/1/2018 to 12/31/2018

|                                                                            |            |    |    |    |
|----------------------------------------------------------------------------|------------|----|----|----|
| Mercy Cancer Center - Sacramento                                           | CA729      | 9  | 6  | 15 |
| Metro Minnesota Community Oncology Research Consortium                     | METROMIN   | 25 | 13 | 38 |
| Michigan Cancer Research Consortium NCORP                                  | MCRC       | 23 | 2  | 25 |
| Michigan State University Clinical Center                                  | MI038      | 0  | 5  | 5  |
| Moffitt Cancer Center                                                      | FL065      | 6  | 17 | 23 |
| Montana Cancer Consortium NCORP                                            | MONTANA    | 17 | 0  | 17 |
| Montefiore Minority Underserved NCORP                                      | MONTEFIORE | 10 | 3  | 13 |
| Mount Sinai Hospital                                                       | NY021      | 6  | 13 | 19 |
| Mount Sinai Medical Center                                                 | FL036      | 0  | 0  | 0  |
| National Cancer Centre Singapore                                           | 47005      | 4  | 0  | 4  |
| National Institutes of Health Clinical Center                              | MD004      | 0  | 0  | 0  |
| NCORP of the Carolinas (Greenville Health System NCORP)                    | GREENVILLE | 5  | 17 | 22 |
| Nevada Cancer Research Foundation NCORP                                    | NCRF       | 2  | 2  | 4  |
| New Hanover Regional Medical Center/Zimmer Cancer Center                   | NC043      | 10 | 0  | 10 |
| New Mexico Minority Underserved NCORP                                      | NEWMEXICO  | 37 | 22 | 59 |
| New York-Presbyterian/Brooklyn Methodist Hospital                          | NY075      | 17 | 3  | 20 |
| Newark Beth Israel Medical Center                                          | NJ015      | 2  | 7  | 9  |
| NorthShore University HealthSystem-Evanston Hospital                       | IL018      | 1  | 2  | 3  |
| Northwell Health NCORP                                                     | NORTHSHOR  | 22 | 4  | 26 |
| Northwest NCI Community Oncology Research Program                          | NORTHWEST  | 23 | 1  | 24 |
| Northwestern Medicine Cancer Center Warrenville                            | IL387      | 15 | 24 | 39 |
| Northwestern University                                                    | IL036      | 7  | 3  | 10 |
| Norton Hospital Pavilion and Medical Campus                                | KY049      | 2  | 1  | 3  |
| Ochsner NCI Community Oncology Research Program                            | OCHSNER    | 11 | 14 | 25 |
| Odette Cancer Centre- Sunnybrook Health Sciences Centre                    | 11118      | 6  | 0  | 6  |
| Ohio State University Comprehensive Cancer Center LAPS                     | LAPS-OH007 | 29 | 9  | 38 |
| Ottawa Hospital and Cancer Center-General Campus                           | 11025      | 1  | 0  | 1  |
| Pacific Cancer Research Consortium NCORP                                   | PCRC       | 14 | 17 | 31 |
| Parkview Hospital Randallia                                                | IN017      | 10 | 25 | 35 |
| Parkview Regional Medical Center                                           | IN181      | 0  | 0  | 0  |
| Penn State Milton S Hershey Medical Center                                 | PA042      | 0  | 0  | 0  |
| Peter MacCallum Cancer Centre                                              | 03003      | 1  | 0  | 1  |
| Piedmont Hospital                                                          | GA027      | 1  | 14 | 15 |
| ProMedica Flower Hospital                                                  | OH012      | 1  | 12 | 13 |
| Puerto Rico Minority Underserved NCORP                                     | SANJUAN    | 1  | 0  | 1  |
| Rabin Medical Center                                                       | 40021      | 0  | 1  | 1  |
| Reading Hospital                                                           | PA107      | 10 | 5  | 15 |
| Rhode Island Hospital                                                      | RI005      | 3  | 3  | 6  |
| Roswell Park Cancer Institute LAPS                                         | LAPS-NY158 | 14 | 1  | 15 |
| Rush University Medical Center                                             | IL043      | 6  | 9  | 15 |
| Rutgers Cancer Institute of New Jersey                                     | NJ066      | 2  | 19 | 21 |
| Saint Joseph Hospital - Orange                                             | CA087      | 2  | 11 | 13 |
| Saint Joseph's Hospital and Medical Center                                 | AZ009      | 13 | 12 | 25 |
| Saitama Medical University International Medical Center                    | 42061      | 17 | 0  | 17 |
| Samsung Medical Center                                                     | 43004      | 0  | 0  | 0  |
| Sanford NCI Community Oncology Research Program of the North Central Plain | SANFORD    | 17 | 3  | 20 |
| Saskatoon Cancer Centre                                                    | 11120      | 18 | 0  | 18 |

Accrual from 1/1/2018 to 12/31/2018

|                                                                            |            |    |     |     |
|----------------------------------------------------------------------------|------------|----|-----|-----|
| Scott and White Memorial Hospital                                          | TX027      | 0  | 0   | 0   |
| Scranton Hematology Oncology                                               | PA302      | 0  | 0   | 0   |
| Seoul National University Hospital                                         | 43002      | 65 | 0   | 65  |
| Sinai Hospital of Baltimore                                                | MD020      | 0  | 0   | 0   |
| Southeast Clinical Oncology Research (SCOR) Consortium NCORP               | SCCC       | 45 | 14  | 59  |
| Stanford University - Stanford Cancer Institute LAPS                       | LAPS-CA141 | 8  | 0   | 8   |
| State University of New York Downstate Medical Center                      | NY178      | 0  | 3   | 3   |
| Staten Island University Hospital                                          | NY035      | 0  | 5   | 5   |
| Stony Brook University Medical Center                                      | NY184      | 2  | 2   | 4   |
| Stroger Hospital of Cook County Minority Underserved NCORP                 | STROGER    | 14 | 5   | 19  |
| Summa Akron City Hospital/Cooper Cancer Center                             | OH055      | 6  | 10  | 16  |
| Sun Yat-sen University Cancer Center                                       | 60021      | 6  | 0   | 6   |
| Sutter Cancer Research Consortium                                          | SUTTER     | 19 | 23  | 42  |
| Tel Aviv Sourasky Medical Center                                           | 40019      | 0  | 0   | 0   |
| The Community Hospital                                                     | IN044      | 0  | 10  | 10  |
| The James Graham Brown Cancer Center at University of Louisville           | KY002      | 2  | 5   | 7   |
| The Methodist Hospital System                                              | TX036      | 3  | 3   | 6   |
| The Research Institute of the McGill University Health Centre (MUHC)       | 11318      | 16 | 0   | 16  |
| The US Oncology Network                                                    | USONC      | 26 | 3   | 29  |
| Thomas Jefferson University Hospital                                       | PA121      | 44 | 5   | 49  |
| Thompson Cancer Survival Center                                            | TN038      | 0  | 1   | 1   |
| Tom Baker Cancer Centre                                                    | 11134      | 8  | 0   | 8   |
| Trinity Cancer Care Center                                                 | ND026      | 1  | 6   | 7   |
| Tulane University Health Sciences Center                                   | LA001      | 0  | 2   | 2   |
| UC Davis Comprehensive Cancer Center LAPS                                  | LAPS-CA189 | 27 | 1   | 28  |
| UC Irvine Health/Chao Family Comprehensive Cancer Center                   | CA088      | 5  | 4   | 9   |
| UC San Diego Moores Cancer Center                                          | CA249      | 12 | 1   | 13  |
| UCLA / Jonsson Comprehensive Cancer Center                                 | CA006      | 1  | 0   | 1   |
| UCSF Medical Center-Mount Zion                                             | CA136      | 13 | 3   | 16  |
| UF Cancer Center at Orlando Health                                         | FL020      | 4  | 7   | 11  |
| UNC Lineberger Comprehensive Cancer Center LAPS                            | LAPS-NC007 | 6  | 32  | 38  |
| University Health Network-Princess Margaret Hospital                       | 11030      | 17 | 0   | 17  |
| University of Alabama at Birmingham / Deep South Research Consortitum LAPS | LAPS-AL002 | 5  | 0   | 5   |
| University of Arizona Medical Center-University Campus                     | AZ017      | 11 | 3   | 14  |
| University of Arkansas for Medical Sciences                                | AR006      | 8  | 3   | 11  |
| University of Chicago Comprehensive Cancer Center LAPS                     | LAPS-IL057 | 11 | 10  | 21  |
| University of Cincinnati/Barrett Cancer Center                             | OH070      | 12 | 133 | 145 |
| University of Colorado Cancer Center LAPS                                  | LAPS-CO070 | 25 | 11  | 36  |
| University of Connecticut                                                  | CT002      | 0  | 1   | 1   |
| University of Florida Health Science Center - Gainesville                  | FL015      | 8  | 42  | 50  |
| University of Illinois                                                     | IL040      | 3  | 1   | 4   |
| University of Iowa/Holden Comprehensive Cancer Center                      | IA018      | 19 | 7   | 26  |
| University of Kansas Cancer Center                                         | KS004      | 22 | 1   | 23  |
| University of Kentucky/Markey Cancer Center                                | KY010      | 0  | 0   | 0   |
| University of Maryland/Greenebaum Cancer Center                            | MD015      | 26 | 2   | 28  |
| University of Massachusetts Memorial Health Care                           | MA009      | 1  | 0   | 1   |
| University of Miami Miller School of Medicine-Sylvester Cancer Center      | FL028      | 14 | 3   | 17  |



Accrual from 1/1/2018 to 12/31/2018

|                                                          |            |    |    |     |
|----------------------------------------------------------|------------|----|----|-----|
| University of Michigan Comprehensive Cancer Center LAPS  | LAPS-MI014 | 36 | 10 | 46  |
| University of Minnesota/Masonic Cancer Center            | MN022      | 1  | 0  | 1   |
| University of Mississippi Medical Center                 | MS005      | 1  | 2  | 3   |
| University of Missouri - Ellis Fischel                   | MO036      | 0  | 0  | 0   |
| University of Nebraska Medical Center                    | NE003      | 2  | 1  | 3   |
| University of Oklahoma Health Sciences Center LAPS       | LAPS-OK003 | 88 | 94 | 182 |
| University of Pennsylvania/Abramson Cancer Center        | PA075      | 13 | 5  | 18  |
| University of Pittsburgh Cancer Institute LAPS           | LAPS-PA015 | 19 | 22 | 41  |
| University of Rochester                                  | NY167      | 12 | 18 | 30  |
| University of South Alabama Mitchell Cancer Institute    | AL068      | 1  | 2  | 3   |
| University of Tennessee - Knoxville                      | TN021      | 2  | 0  | 2   |
| University of Tennessee Health Science Center            | TN030      | 3  | 5  | 8   |
| University of Texas Health Science Center at San Antonio | TX059      | 10 | 15 | 25  |
| University of Texas MD Anderson Cancer Center LAPS       | LAPS-TX035 | 42 | 14 | 56  |
| University of Texas Medical Branch                       | TX045      | 6  | 3  | 9   |
| University of Texas Southwestern Medical Center LAPS     | LAPS-TX011 | 36 | 1  | 37  |
| University of Utah - Huntsman Cancer Institute LAPS      | LAPS-UT003 | 17 | 6  | 23  |
| University of Vermont College of Medicine                | VT004      | 10 | 4  | 14  |
| University of Virginia Cancer Center                     | VA009      | 15 | 1  | 16  |
| University of Wisconsin Carbone Cancer Center LAPS       | LAPS-WI020 | 23 | 19 | 42  |
| USC Norris Comprehensive Cancer Center LAPS              | LAPS-CA011 | 13 | 2  | 15  |
| Vanderbilt University - Ingram Cancer Center LAPS        | LAPS-TN008 | 6  | 1  | 7   |
| Vassar Brothers Medical Center                           | NY131      | 4  | 6  | 10  |
| VCU Massey Cancer Center Minority Underserved NCORP      | VCU        | 10 | 13 | 23  |
| Veterans Administration Long Beach Medical Center        | CA041      | 6  | 0  | 6   |
| Virginia Oncology Associates-Hampton                     | VA084      | 0  | 0  | 0   |
| Wake Forest University Health Sciences                   | NC002      | 5  | 5  | 10  |
| Walter Reed National Military Medical Center             | MD001      | 3  | 0  | 3   |
| Washington University - Siteman Cancer Center LAPS       | LAPS-MO011 | 99 | 0  | 99  |
| Wayne State University - Karmanos Cancer Institute LAPS  | LAPS-MI020 | 58 | 17 | 75  |
| WellSpan Health-York Hospital                            | PA047      | 6  | 10 | 16  |
| West Virginia University Charleston Division             | WV004      | 3  | 12 | 15  |
| West Virginia University Healthcare                      | WV025      | 6  | 26 | 32  |
| Wichita NCI Community Oncology Research Program          | WICHITA    | 11 | 1  | 12  |
| Wisconsin NCI Community Oncology Research Program        | WINCORP    | 11 | 6  | 17  |
| Women and Infants Hospital                               | RI012      | 34 | 18 | 52  |
| Women's Cancer Center of Nevada                          | NV049      | 12 | 0  | 12  |
| Yale University - Yale Cancer Center LAPS                | LAPS-CT018 | 13 | 7  | 20  |
| Yonsei University Health System-Severance Hospital       | 43027      | 13 | 0  | 13  |

| Accrual For Agenda Book from 1/1/2018 to 12/31/2018             |            |    |    |    |    | Run Date: 1/04/2019 |    |    |    |    |  |  |  |  |  |  |                      |
|-----------------------------------------------------------------|------------|----|----|----|----|---------------------|----|----|----|----|--|--|--|--|--|--|----------------------|
|                                                                 |            |    |    |    |    |                     |    |    |    |    |  |  |  |  |  |  | Netw<br>ork<br>Total |
| Main Member Network                                             | CTEP ID    | GY | BN | BR | CC | OT                  | GI | GU | HN | LU |  |  |  |  |  |  |                      |
| Abington Memorial Hospital-Asplundh Cancer Pavilion             | PA501      | 8  | 0  | 0  | 0  | 0                   | 1  | 0  | 0  | 0  |  |  |  |  |  |  | 9                    |
| Advocate Lutheran General Hospital                              | IL010      | 0  | 0  | 0  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 0                    |
| Allan Blair Cancer Centre                                       | 11076      | 0  | 0  | 9  | 0  | 0                   | 0  | 8  | 0  | 0  |  |  |  |  |  |  | 17                   |
| Allegheny General Hospital                                      | PA009      | 6  | 0  | 3  | 0  | 0                   | 3  | 1  | 0  | 0  |  |  |  |  |  |  | 13                   |
| AMITA Health Alexian Brothers Medical Center                    | IL280      | 4  | 0  | 2  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 6                    |
| Arizona Center for Cancer Care-Peoria                           | AZ127      | 0  | 0  | 5  | 0  | 0                   | 0  | 14 | 0  | 0  |  |  |  |  |  |  | 19                   |
| Aultman Health Foundation                                       | OH100      | 0  | 0  | 4  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 4                    |
| Aurora NCI Community Oncology Research Program                  | AURORA     | 0  | 0  | 10 | 0  | 0                   | 0  | 10 | 0  | 0  |  |  |  |  |  |  | 20                   |
| Avera Cancer Institute                                          | SD021      | 1  | 0  | 0  | 0  | 0                   | 1  | 0  | 0  | 0  |  |  |  |  |  |  | 2                    |
| Baptist Health Cancer Research Network                          | BHCRN      | 1  | 0  | 2  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 3                    |
| Bay Area Tumor Institute NCORP                                  | BATI       | 0  | 0  | 3  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 3                    |
| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Ce | TX041      | 0  | 0  | 0  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 0                    |
| Baystate Medical Center                                         | MA004      | 13 | 0  | 0  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 13                   |
| Beaumont NCI Community Oncology Research Program                | BEAUMONT   | 0  | 1  | 1  | 0  | 0                   | 3  | 5  | 0  | 0  |  |  |  |  |  |  | 10                   |
| Berkshire Hematology Oncology PC                                | MA125      | 0  | 0  | 1  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 1                    |
| Boston Medical Center                                           | MA043      | 0  | 0  | 0  | 0  | 0                   | 0  | 4  | 0  | 0  |  |  |  |  |  |  | 4                    |
| Cancer Alliance of Nebraska                                     | MVCC       | 0  | 0  | 0  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 0                    |
| Cancer Research Consortium of West Michigan NCORP               | CRCWM      | 5  | 0  | 6  | 6  | 0                   | 2  | 6  | 0  | 0  |  |  |  |  |  |  | 25                   |
| Cancer Research for the Ozarks NCORP                            | OZARKS     | 2  | 0  | 4  | 2  | 0                   | 0  | 7  | 1  | 0  |  |  |  |  |  |  | 16                   |
| Cancer Trials Ireland                                           | ICORG      | 0  | 0  | 4  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 4                    |
| Carle Cancer Center NCI Community Oncology Research Program     | CARLE      | 0  | 0  | 0  | 7  | 0                   | 2  | 2  | 0  | 0  |  |  |  |  |  |  | 11                   |
| Carolinas Medical Center/Levine Cancer Institute                | NC042      | 5  | 0  | 11 | 0  | 0                   | 1  | 0  | 0  | 0  |  |  |  |  |  |  | 17                   |
| Catholic Health Initiatives NCORP                               | CORA       | 4  | 0  | 2  | 12 | 0                   | 1  | 0  | 0  | 0  |  |  |  |  |  |  | 19                   |
| Cedars-Sinai Medical Center                                     | CA016      | 2  | 0  | 0  | 0  | 0                   | 1  | 5  | 0  | 0  |  |  |  |  |  |  | 8                    |
| Centre Hospitalier Universitaire de Sherbrooke-Fleurimont       | 11065      | 0  | 0  | 2  | 1  | 0                   | 0  | 10 | 0  | 0  |  |  |  |  |  |  | 13                   |
| Chinese University of Hong Kong-Prince of Wales Hospital        | 34003      | 0  | 0  | 0  | 0  | 0                   | 0  | 0  | 12 | 0  |  |  |  |  |  |  | 12                   |
| CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)                      | 11073      | 0  | 0  | 1  | 0  | 0                   | 0  | 27 | 0  | 0  |  |  |  |  |  |  | 28                   |
| CHUM - Centre Hospitalier de l'Universite de Montreal           | 11062      | 0  | 0  | 2  | 2  | 0                   | 1  | 33 | 0  | 0  |  |  |  |  |  |  | 38                   |
| City of Hope Comprehensive Cancer Center                        | CA043      | 0  | 0  | 4  | 1  | 0                   | 0  | 0  | 1  | 1  |  |  |  |  |  |  | 7                    |
| CIUSSEMTL-Hopital Maisonneuve-Rosemont                          | 11060      | 0  | 0  | 0  | 0  | 0                   | 0  | 4  | 0  | 0  |  |  |  |  |  |  | 4                    |
| Colorado Cancer Research Program NCORP                          | CCRP       | 0  | 0  | 6  | 0  | 0                   | 1  | 0  | 1  | 0  |  |  |  |  |  |  | 8                    |
| Columbia Saint Mary's Water Tower Medical Commons               | WI161      | 0  | 0  | 0  | 0  | 0                   | 0  | 4  | 0  | 0  |  |  |  |  |  |  | 4                    |
| Columbia University Minority Underserved NCORP                  | COLUMBIA   | 6  | 0  | 1  | 1  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 8                    |
| Columbus NCI Community Oncology Research Program                | COLUMBUS   | 3  | 0  | 3  | 0  | 0                   | 0  | 3  | 0  | 0  |  |  |  |  |  |  | 9                    |
| Community Cancer Center North                                   | IN006      | 0  | 0  | 2  | 1  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 3                    |
| Cooper Hospital University Medical Center                       | NJ036      | 4  | 0  | 4  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 8                    |
| Covenant Medical Center-Lakeside                                | TX054      | 0  | 0  | 0  | 0  | 0                   | 0  | 0  | 0  | 0  |  |  |  |  |  |  | 0                    |
| Cross Cancer Institute                                          | 11132      | 0  | 0  | 3  | 0  | 0                   | 0  | 1  | 1  | 0  |  |  |  |  |  |  | 5                    |
| CWRU Case Comprehensive Cancer Center LAPS                      | LAPS-OH029 | 23 | 5  | 3  | 0  | 0                   | 5  | 44 | 15 | 3  |  |  |  |  |  |  | 98                   |
| Dana-Farber / Partners CancerCare LAPS                          | LAPS-MA03  | 0  | 0  | 1  | 0  | 0                   | 18 | 6  | 0  | 0  |  |  |  |  |  |  | 25                   |
| Dartmouth College - Norris Cotton Cancer Center LAPS            | LAPS-NH012 | 4  | 1  | 0  | 0  | 0                   | 0  | 14 | 1  | 0  |  |  |  |  |  |  | 20                   |

|                                                                    |            |    |   |    |    |   |   |    |    |   |    |
|--------------------------------------------------------------------|------------|----|---|----|----|---|---|----|----|---|----|
| Dayton NCI Community Oncology Research Program                     | DAYTON     | 1  | 0 | 1  | 0  | 0 | 1 | 0  | 0  | 0 | 3  |
| Delaware/Christiana Care NCI Community Oncology Research Program   | CHRISTIANA | 2  | 0 | 4  | 6  | 0 | 0 | 26 | 0  | 0 | 38 |
| Dell Seton Medical Center at The University of Texas               | TX063      | 1  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 1  |
| Duke University - Duke Cancer Institute LAPS                       | LAPS-NC010 | 6  | 0 | 3  | 0  | 0 | 0 | 6  | 0  | 1 | 16 |
| Edward Hospital/Cancer Center                                      | IL104      | 0  | 0 | 4  | 0  | 0 | 0 | 0  | 0  | 0 | 4  |
| Einstein Medical Center Philadelphia                               | PA094      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Emory University - Winship Cancer Institute LAPS                   | LAPS-GA005 | 1  | 2 | 7  | 0  | 0 | 3 | 17 | 3  | 3 | 36 |
| Essentia Health NCI Community Oncology Research Program            | ESSENTIA   | 0  | 0 | 0  | 1  | 0 | 0 | 0  | 0  | 0 | 1  |
| Florida Hospital Orlando                                           | FL086      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Fox Chase Cancer Center                                            | PA086      | 3  | 0 | 2  | 0  | 0 | 1 | 1  | 1  | 0 | 8  |
| Franciscan Health Indianapolis                                     | IN087      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Fred Hutchinson Cancer Research Center LAPS                        | LAPS-WA00  | 1  | 4 | 2  | 0  | 0 | 2 | 0  | 1  | 0 | 10 |
| Froedtert and the Medical College of Wisconsin                     | WI013      | 4  | 0 | 2  | 0  | 0 | 1 | 14 | 0  | 0 | 21 |
| Geisinger Cancer Institute NCI Community Oncology Research Program | GEISINGER  | 2  | 0 | 2  | 1  | 0 | 0 | 0  | 1  | 0 | 6  |
| Georgia Cares Minority Underserved NCORP                           | GRU        | 7  | 0 | 3  | 0  | 0 | 0 | 0  | 0  | 0 | 10 |
| Georgia NCI Community Oncology Research Program                    | GEORGIA    | 3  | 0 | 4  | 2  | 0 | 0 | 8  | 0  | 0 | 17 |
| Greater Baltimore Medical Center                                   | MD018      | 1  | 0 | 1  | 0  | 0 | 1 | 0  | 0  | 0 | 3  |
| Gulf South Minority Underserved NCORP                              | GULFSOUTH  | 1  | 0 | 3  | 1  | 0 | 0 | 4  | 0  | 0 | 9  |
| Hartford Hospital                                                  | CT009      | 1  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 1  |
| Hawaii Minority Underserved NCORP                                  | HAWAII     | 2  | 0 | 2  | 0  | 0 | 0 | 5  | 1  | 0 | 10 |
| Heartland Cancer Research NCORP                                    | HEARTLAND  | 0  | 0 | 8  | 1  | 0 | 3 | 18 | 3  | 0 | 33 |
| Henry Ford Hospital                                                | MI026      | 0  | 0 | 6  | 0  | 0 | 0 | 6  | 4  | 0 | 16 |
| Indiana University - Melvin and Bren Simon Cancer Center LAPS      | LAPS-IN007 | 8  | 0 | 1  | 0  | 0 | 2 | 1  | 0  | 0 | 12 |
| Iowa-Wide Oncology Research Coalition NCORP                        | IWORC      | 0  | 0 | 1  | 4  | 0 | 1 | 1  | 0  | 0 | 7  |
| James A. Haley Veterans Affairs Hospital                           | FL064      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Jewish General Hospital                                            | 11116      | 0  | 0 | 2  | 0  | 0 | 0 | 0  | 0  | 0 | 2  |
| JHU Sidney Kimmel Comprehensive Cancer Center LAPS                 | LAPS-MD01  | 4  | 0 | 4  | 0  | 0 | 0 | 0  | 0  | 0 | 8  |
| Juravinski Cancer Centre at Hamilton Health Sciences               | 11183      | 0  | 2 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 2  |
| Kaiser Permanente NCI Community Oncology Research Program          | KAISER     | 17 | 3 | 20 | 21 | 0 | 1 | 9  | 7  | 0 | 78 |
| Kaiser Permanente-Gaithersburg Medical Center                      | MD198      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Kansas City NCI Community Oncology Research Program                | KANSASCITY | 0  | 0 | 0  | 1  | 0 | 0 | 1  | 0  | 0 | 2  |
| Kantonsspital Aarau                                                | 67029      | 0  | 0 | 0  | 0  | 0 | 0 | 15 | 0  | 0 | 15 |
| Kingston Health Sciences Centre                                    | 11021      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Lahey Hospital and Medical Center                                  | MA017      | 2  | 0 | 1  | 0  | 0 | 0 | 0  | 0  | 0 | 3  |
| Lakeland Regional Health Hollis Cancer Center                      | FL071      | 0  | 0 | 0  | 0  | 0 | 0 | 0  | 0  | 0 | 0  |
| Legacy Good Samaritan Hospital and Medical Center                  | OR013      | 3  | 0 | 1  | 0  | 0 | 1 | 0  | 0  | 0 | 5  |
| London Regional Cancer Program                                     | 11137      | 0  | 0 | 1  | 0  | 0 | 2 | 0  | 0  | 0 | 3  |
| Loyola University Medical Center                                   | IL017      | 4  | 0 | 0  | 0  | 0 | 0 | 9  | 1  | 0 | 14 |
| Main Line Health NCORP                                             | MAINLINE   | 1  | 0 | 3  | 1  | 0 | 0 | 4  | 0  | 0 | 9  |
| Maine Medical Center- Scarborough Campus                           | ME018      | 13 | 1 | 0  | 0  | 0 | 0 | 2  | 0  | 0 | 16 |
| Mayo Clinic LAPS                                                   | LAPS-MN02  | 7  | 2 | 6  | 1  | 0 | 1 | 1  | 2  | 0 | 20 |
| Medical University of South Carolina Minority Underserved NCORP    | MUSC       | 0  | 0 | 2  | 2  | 0 | 0 | 14 | 0  | 0 | 18 |
| MedStar Franklin Square Medical Center/Weinberg Cancer Institute   | MD029      | 0  | 0 | 1  | 0  | 0 | 0 | 0  | 0  | 0 | 1  |
| Memorial Sloan-Kettering Cancer Center LAPS                        | LAPS-NY016 | 13 | 0 | 23 | 0  | 0 | 0 | 0  | 12 | 3 | 51 |
| Mercy Cancer Center - Sacramento                                   | CA729      | 0  | 0 | 4  | 0  | 0 | 0 | 5  | 0  | 0 | 9  |
| Metro Minnesota Community Oncology Research Consortium             | METROMIN   | 12 | 0 | 4  | 3  | 0 | 3 | 3  | 0  | 0 | 25 |
| Michigan Cancer Research Consortium NCORP                          | MCRC       | 1  | 0 | 0  | 12 | 0 | 4 | 6  | 0  | 0 | 23 |

Accrual from 1/1/2018 to 12/31/2018

|                                                                       |            |    |    |    |   |   |   |    |   |   |    |
|-----------------------------------------------------------------------|------------|----|----|----|---|---|---|----|---|---|----|
| Michigan State University Clinical Center                             | MI038      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Moffitt Cancer Center                                                 | FL065      | 3  | 0  | 2  | 0 | 0 | 0 | 0  | 1 | 0 | 6  |
| Montana Cancer Consortium NCORP                                       | MONTANA    | 7  | 0  | 2  | 0 | 0 | 1 | 7  | 0 | 0 | 17 |
| Montefiore Minority Underserved NCORP                                 | MONTEFIORE | 0  | 0  | 8  | 0 | 0 | 0 | 0  | 2 | 0 | 10 |
| Mount Sinai Hospital                                                  | NY021      | 2  | 0  | 3  | 0 | 0 | 0 | 0  | 1 | 0 | 6  |
| Mount Sinai Medical Center                                            | FL036      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| National Cancer Centre Singapore                                      | 47005      | 0  | 0  | 0  | 0 | 0 | 0 | 1  | 3 | 0 | 4  |
| National Institutes of Health Clinical Center                         | MD004      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| NCORP of the Carolinas (Greenville Health System NCORP)               | GREENVILLE | 2  | 0  | 1  | 2 | 0 | 0 | 0  | 0 | 0 | 5  |
| Nevada Cancer Research Foundation NCORP                               | NCRF       | 0  | 0  | 2  | 0 | 0 | 0 | 0  | 0 | 0 | 2  |
| New Hanover Regional Medical Center/Zimmer Cancer Center              | NC043      | 0  | 0  | 0  | 0 | 0 | 0 | 10 | 0 | 0 | 10 |
| New Mexico Minority Underserved NCORP                                 | NEWMEXICO  | 9  | 1  | 11 | 1 | 0 | 1 | 13 | 0 | 1 | 37 |
| New York-Presbyterian/Brooklyn Methodist Hospital                     | NY075      | 0  | 0  | 0  | 1 | 0 | 0 | 15 | 1 | 0 | 17 |
| Newark Beth Israel Medical Center                                     | NJ015      | 0  | 0  | 2  | 0 | 0 | 0 | 0  | 0 | 0 | 2  |
| NorthShore University HealthSystem-Evanston Hospital                  | IL018      | 1  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 1  |
| Northwell Health NCORP                                                | NORTHSHORE | 5  | 0  | 0  | 5 | 0 | 1 | 10 | 1 | 0 | 22 |
| Northwest NCI Community Oncology Research Program                     | NORTHWEST  | 0  | 0  | 8  | 3 | 0 | 1 | 11 | 0 | 0 | 23 |
| Northwestern Medicine Cancer Center Warrenville                       | IL387      | 0  | 12 | 3  | 0 | 0 | 0 | 0  | 0 | 0 | 15 |
| Northwestern University                                               | IL036      | 1  | 1  | 2  | 1 | 0 | 0 | 0  | 1 | 1 | 7  |
| Norton Hospital Pavilion and Medical Campus                           | KY049      | 1  | 0  | 1  | 0 | 0 | 0 | 0  | 0 | 0 | 2  |
| Ochsner NCI Community Oncology Research Program                       | OCHSNER    | 4  | 0  | 5  | 0 | 0 | 0 | 2  | 0 | 0 | 11 |
| Odette Cancer Centre- Sunnybrook Health Sciences Centre               | 11118      | 2  | 0  | 0  | 0 | 0 | 0 | 4  | 0 | 0 | 6  |
| Ohio State University Comprehensive Cancer Center LAPS                | LAPS-OH001 | 9  | 0  | 6  | 1 | 0 | 4 | 5  | 1 | 3 | 29 |
| Ottawa Hospital and Cancer Center-General Campus                      | 11025      | 0  | 0  | 0  | 0 | 0 | 0 | 1  | 0 | 0 | 1  |
| Pacific Cancer Research Consortium NCORP                              | PCRC       | 8  | 0  | 4  | 0 | 0 | 1 | 1  | 0 | 0 | 14 |
| Parkview Hospital Randallia                                           | IN017      | 6  | 0  | 1  | 0 | 0 | 1 | 1  | 1 | 0 | 10 |
| Parkview Regional Medical Center                                      | IN181      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Penn State Milton S Hershey Medical Center                            | PA042      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Peter MacCallum Cancer Centre                                         | 03003      | 0  | 0  | 0  | 0 | 0 | 1 | 0  | 0 | 0 | 1  |
| Piedmont Hospital                                                     | GA027      | 0  | 0  | 0  | 0 | 0 | 0 | 1  | 0 | 0 | 1  |
| ProMedica Flower Hospital                                             | OH012      | 0  | 0  | 0  | 0 | 0 | 0 | 1  | 0 | 0 | 1  |
| Puerto Rico Minority Underserved NCORP                                | SANJUAN    | 0  | 0  | 1  | 0 | 0 | 0 | 0  | 0 | 0 | 1  |
| Rabin Medical Center                                                  | 40021      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Reading Hospital                                                      | PA107      | 0  | 0  | 0  | 0 | 0 | 0 | 10 | 0 | 0 | 10 |
| Rhode Island Hospital                                                 | RI005      | 0  | 0  | 3  | 0 | 0 | 0 | 0  | 0 | 0 | 3  |
| Roswell Park Cancer Institute LAPS                                    | LAPS-NY158 | 9  | 0  | 0  | 0 | 0 | 1 | 3  | 1 | 0 | 14 |
| Rush University Medical Center                                        | IL043      | 1  | 0  | 0  | 0 | 0 | 0 | 5  | 0 | 0 | 6  |
| Rutgers Cancer Institute of New Jersey                                | NJ066      | 0  | 2  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 2  |
| Saint Joseph Hospital - Orange                                        | CA087      | 1  | 0  | 1  | 0 | 0 | 0 | 0  | 0 | 0 | 2  |
| Saint Joseph's Hospital and Medical Center                            | AZ009      | 0  | 12 | 1  | 0 | 0 | 0 | 0  | 0 | 0 | 13 |
| Saitama Medical University International Medical Center               | 42061      | 8  | 1  | 8  | 0 | 0 | 0 | 0  | 0 | 0 | 17 |
| Samsung Medical Center                                                | 43004      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Sanford NCI Community Oncology Research Program of the North Carolina | SANFORD    | 2  | 0  | 3  | 7 | 0 | 2 | 0  | 3 | 0 | 17 |
| Saskatoon Cancer Centre                                               | 11120      | 0  | 0  | 2  | 3 | 0 | 0 | 13 | 0 | 0 | 18 |
| Scott and White Memorial Hospital                                     | TX027      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Scranton Hematology Oncology                                          | PA302      | 0  | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 0 | 0  |
| Seoul National University Hospital                                    | 43002      | 60 | 0  | 0  | 0 | 0 | 0 | 0  | 0 | 5 | 65 |

Accrual from 1/1/2018 to 12/31/2018

|                                                                       |            |    |   |    |   |   |    |    |    |   |    |
|-----------------------------------------------------------------------|------------|----|---|----|---|---|----|----|----|---|----|
| Sinai Hospital of Baltimore                                           | MD020      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| Southeast Clinical Oncology Research (SCOR) Consortium NCORP          | SCCC       | 9  | 0 | 11 | 1 | 0 | 1  | 21 | 2  | 0 | 45 |
| Stanford University - Stanford Cancer Institute LAPS                  | LAPS-CA141 | 1  | 0 | 0  | 0 | 0 | 0  | 0  | 7  | 0 | 8  |
| State University of New York Downstate Medical Center                 | NY178      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| Staten Island University Hospital                                     | NY035      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| Stony Brook University Medical Center                                 | NY184      | 1  | 0 | 0  | 0 | 0 | 0  | 1  | 0  | 0 | 2  |
| Stroger Hospital of Cook County Minority Underserved NCORP            | STROGER    | 6  | 0 | 6  | 1 | 0 | 0  | 0  | 1  | 0 | 14 |
| Summa Akron City Hospital/Cooper Cancer Center                        | OH055      | 0  | 0 | 5  | 0 | 0 | 0  | 1  | 0  | 0 | 6  |
| Sun Yat-sen University Cancer Center                                  | 60021      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 6  | 0 | 6  |
| Sutter Cancer Research Consortium                                     | SUTTER     | 11 | 1 | 2  | 0 | 0 | 1  | 2  | 2  | 0 | 19 |
| Tel Aviv Sourasky Medical Center                                      | 40019      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| The Community Hospital                                                | IN044      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| The James Graham Brown Cancer Center at University of Louisville      | KY002      | 0  | 0 | 1  | 0 | 0 | 0  | 0  | 1  | 0 | 2  |
| The Methodist Hospital System                                         | TX036      | 0  | 0 | 3  | 0 | 0 | 0  | 0  | 0  | 0 | 3  |
| The Research Institute of the McGill University Health Centre (MUHC)  | 11318      | 0  | 1 | 3  | 2 | 0 | 0  | 9  | 1  | 0 | 16 |
| The US Oncology Network                                               | USONC      | 0  | 0 | 11 | 0 | 0 | 0  | 15 | 0  | 0 | 26 |
| Thomas Jefferson University Hospital                                  | PA121      | 6  | 1 | 2  | 0 | 0 | 3  | 14 | 18 | 0 | 44 |
| Thompson Cancer Survival Center                                       | TN038      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| Tom Baker Cancer Centre                                               | 11134      | 0  | 0 | 2  | 0 | 0 | 1  | 4  | 1  | 0 | 8  |
| Trinity Cancer Care Center                                            | ND026      | 0  | 0 | 1  | 0 | 0 | 0  | 0  | 0  | 0 | 1  |
| Tulane University Health Sciences Center                              | LA001      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| UC Davis Comprehensive Cancer Center LAPS                             | LAPS-CA189 | 0  | 0 | 3  | 0 | 0 | 1  | 23 | 0  | 0 | 27 |
| UC Irvine Health/Chao Family Comprehensive Cancer Center              | CA088      | 0  | 4 | 1  | 0 | 0 | 0  | 0  | 0  | 0 | 5  |
| UC San Diego Moores Cancer Center                                     | CA249      | 7  | 0 | 0  | 1 | 0 | 0  | 1  | 3  | 0 | 12 |
| UCLA / Jonsson Comprehensive Cancer Center                            | CA006      | 1  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 1  |
| UCSF Medical Center-Mount Zion                                        | CA136      | 3  | 0 | 1  | 0 | 0 | 0  | 7  | 2  | 0 | 13 |
| UF Cancer Center at Orlando Health                                    | FL020      | 1  | 0 | 3  | 0 | 0 | 0  | 0  | 0  | 0 | 4  |
| UNC Lineberger Comprehensive Cancer Center LAPS                       | LAPS-NC007 | 0  | 0 | 2  | 0 | 0 | 0  | 4  | 0  | 0 | 6  |
| University Health Network-Princess Margaret Hospital                  | 11030      | 0  | 0 | 0  | 0 | 0 | 14 | 1  | 2  | 0 | 17 |
| University of Alabama at Birmingham / Deep South Research Consortium  | LAPS-AL002 | 2  | 0 | 1  | 0 | 0 | 0  | 0  | 2  | 0 | 5  |
| University of Arizona Medical Center-University Campus                | AZ017      | 6  | 0 | 0  | 0 | 0 | 0  | 1  | 4  | 0 | 11 |
| University of Arkansas for Medical Sciences                           | AR006      | 2  | 0 | 2  | 0 | 0 | 0  | 4  | 0  | 0 | 8  |
| University of Chicago Comprehensive Cancer Center LAPS                | LAPS-IL057 | 5  | 0 | 4  | 0 | 0 | 0  | 2  | 0  | 0 | 11 |
| University of Cincinnati/Barrett Cancer Center                        | OH070      | 1  | 1 | 1  | 0 | 0 | 3  | 0  | 6  | 0 | 12 |
| University of Colorado Cancer Center LAPS                             | LAPS-CO070 | 10 | 1 | 2  | 1 | 0 | 4  | 6  | 1  | 0 | 25 |
| University of Connecticut                                             | CT002      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| University of Florida Health Science Center - Gainesville             | FL015      | 0  | 1 | 1  | 0 | 0 | 3  | 0  | 0  | 3 | 8  |
| University of Illinois                                                | IL040      | 0  | 0 | 2  | 0 | 0 | 1  | 0  | 0  | 0 | 3  |
| University of Iowa/Holden Comprehensive Cancer Center                 | IA018      | 13 | 0 | 3  | 0 | 0 | 2  | 0  | 1  | 0 | 19 |
| University of Kansas Cancer Center                                    | KS004      | 3  | 0 | 10 | 1 | 0 | 1  | 7  | 0  | 0 | 22 |
| University of Kentucky/Markey Cancer Center                           | KY010      | 0  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 0  |
| University of Maryland/Greenebaum Cancer Center                       | MD015      | 0  | 1 | 7  | 0 | 0 | 3  | 12 | 0  | 3 | 26 |
| University of Massachusetts Memorial Health Care                      | MA009      | 1  | 0 | 0  | 0 | 0 | 0  | 0  | 0  | 0 | 1  |
| University of Miami Miller School of Medicine-Sylvester Cancer Center | FL028      | 2  | 1 | 8  | 0 | 0 | 1  | 2  | 0  | 0 | 14 |
| University of Michigan Comprehensive Cancer Center LAPS               | LAPS-MI014 | 1  | 0 | 2  | 0 | 0 | 0  | 30 | 0  | 3 | 36 |
| University of Minnesota/Masonic Cancer Center                         | MN022      | 0  | 0 | 0  | 0 | 0 | 0  | 1  | 0  | 0 | 1  |
| University of Mississippi Medical Center                              | MS005      | 0  | 0 | 1  | 0 | 0 | 0  | 0  | 0  | 0 | 1  |

Accrual from 1/1/2018 to 12/31/2018

|                                                          |            |    |    |   |   |   |   |    |   |    |    |
|----------------------------------------------------------|------------|----|----|---|---|---|---|----|---|----|----|
| University of Missouri - Ellis Fischel                   | MO036      | 0  | 0  | 0 | 0 | 0 | 0 | 0  | 0 | 0  | 0  |
| University of Nebraska Medical Center                    | NE003      | 1  | 0  | 0 | 0 | 0 | 0 | 1  | 0 | 0  | 2  |
| University of Oklahoma Health Sciences Center LAPS       | LAPS-OK003 | 72 | 1  | 6 | 0 | 0 | 2 | 6  | 0 | 1  | 88 |
| University of Pennsylvania/Abramson Cancer Center        | PA075      | 10 | 1  | 0 | 0 | 0 | 1 | 0  | 0 | 1  | 13 |
| University of Pittsburgh Cancer Institute LAPS           | LAPS-PA015 | 11 | 0  | 3 | 0 | 0 | 3 | 0  | 2 | 0  | 19 |
| University of Rochester                                  | NY167      | 10 | 0  | 0 | 0 | 0 | 0 | 0  | 1 | 1  | 12 |
| University of South Alabama Mitchell Cancer Institute    | AL068      | 0  | 0  | 1 | 0 | 0 | 0 | 0  | 0 | 0  | 1  |
| University of Tennessee - Knoxville                      | TN021      | 2  | 0  | 0 | 0 | 0 | 0 | 0  | 0 | 0  | 2  |
| University of Tennessee Health Science Center            | TN030      | 0  | 0  | 3 | 0 | 0 | 0 | 0  | 0 | 0  | 3  |
| University of Texas Health Science Center at San Antonio | TX059      | 0  | 0  | 5 | 0 | 0 | 0 | 5  | 0 | 0  | 10 |
| University of Texas MD Anderson Cancer Center LAPS       | LAPS-TX035 | 6  | 3  | 8 | 2 | 0 | 4 | 0  | 0 | 19 | 42 |
| University of Texas Medical Branch                       | TX045      | 0  | 0  | 0 | 1 | 0 | 0 | 5  | 0 | 0  | 6  |
| University of Texas Southwestern Medical Center LAPS     | LAPS-TX011 | 13 | 0  | 2 | 0 | 0 | 2 | 12 | 2 | 5  | 36 |
| University of Utah - Huntsman Cancer Institute LAPS      | LAPS-UT003 | 2  | 0  | 8 | 0 | 0 | 1 | 6  | 0 | 0  | 17 |
| University of Vermont College of Medicine                | VT004      | 0  | 0  | 2 | 0 | 0 | 1 | 7  | 0 | 0  | 10 |
| University of Virginia Cancer Center                     | VA009      | 12 | 0  | 0 | 0 | 0 | 0 | 3  | 0 | 0  | 15 |
| University of Wisconsin Carbone Cancer Center LAPS       | LAPS-WI020 | 3  | 1  | 5 | 3 | 0 | 3 | 7  | 1 | 0  | 23 |
| USC Norris Comprehensive Cancer Center LAPS              | LAPS-CA011 | 1  | 0  | 5 | 0 | 0 | 1 | 6  | 0 | 0  | 13 |
| Vanderbilt University - Ingram Cancer Center LAPS        | LAPS-TN008 | 2  | 0  | 0 | 1 | 0 | 3 | 0  | 0 | 0  | 6  |
| Vassar Brothers Medical Center                           | NY131      | 0  | 0  | 4 | 0 | 0 | 0 | 0  | 0 | 0  | 4  |
| VCU Massey Cancer Center Minority Underserved NCORP      | VCU        | 3  | 3  | 1 | 0 | 0 | 1 | 2  | 0 | 0  | 10 |
| Veterans Administration Long Beach Medical Center        | CA041      | 0  | 0  | 0 | 0 | 0 | 0 | 6  | 0 | 0  | 6  |
| Virginia Oncology Associates-Hampton                     | VA084      | 0  | 0  | 0 | 0 | 0 | 0 | 0  | 0 | 0  | 0  |
| Wake Forest University Health Sciences                   | NC002      | 0  | 1  | 4 | 0 | 0 | 0 | 0  | 0 | 0  | 5  |
| Walter Reed National Military Medical Center             | MD001      | 3  | 0  | 0 | 0 | 0 | 0 | 0  | 0 | 0  | 3  |
| Washington University - Siteman Cancer Center LAPS       | LAPS-MO01  | 30 | 13 | 2 | 0 | 1 | 0 | 42 | 0 | 11 | 99 |
| Wayne State University - Karmanos Cancer Institute LAPS  | LAPS-MI020 | 2  | 0  | 6 | 3 | 0 | 1 | 46 | 0 | 0  | 58 |
| WellSpan Health-York Hospital                            | PA047      | 0  | 0  | 1 | 0 | 0 | 0 | 5  | 0 | 0  | 6  |
| West Virginia University Charleston Division             | WV004      | 0  | 0  | 3 | 0 | 0 | 0 | 0  | 0 | 0  | 3  |
| West Virginia University Healthcare                      | WV025      | 0  | 0  | 4 | 0 | 0 | 1 | 1  | 0 | 0  | 6  |
| Wichita NCI Community Oncology Research Program          | WICHITA    | 0  | 0  | 1 | 6 | 0 | 1 | 2  | 1 | 0  | 11 |
| Wisconsin NCI Community Oncology Research Program        | WINCORP    | 6  | 0  | 3 | 1 | 0 | 0 | 1  | 0 | 0  | 11 |
| Women and Infants Hospital                               | RI012      | 29 | 0  | 5 | 0 | 0 | 0 | 0  | 0 | 0  | 34 |
| Women's Cancer Center of Nevada                          | NV049      | 12 | 0  | 0 | 0 | 0 | 0 | 0  | 0 | 0  | 12 |
| Yale University - Yale Cancer Center LAPS                | LAPS-CT018 | 5  | 0  | 1 | 0 | 0 | 0 | 6  | 1 | 0  | 13 |
| Yonsei University Health System-Severance Hospital       | 43027      | 8  | 0  | 3 | 0 | 0 | 0 | 0  | 0 | 2  | 13 |
|                                                          |            |    |    |   |   |   |   |    |   |    |    |

# NRG Oncology Winter 2019 Exhibitor Companies

NRG wishes to acknowledge the following exhibitors:

American College of Radiology  
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Cancer Trials Support Unit (CTSU)  
Caris Life Sciences  
Clovis Oncology  
Genmab & Seattle Genetics  
Mitra Biotech  
NCI CIRB  
Novocure, Inc.  
Tempus  
Tesaro  
TS Medical USA  
VBL Therapeutics  
Wolters Kluwer

Please take the time to visit the exhibit booths located:  
**North 120 Lobby on the 1st level of the North Building**

## Exhibit hours are:

Friday, February 8, 2019 - 7:00 am - 5:00 pm  
Saturday, February 9, 2019- 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.

# NRG Oncology Winter 2019 Exhibiting Companies

## 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)

## AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases.

AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

## Best Medical International

The TeamBest family of companies has been proudly developing, manufacturing, and delivering reliable medical equipment and supplies for more than 40 years. TeamBest includes over a dozen companies offering complementary products and services for brachytherapy, health physics, radiation oncology, blood irradiation, vascular therapy, imaging, and medical particle acceleration. TeamBest is the single source for an expansive line of life saving medical equipment and supplies. Our trusted team is constantly expanding and innovating to provide the most reliable and cutting edge medical equipment and supplies to the global healthcare and research industries.

## Cancer Trials Support Unit (CTSU) (A service of the NCI)

Our company objective is to spread awareness of the CTSU.

## 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. To learn more, please visit [www.CarisLifeSciences.com](http://www.CarisLifeSciences.com) or follow us on Twitter (@CarisLS).

## Clovis Oncology

Founded in 2009, Clovis Oncology 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, diagnostic tools intended to direct a compound in development to the patients most likely to benefit from their use.

## Genmab and Seattle Genetics

### About Genmab

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer. Founded in 1999, the company has two approved antibodies, DARZALEX® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications and other blood cancers. A subcutaneous formulation of ofatumumab is in development for relapsing multiple sclerosis. Genmab also has a broad clinical and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies - the DuoBody® platform for generation of bispecific antibodies, the HexaBody® platform, which creates effector function enhanced antibodies and the HexElect™ platform, which combines two co-dependently acting HexaBody molecules to introduce selectivity while maximizing therapeutic potency. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab has alliances with top tier pharmaceutical and biotechnology companies. For more information visit [www.genmab.com](http://www.genmab.com).

### About 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. ADCE-TRIS® (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,



# NRG Oncology Winter 2019 Exhibiting Companies

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.

## **Mitra Biotech**

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

CANscript delivers powerful, individualized treatment response predictions – with exceptionally high correlation to clinical outcomes – to inform patient-specific cancer treatment selection and support more effective and efficient cancer drug development.

Founded in 2010, Mitra is headquartered in Greater Boston and maintains a significant research and laboratory presence in Bengaluru, India.

## **NCI CIRB**

The NCI Central Institutional Review Board is dedicated to protecting the rights and welfare of participants in cancer clinical trials. Institutions across the country rely on our national experts to ensure that clinical trials are reviewed efficiently and with the highest ethical and quality standards. We play a critical role in helping the National Cancer Institute accelerate scientific discovery and improve cancer prevention, treatment and care.

## **Novocure, Inc.**

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

## **TEMPUS**

Tempus is a technology company transforming cancer care by allowing physicians to personalize treatment using big data and analytics. The company is building the world's largest library of molecular and clinical data and an operating system to make that data accessible and useful to researchers, physicians and the patients they treat.

## **TESARO**

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

## **TS Medical USA**

TS Medical USA is a provider of infrared, laser medical devices. By using our strong collaboration with our clinical partners, TS Medical USA continuously delivers innovative and alternative therapies to fulfill clinical needs and improve patient outcomes.

## **VBL Therapeutics**

VBL Therapeutics is a publicly traded, late stage clinical biopharmaceutical company focused on the discovery, development and commercialization of first in class treatments for cancer. VBL is currently recruiting patients with platinum resistant ovarian cancer to the phase III study – OVAL.

## **Wolters Kluwer**

Wolters Kluwer is a leading medical publisher which has new editions of DeVita's Principles & Practice of Oncology, Perez & Brady's Radiation Oncology and Wintrobe's Hematology.

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AbbVie  
Astellas  
AstraZeneca  
Celgene  
Genentech  
Genomic Health  
Lilly  
Novartis  
Novocure  
Pfizer  
Seattle Genetics  
Tesaro

# *SAVE THE DATE*

**July, 18 - 20, 2019**

**NRG Oncology Semiannual Meeting  
Philadelphia Marriott Downtown  
Philadelphia, PA**



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## Notes

# SAVE THE DATES

## Future NRG Oncology Semiannual Meetings

**July 18- 20, 2019**

Philadelphia Marriott Downtown  
Philadelphia, PA

**January 9- 11, 2020**

Marriott Marquis  
Houston, TX

**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

