

NRG ONCOLOGY
SEMIANNUAL MEETING

#NRG19



PROGRAM

NRG
ONCOLOGY

Advancing Research. Improving Lives.™



JULY 18-20, 2019

PHILADELPHIA MARRIOTT DOWNTOWN

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Welcome

to the July 2019 NRG Oncology Semiannual Meeting

It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Philadelphia, PA, July 18-20, 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 of criteria for rigorous review of our science, and in the educational opportunities including specific workshops convened by NRG Oncology experts.

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

Meeting highlights include:

A day-long summer Symposium titled, "Uterine Sarcomas and Carcinosarcomas: from Pathology to Practice" with noted Oncologists and Scientists serving as speakers and moderators. The targeted audiences are members and non-members of the NRG research teams to include: Gynecologic Oncologists, Medical Oncologists, Radiation Oncologists, Pathologists, and other MDs engaged in oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, and other interested Allied Health professionals. The speakers will focus their presentations on the diagnosis and management of high-grade uterine sarcomas, low grade sarcomas, and uterine carcinosarcomas.

Thursday, July 18 - 8-3 pm

Patient Reported Outcomes: Upping the game for PRO methods and design in clinical trials - NRG Oncology will be holding a workshop at the NRG Semiannual Meeting related to improving statistical methods to meet study goals, analyzing longitudinal PRO

data as well as a panel discussion with NCORP Pls.

Thursday, July 18, 2019, 1-5 pm and will be open to all attendees

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, head and neck, and colorectal cancer.

Friday, July 19 - 8-10 am

Health Disparities Workshop Special Session: Sexual and Gender Minority Related Activities at the NIH.

Friday, July 19 - 10-11:30 am

Social Media Workshop 1-on-1's at #NRG19

Are you ready to get started on Twitter? Let our social media experts show you how simple it is to set up a new account or make your existing account more engaging. At #NRG19, we have scheduled two Social Media 1-on-1 Workshops where our Twitter experts will be on hand to show you the how-to's of Twitter. If you are interested in learning more about tweeting, retweeting, hashtags, following, and more, stop by during one of the following sessions and bring your smartphone and/or laptop. No previous social media experience required!

Friday, July 19, 12:30-1 pm and Saturday, July 20, 10-11 am

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

Friday, July 19, 1-2 pm

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 Philadelphia!



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



Robert Mannel, MD
NRG Oncology Group Chair



Norman Wolmark, MD
NRG Oncology Group Chair

NRG Oncology Mission Statement

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

For the Educational Objectives, we list the following:

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

Disclosure Information

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

Continuing Medical Education (CME) Information

Accreditation Statement

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

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

AMA PRA Category 1 Credits™

The GOG Foundation, Inc. designates this live activity for a maximum of 26.5 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 who 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.

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
Email: lcalthoun@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:
August 9, 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.

FINAL LISTING OF APPROVED CME CREDITS

The following sessions/workshops have been approved to receive CME credits
Accredited by the GOG Foundation, Inc. in Philadelphia, PA July 18-20, 2019
AMA PRA Category 1 credits™

	THURSDAY	FRIDAY	SATURDAY
Symposium –“Uterine Sarcomas and Carcinosarcomas: from Pathology to Practice” Green CME Tickets	5.75		
WORKSHOP AGENDAS			
Brain Tumor workshop		2	
Breast Cancer workshop			3
Breast Cancer Rare and Genetically Linked subcommittee workshop		2	
Canadian Members workshop			1
Cancer Prevention and Control workshop		2	
Cervix Cancer workshop		2	1
Gastrointestinal Cancer workshop			2
Genitourinary Cancer workshop			2
Gynecologic Cancer workshop			2
GYN Developmental Therapeutics/Phase I workshop			1
GYN Dev. Therapeutics/Phase I/Translational Science workshop	2		
Head and Neck Cancer workshop			2
Health Disparities workshop		1.5	
Immunotherapy and Immune Modulation workshop	2	1.5	
International Members workshop		1	
Lung Cancer workshop			2
Medical Oncology workshop			1
NRG – LU003 Kick-off			1
NRG Oncology Protocol NRG-BR005 workshop			1
NRG Protocol G1004, G1002 and G1005 workshop		1	
NRG Protocol Workshop: NRG BR003 and BR004		1	
NRG Scientific Session - NRG Oncology Research Review Yellow CME Tickets		2	
NRG Surgical Oncology workshop			1
Ovarian Cancer workshop		2	1
Patient Centered Outcomes Research (PCOR) CME Tickets	2		
Patient Reported Outcomes: Upping the game for PRO methods and design clinical trials CME Tickets	4		
Pharmacy Subcommittee workshop		1	
Rare Tumor workshop		2	
Social Media and Mobile Technology workshop		1	
Translational Science workshop	1.5		
Translational Science GYN workshop		1.5	
Translational Science Lung Cancer workshop		2	
Uterine Corpus Cancer workshop		2	1
PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD's			
PSC-Clinical Trial Nurse/Clinical Research Assoc Ed Session CME Tickets	4		
PSC-Clinical Trial Nurse/Clinical Research Assoc Ed Session Roundtables CME Tickets	3		
PSC Clinical Trial Nurse Subcommittee		1	
PSC Clinical Research Associate Subcommittee		.5	
PSC Quality Control Working Group (Closed)	.75		
PSC Mentorship Working Group (Closed)	1.5		
PSC Protocol Review Working Group (Closed)	.75		

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:

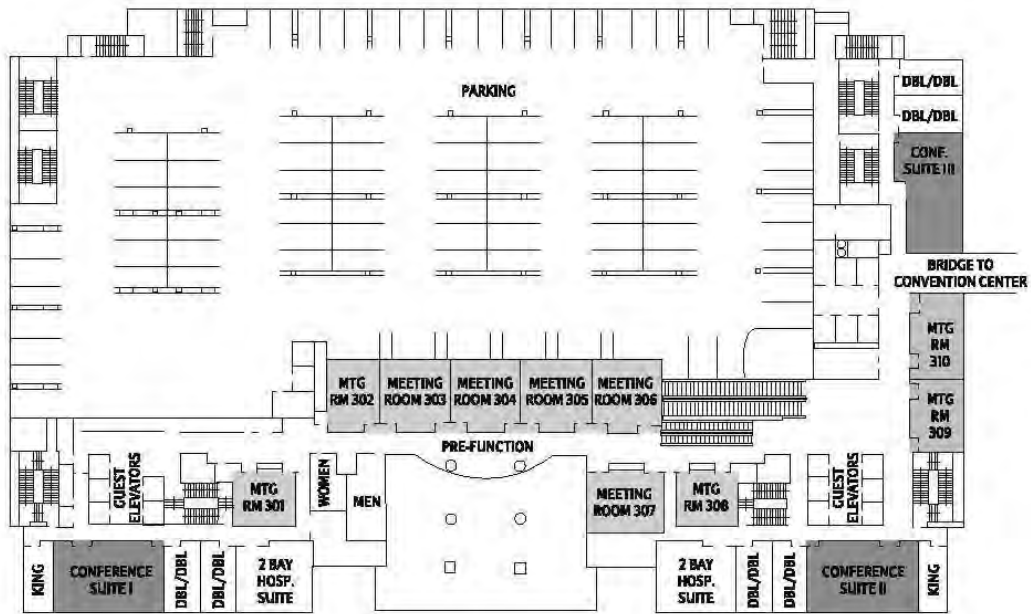
Network Login: nrgmeeting

Passcode: n1r2g345



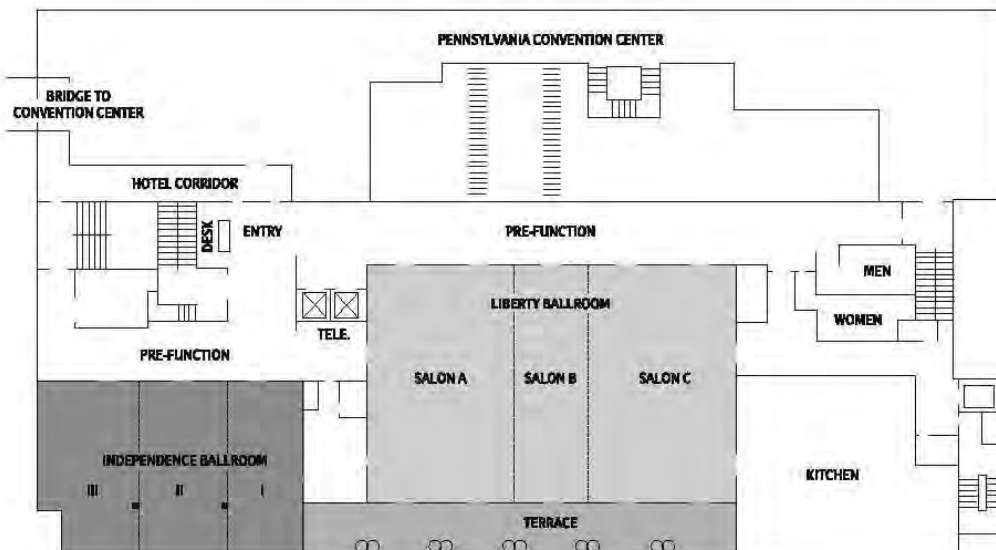
Hotel Floor Plan

Philadelphia Marriott Downtown – Level 3

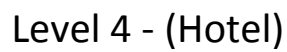


Level 3 - (Hotel)

Level 3 – (Convention Center)



Philadelphia Marriott Downtown – Levels 4 & 5



Service Corridor

BANQUET STORAGE

PRE-FUNCTION

SALON A

SALON B

SALON C

SALON D

SALON F

GRAND BALLROOM

SALON E

SALON G

SALON H

SALON I

SALON J

SALON K

SALON L

BANQUET KITCHEN

FREIGHT ELEV.

SERVICE ELEVATORS

PRE-FUNCTION 9,000 SQUARE FEET

ESCALATORS

ESCALATORS

OPEN TO BELOW

MEETING ROOM 501

MEN

STORAGE

WOMEN

REGISTRATION I

MEETING ROOM 502

MEN

STORAGE

WOMEN

REGISTRATION II

GUEST ELEVATORS

GUEST ELEVATORS

NRG ONCOLOGY SEMIANNUAL MEETING

FINAL SCHEDULE

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 18 – 20, 2019

Thursday, July 18, 2019		
6:30 am – 8:30 am	Symposium Breakfast	Salon CD/5 th Fl.
7:00 am – 8:00 am	PSC CTN/CRA Workshop and Educational Session Breakfast	Salon HIJ/5 th Fl.
7:00 am – 6:00 pm	Registration/CME/Information Desk	Grand Ballroom Foyer/5 th Fl.
10:25 am – 10:45 am	Symposium Coffee Break	Salon CD/5 th Fl.
12:00 pm – 1:00 pm	Symposium Lunch	Salon CD/5 th Fl.
2:00 pm – 6:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Room 406/4 th Fl.
4:00 pm – 6:00 pm	Exhibit Setup	Franklin Hall Foyer/4 th Fl.
8:00 am – 10:00 am	NRG DMC Panel B *	Room 405/4 th Fl.
8:00 am – 1:00 pm	PSC Clinical Trial Nurse/Clinical Research Associate Workshop and Educational Lunch Session	Salon HIJ/5 th Fl.
8:00 am – 3:00 pm	Summer Symposium - “Uterine Sarcomas and Carcinosarcomas: From Pathology to Practice”	Salon E/5 th Fl.
9:00 am – 12:00 pm	NCORP Research Base PI Meeting (<i>Invitation Only</i>)	Room 407/4 th Fl.
9:00 am – 1:00 pm	SOCRA Certification Exam	Room 308/3 rd Fl.
10:30 am – 12:30 pm	NRG DMC Panel A *	Room 405/4 th Fl.
1:00 pm – 5:00 pm	PRO Workshop – <i>Patient Reported Outcomes: Upping the game for PRO methods and design in clinical trials</i>	105AB/1 st Level/PA Convention Center
1:30 pm – 4:30 pm	PSC Clinical Trial Nurse/Clinical Research Associate Workshop – Roundtable Educational Session	Liberty ABC/3 rd Fl.
2:00 pm – 4:00 pm	GYN Developmental Therapeutics/Phase 1/Translational Science Workshops	Salon GKL/5 th Fl.
2:00 pm – 4:00 pm	Immunotherapy and Immune Modulation Workshop	Salon F/5 th Fl.
2:30 pm – 4:00 pm	Comparative Effectiveness Research (CER) Committee *	Room 405/4 th Fl.
3:00 pm – 5:00 pm	NRG-Harvard-Ohio State-Case Western R01 Grant Meeting *	Room 401-402/4 th Fl.
4:00 pm – 5:15 pm	An Introduction to NRG Oncology	Salon AB/5 th Fl.
4:00 pm – 5:30 pm	Translational Science Workshop	Salon E/5 th Fl.
4:30 pm – 6:30 pm	PSC Education & Training Working Group *	Room 413/4 th Fl.
4:30 pm – 6:30 pm	PSC Mentorship Working Group *	Room 403/4 th Fl.
4:30 pm – 6:30 pm	PSC Protocol Review Working Group *	Room 411-412/4 th Fl.
5:00 pm – 6:00 pm	Patient Centered Outcomes Research (PCOR) Workshop	Salon GKL/5 th Fl.
5:15 pm – 6:00 pm	New Investigator Networking Reception	Salon D/5 th Fl.
5:30 pm – 7:00 pm	PSC Quality Control Working Group *	Room 404/4 th Fl.
6:00 pm – 7:00 pm	Early Phase Trial Oversight Committee *	Room 309-310/3 rd Fl.
6:00 pm – 8:00 pm	NCORP Concept Review (<i>Invitation Only</i>)	Room 408-409/4 th Fl.
6:00 pm – 8:00 pm	NRG Oncology Japan Meeting	Room 401-402/4 th Fl.
6:00 pm – 8:00 pm	Ancillary Projects Committee *	Room 405/4 th Fl.

Revised 7/9/2019

*Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING

FINAL SCHEDULE

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 18 – 20, 2019

Friday, July 19, 2019		
6:30 am – 8:30 am	Continental Breakfast	Franklin Hall Foyer/4 th Fl.
7:00 am – 5:00 pm	Exhibits	Franklin Hall Foyer/4 th Fl.
7:00 am – 5:30 pm	Registration/CME/Information Desk	Grand Ballroom Foyer/5 th Fl.
8:00 am – 5:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Room 406/4 th Fl.
9:00 am – 1:00 pm	CTN/CRA Information Table	Grand Ballroom Foyer/5 th Fl.
10:00 am – 11:00 am	General Coffee Break	Franklin Hall Foyer/4 th Fl.
2:00 pm – 3:30 pm	General Coffee Break	Franklin Hall Foyer/4 th Fl.
6:45 am – 9:00 am	Patient Advocates Meeting *	Room 308/3 rd Fl.
7:00 am – 8:00 am	Digital Health Working Group	Franklin 3-4/4 th Fl.
7:00 am – 8:00 am	GYN Cancer Committee Executive Session *	Room 401-402/4 th Fl.
7:00 am – 8:00 am	Local Regional Breast Cancer Subcommittee *	Room 309-310/3 rd Fl.
7:00 am – 9:00 am	Medical Physics Subcommittee Meeting	Franklin 7/4 th Fl.
7:00 am – 9:00 am	PSC Clinical Trials Nurse Subcommittee * (<i>Open for first hour</i>)	Salon IJ/5 th Fl.
7:00 am – 9:00 am	PSC Clinical Research Associate Subcommittee * (<i>Open for first hour</i>)	Room 303-304/3 rd Fl.
7:00 am – 12:00 pm	GYN/RT Case Review	Room 406/4 th Fl.
8:00 am – 9:00 am	NRG SDMC Executive Committee *	Room 309-310/3 rd Fl.
8:00 am – 9:00 am	Protocol 210 Subcommittee	Room 408-409/4 th Fl.
8:00 am – 10:00 am	Ovarian Cancer Workshop	Salon GKL/5 th Fl.
8:00 am – 10:00 am	Scientific Session – <i>NRG Oncology Research Review</i>	Salon EF/5 th Fl.
8:00 am – 10:30 am	Translational Science Brain Cancer Subcommittee/Low-Grade Glioma Working Group	105AB/1 st Level/PA Convention Center
8:30 am – 9:30 am	Radiation Oncology GYN Working Group	Salon AB/5 th Fl.
9:00 am – 10:00 am	Protocol Operations Management *	Room 403/4 th Fl.
9:00 am – 10:00 am	VA/MTF Meeting	Salon IJ/5 th Fl.
9:00 am – 10:30 am	Cancer Prevention and Control Committee Meeting (<i>Invitation Only</i>)	Franklin 3-4/4 th Fl.
10:00 am – 11:00 am	Communications Committee *	Salon AB/5 th Fl.
10:00 am – 11:00 am	International Members Meeting	Salon IJ/5 th Fl.
10:00 am – 11:00 am	NRG BR003 and NRG BR004 Workshops	Franklin 9-10/4 th Fl.
10:00 am – 11:30 am	Health Disparities Workshop: Sexual and Gender Minority Related Activities at the National Institutes of Health	Franklin 1-2/4 th Fl.
10:00 am – 12:00 pm	Cervix Cancer Workshop	Salon GKL/5 th Fl.
10:00 am – 12:00 pm	Sarcoma Working Group	Franklin 7/4 th Fl.
10:30 am – 11:00 am	NRG-BN006 Information Session	Franklin 13/4 th Fl.
10:30 am – 11:30 am	Translational Science Operations/SMDC/Biospecimen Bank Working Group *	Room 308/3 rd Fl.
11:00 am – 12:00 pm	Protocol 225 Information Session	Room 404/4 th Fl.
11:00 am – 12:00 pm	New Investigators Committee *	Room 411-412/4 th Fl.
11:00 am – 12:00 pm	NRG-GU007 Kick-Off Session	Franklin 13/4 th Fl.

Revised 7/9/2019

*Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING

FINAL SCHEDULE

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 18 – 20, 2019

Friday, July 19, 2019		
11:00 am – 12:30 pm	Audit Training Workshop	Franklin 9-10/4 th Fl.
11:00 am – 12:30 pm	Immunotherapy and Immune Modulation Workshop	Liberty ABC/3 rd Fl.
11:00 am – 1:00 pm	Imaging Committee	Room 414-415/4 th Fl.
11:00 am – 1:00 pm	Neurosurgical Subcommittee	105AB/1 st Level/PA Convention Center
11:00 am – 1:00 pm	Older Adult Working Group	Salon IJ/5 th Fl.
11:00 am – 1:00 pm	NRG Oncology Foundation Board of Directors *	Room 408-409/4 th Fl.
11:00 am – 1:00 pm	Breast Cancer Rare and Genetically Linked Subcommittee Workshop	Franklin 5-6/4 th Fl.
11:30 am – 12:30 pm	Social Media and Mobile Technology Workshop	Salon CD/5 th Fl.
11:30 am – 1:00 pm	Cancer Care Delivery Research Session Workshop	Salon H/5 th Fl.
12:00 pm – 1:00 pm	GYN GTN Subcommittee	Independence 1-3/3 rd Fl.
12:00 pm – 1:00 pm	NRG Pharmacy Subcommittee	Room 309-310/3 rd Fl.
12:00 pm – 1:00 pm	Pathology Committee	Room 303-304/3 rd Fl.
12:00 pm – 1:00 pm	SWOG/NRG S1806 (Boxed lunches will be provided to those who register for the session prior to July 9 th)	Franklin 7/4 th Fl.
12:30 pm – 1:00 pm	Social Media Workshop 1-on-1s	Salon CD/5 th Fl.
1:00 pm – 2:00 pm	NRG Oncology General Session	Salon EF/5 th Fl.
2:00 pm – 3:00 pm	NRG GI004, GI002, and GI005 Workshop	Franklin 9-10/4 th Fl.
2:00 pm – 3:00 pm	Translational Science Head & Neck Cancer Subcommittee	105AB/1 st Level/PA Convention Center
2:00 pm – 3:30 pm	Publications Committee *	Room 309-310/3 rd Fl.
2:00 pm – 3:30 pm	Translational Science Breast Cancer Subcommittee	Liberty ABC/3 rd Fl.
2:00 pm – 4:00 pm	Translational Science GU Cancer Subcommittee	Salon IJ/5 th Fl.
2:00 pm – 4:00 pm	Rare Tumor Workshop	Franklin 11-12/4 th Fl.
2:00 pm – 4:00 pm	Radiation Oncology Committee Meeting	Franklin 1-2/4 th Fl.
2:00 pm – 5:00 pm	Brain Tumor Core Committee *	Salon H/5 th Fl.
2:30 pm – 4:30 pm	Uterine Corpus Cancer Workshop	Salon GKL/5 th Fl.
2:30 pm – 4:30 pm	Cancer Prevention and Control Workshop	Franklin 5-6/4 th Fl.
3:00 pm – 4:00 pm	NRG-LU005 Kick-Off Session/Training	Franklin 13/4 th Fl.
3:00 pm – 5:00 pm	Health Disparities Committee	Independence 1-3/3 rd Fl.
3:00 pm – 6:00 pm	Head & Neck Cancer Core Committee *	Franklin 3-4/4 th Fl.
3:30 pm – 6:30 pm	Breast Cancer Working Group *	Salon AB/5 th Fl.
4:00 pm – 5:00 pm	NRG Oncology Human Research Committee *	Room 401-402/4 th Fl.
4:00 pm – 5:30 pm	Translational Science GYN Workshop	Franklin 11-12/4 th Fl.
4:00 pm – 6:00 pm	Genitourinary Cancer Core Committee *	Salon IJ/5 th Fl.
4:00 pm – 6:00 pm	Translational Science Lung Cancer Workshop	105AB/1 st Level/PA Convention Center
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group Meeting	Room 408-409/4 th Fl.
5:00 pm – 7:00 pm	Brain Tumor Workshop	Salon H/5 th Fl.
6:00 pm – 8:00 pm	NRG Oncology Welcome Reception	Salon EF/5 th Fl.



Advancing Research. Improving Lives.™

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL SCHEDULE
Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 18 – 20, 2019

Saturday, July 20, 2019		
6:30 am – 8:30 am	Continental Breakfast	Franklin Hall Foyer/4 th Fl.
7:00 am – 2:00 pm	Exhibits	Franklin Hall Foyer/4 th Fl.
7:00 am – 3:00 pm	Registration/CME/Information Desk	Grand Ballroom Foyer/5 th Fl.
8:00 am – 1:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Room 406/4 th Fl.
10:00 am – 12:00 pm	General Coffee Break	Franklin Hall Foyer/4 th Fl.
7:00 am – 8:00 am	Surgical Oncology Workshop	Salon AB/5 th Fl.
7:00 am – 8:00 am	Canadian Members Meeting	Room 404/4 th Fl.
7:00 am – 8:00 am	NRG SDMC Data Management Working Group *	Room 308/3 rd Fl.
7:00 am – 8:00 am	NRG SDMC Statistical Working Group *	Room 309-310/3 rd Fl.
7:00 am – 8:00 am	Medical Oncology Workshop	Franklin 9-10/4 th Fl.
7:00 am – 8:30 am	Proton Working Group Meeting	Salon CD/5 th Fl.
7:00 am – 9:30 am	Protocol Support Committee Business Meeting *	Room 303-304/3 rd Fl.
8:00 am – 9:00 am	NRG BR005 Workshop CANCELLED	Salon AB/5 th Fl.
8:00 am – 9:00 am	GYN Developmental Therapeutics/Phase I Workshops	Salon GKL/5 th Fl.
8:00 am – 9:30 am	Safety Review Committee *	Room 309-310/3 rd Fl.
8:00 am – 10:00 am	NCORP PI & Administrators Meeting	Franklin 9-10/4 th Fl.
8:00 am – 10:00 am	Genitourinary Cancer Workshop	Franklin 5-6/4 th Fl.
8:00 am – 10:00 am	Head & Neck Surgical Subcommittee	Franklin 7/4 th Fl.
8:00 am – 10:00 am	Lung Cancer Core Committee *	Salon IJ/5 th Fl.
8:00 am – 10:30 am	GI Colorectal Cancer Subcommittee *	Salon E/5 th Fl.
9:00 am – 10:00 am	Ovarian Cancer Workshop	Salon GKL/5 th Fl.
9:00 am – 10:00 am	Cervix Cancer Workshop	Salon F/5 th Fl.
9:00 am – 10:00 am	Uterine Corpus Cancer Workshop	Franklin 11-12/4 th Fl.
9:00 am – 10:00 am	Quality Assurance Audit Meeting *	Room 308/3 rd Fl.
9:00 am – 1:00 pm	Breast Cancer Workshop	Liberty ABC/3 rd Fl.
10:00 am – 11:00 am	Social Media Workshop 1-on-1s	Franklin 9-10/4 th Fl.
10:00 am – 11:30 am	Membership Committee *	Room 309-310/3 rd Fl.
10:00 am – 12:00 pm	Gynecologic Cancer Workshop	Salon GKL/5 th Fl.
10:00 am – 12:00 pm	Radiation-Developmental Therapeutics Workshop	Salon AB/5 th Fl.
10:00 am – 12:00 pm	Head & Neck Cancer Workshop	Franklin 5-6/4 th Fl.
10:30 am – 11:30 am	NRG-LU003 Kick-Off Meeting	105AB/1 st Level/PA Convention Center
10:30 am – 12:30 pm	GI Non-Colorectal Cancer Subcommittee *	Salon E/5 th Fl.
12:00 pm – 1:00 pm	Voting Members PI Meeting *	Salon CD/5 th Fl.
12:30 pm – 2:30 pm	Gastrointestinal Cancer Workshop	Franklin 9-10/4 th Fl.
1:00 pm – 3:00 pm	Lung Cancer Workshop	Franklin 5-6/4 th Fl.
3:00 pm – 6:00 pm	Research Strategy Meeting *	Salon H/5 th Fl.

Revised 7/9/2019

*Sessions for Committee Member

Information Technology Resource Center

**NRG Semi-Annual
Meeting**

**Philadelphia, PA
July 18 -20, 2019**

**Philadelphia Marriott
Downtown
Room 406
4th Level**

**Open
Thurs. Jul 18: 2PM-6PM
Fri. Jul 19: 8AM-5PM
Sat. Jul 20: 8AM-1PM**



<http://www.nrgoncology.org>



The Self-Service Resource Center will feature:

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Special Events/Sessions Workshops

Patient Reported Outcomes: Upping the game for PRO methods and design in clinical trials

Date: Thursday, July 18, 2019
Start and End Time: 1:00 pm – 5:00 pm Eastern Time

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss case studies of NRG clinical trials using patient reported outcome (PRO) designs
2. Discuss how to improve and standardize PROs for clinical trials
3. Apply standards and procedures required to improve PRO designs and statistical methods

- 1:00 - 1:05pm: Welcome and Introductions - **Deborah Watkins Bruner, RN, PhD, FAAN (Co-PI, NRG NCORP, Senior Vice President for Research, Emory Univ.)**
- 1:05 - 1:15pm: How to improve PRO designs that inform future trials or implementation research – **Deborah Watkins Bruner, RN, PhD, FAAN**
- 1:15 - 1:20pm: Q&A
- 1:20-1:40pm: Improving statistical methods to meet the goals – **James Dignam, PhD (SDMC Executive Director, NRG Oncology; Professor, Biostatistics, The University of Chicago)**
- 1:40 - 1:45pm: Q&A
- 1:50 - 2:35pm: Case Study 1 – RTOG 0415: A Phase III Randomized Study of Hypofractionated 3DCRT/IMRT versus Conventionally Fractionated 3DCRT/IMRT in Patients Treated for Favorable-Risk Prostate Cancer
- 1:50 - 2:05 pm: Introduction to PRO study design in RTOG 0415 – **Stephanie Pugh, PhD (NCORP Deputy Director, Statistics, NRG Oncology)**
 - 2:05 - 2:25pm: Analyzing longitudinal PRO data using effect sizes – **Don Hedeker, PhD (Professor, Biostatistics, The Univ. of Chicago)**
- 2:25 – 2:35pm Q&A
- 2:35 - 2:50pm: BREAK
- 2:50 - 3:45pm: Case Study 2 Introduction– RTOG 1203: A Randomized Phase III Study of Standard vs. IMRT Pelvic Radiation for Post-Operative Treatment of Endometrial and Cervical Cancer (TIME-C)
- 2:50 - 3:05pm: Introduction to PRO study design in RTOG 1203 - **Karen Gil, PhD (Professor, Obstetrics and Gynecology, Summa Health System; NRG Oncology Cervix/Vulva Cancer Subcommittee member)**
 - 3:05 - 3:35pm: PRO-CTCAE/moonshot and Standardizing QOL analysis - **KEYNOTE SPEAKER Amylou Dueck, PhD (Associate Professor, Biostatistics, Mayo Clinic, AZ)**
- 3:35 - 3:45pm: Q&A
- 3:45 – 4:15pm: Panel Discussion NCORP Pls – **Moderator: Benjamin Movsas, MD, Co-Chair NRG Patient Centered Outcome Research Committee (PCOR), Chair, Radiation Oncology, Henry Ford Hospital, Detroit**

Discussion of templates and guidance in design and analysis

- Do PRO guidance cover the use in CCDR adequately:
Kathryn Weaver, PhD, MPH, Associate Professor, Wake Forest Univ.; CCDR Lead, Wake Forest NCORP
- Use of PROs in statistical design, are they adequately addressing issues in health disparities?
Electra Paskett, PhD, Professor, The Ohio State Univ.; Deputy Director, Alliance NCORP
- Observations from symptom management trials - would more templates or guidance improve design?
Karen Mustian, PhD, MPH, Professor, Univ. of Rochester
- ECOG-ACRIN NCORP- **Lynne Wagner, PhD, Professor, Wake Forest Univ.; Co-PI,**

- 4:15 - 4:30pm: **Q&A**
- 4:30 – 4:45pm: **Conclusion & Action Items - Deborah Watkins Bruner, RN, PhD, FAAN**
- NRG Oncology Semiannual Meeting | July 2019

NRG Oncology Scientific Session

Research Review Hosted by the Publications Committee

Friday, July 19, 2019

8:00-10:00 am

Room: Salon EF

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PRESENTATIONS



Patient-reported outcomes of NRG Oncology/RTOG 0232: a phase III study comparing combined external beam radiation and transperineal interstitial permanent brachytherapy with brachytherapy alone in intermediate risk prostate cancer.

Presenter: Deborah W. Bruner, PhD

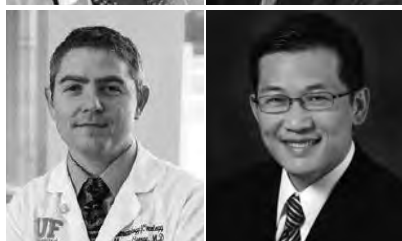
Discussant: Ronald C. Chen, MD



Receipt of adjuvant endometrial cancer treatment according to race: an NRG Oncology/Gynecologic Oncology Group 210 Study.

Presenter: Ashley S. Felix, PhD

Discussant: William (Rusty) Robinson, MD



NRG-GI002: A phase II clinical trial platform using total neoadjuvant therapy (TNT) in locally-advanced rectal cancer (LARC): first experimental arm (EA) initial results.

Presenter: Thomas J. George, MD

Discussant: Steven H. Lin, MD



Initial reporting of NRG-LU001 (NCT02186847), randomized phase II trial of concurrent chemoradiotherapy (CRT) +/- metformin HCL in locally advanced non-small cell lung cancer (NSCLC).

Presenter: Theodoros Tsakiridis, MD

Discussant: Adam P. Dicker, MD



Randomized trial of intravenous versus intraperitoneal chemotherapy plus bevacizumab in advanced ovarian carcinoma: An NRG Oncology/Gynecologic Oncology Group Study.

Presenter: Joan L. Walker, MD

Discussant: Ursula A. Matulonis, MD



Patient-reported outcomes (PROs) in NRG Oncology/NSABP B-39/RTOG 0413: a randomized phase III study of conventional whole breast irradiation (WBI) v partial breast irradiation (PBI) in stage 0, I, or II breast cancer.

Presenter: Patricia A. Ganz, MD



Evolutionary action score of TP53 analysis in pathologically high-risk HPV-negative head and neck cancer from a phase II clinical trial: NRG Oncology RTOG 0234.

Presenter: Chieko Michikawa, DDS, PhD

NRG Scientific Session NRG Oncology Research Review

Date: Friday, July 19, 2019
Start and End Time: 8:00 am – 10:00 am

Chair: Harry Bear, MD
Co-Chair: Elizabeth M Gore, MD (Moderator); Thomas B Julian, MD; and Krishnansu S Tewari, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Understand the differences in patient reported outcomes between combined external beam therapy and transperineal interstitial permanent brachytherapy among patients with intermediate risk prostate cancer.
2. Discuss the impact of race on adjuvant treatment with chemotherapy observed for women with endometrial cancer.
3. Discuss patient reported outcomes for women treated with conventional whole breast irradiation vs partial breast radiation for early-stage breast cancer.
4. Describe the initial results of the use of total neoadjuvant therapy in locally advanced rectal cancer.
5. Discuss how the translational analysis assessed the predictive value for treatment outcomes to adjuvant bio-chemoradiotherapy and validated prior findings that EAp53 is a prognostic marker for locally advanced HNSCC patients.
6. Investigate whether metformin can improve outcomes of curative CRT in locally advanced-NSCLC and examine the effects of metformin on 12-month progression free survival.
7. Describe the impact of two different intraperitoneal chemotherapy regimens on progression-free survival among women with newly diagnosed advanced ovarian carcinoma.

WORKSHOP AGENDA

8:00 – 8:05 am	Welcome	Elizabeth M Gore, MD
8:05 – 8:17 am	Patient reported outcomes of NRG Oncology/RTOG 0232: a phase III study comparing combined external beam radiation and transperineal interstitial permanent brachytherapy with brachytherapy alone in intermediate risk prostate cancer.	Deborah W. Bruner, PhD, MD
8:17 – 8:22 am	Discussant	Ronald C. Chen, MD
8:22 – 8:34 am	Receipt of adjuvant endometrial cancer treatment according to race: an NRG Oncology/Gynecologic Oncology Group 210 Study.	Ashley S. Felix, MD
8:34 – 8:39 am	Discussant	William (Rusty) Robinson, MD
8:39 – 8:51 am	Patient-reported outcomes (PROs) in NRG Oncology/NSABP B-39/RTOG 0413: a randomized phase III study of conventional whole breast irradiation (WBI) v partial breast irradiation (PBI) in stage 0, I, or II breast cancer.	Patricia A. Ganz, MD
8:51 – 9:03 am	NRG-GI002: A phase II clinical trial platform using total neoadjuvant therapy (TNT) in locally advanced rectal cancer (LARC): first experimental arm (EA) initial results.	Thomas J. George, MD
9:03 – 9:08 am	Discussant	Steven H. Lin, MD
9:08 – 9:20 am	Evolutionary action score of TP53 analysis in pathologically high-risk HPV-negative head and neck cancer from a phase II clinical trial: NRG Oncology RTOG 0234.	Chieko Michikawa, DDS, PhD
9:20 – 9:32 am	Initial reporting of NRG-LU001 (NCT02186847), randomized phase II trial of concurrent chemoradiotherapy (CRT) +/- metformin HCL in locally advanced non-small cell lung cancer (NSCLC).	Theodoros Tsakiridis, MD
9:32 – 9:37 am	Discussant	Adam P. Dicker, MD
9:37 – 9:49 am	Randomized trial of intravenous versus intraperitoneal chemotherapy plus bevacizumab in advanced ovarian carcinoma: An NRG Oncology/Gynecologic Oncology Group Study.	Joan L. Walker, MD
9:49 – 9:54 am	Discussant	Ursula A. Matulonis, MD

NRG Oncology Social Media Workshop

*Presented by the NRG Oncology Communications Committee
at the NRG Oncology July 2019 Semiannual Meeting*

Friday, July 19, 2019
11:30 am-12:30 pm

*Philadelphia Marriott Downtown
Philadelphia, PA*



PRESENTATIONS

Welcome and Introductions
Thomas George, MD

Social Media Hype vs. Hope in Oncology
Miriam (Mimi) Knoll, MD

Patient Engagement Through Social Media for Clinical Trials
Daniel Spratt, MD & Thomas George, MD

Blogging 101 - How and Why to Use this Form of Social Media
Merry-Jennifer Markham, MD

#NRG19

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NRG Oncology Semiannual Meeting | July 2019

SPEAKERS



Thomas George, MD
University of Florida
Session Co-Chair
@TGeorgeMD



Miriam Knoll, MD
Hackensack University Medical Center
Session Co-Chair
@MKnoll_MD



Daniel Spratt, MD
University of Michigan
@DrSpratticus



Merry-Jennifer Markham, MD
University of Florida
@DrMarkham

Social Media and Mobile Technology Workshop Agenda

Date: Friday, July 19, 2019
Start and End Time: 11:30 am to 12:30 pm (EST)
Chairs: Thomas George, MD & Miriam Knoll, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Recognize the value that social media engagement may provide for oncology professionals, patients and policy.
2. Appreciate the different tools available via social media to reach an intended audience.
3. Recognize the potential benefits to professional development including clinical research of social media.
4. Understand the opportunities for blogging and how that specific social media method can be operationalized.

WORKSHOP AGENDA

A.	11:30 – 11:35	Welcome and Introduction	Thomas George, MD
B.	10:35 – 11:50	Social media hype vs. hope in oncology	Miriam Knoll, MD
C.	11:50 – 12:05	Patient engagement through social media for clinical trials	Daniel Spratt, MD & Thomas George, MD
D.	12:05 – 12:20	Blogging 101 – How and why to use this form of social media	Merry Jennifer Markham, 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.

SUPPLEMENTAL SESSIONS:

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

NRG Oncology Social Media 1-on-1

Friday, July 19, 2019
12:30-1:00pm

Saturday, July 20, 2019
10:00-11:00am

*Philadelphia Marriott Downtown
Philadelphia, PA*



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



Miriam Knoll, MD
Hackensack University
Medical Center
@Mknoll_MD



Michelle Shepard
NRG Oncology
@MichelleShepard



Scott Gould
NRG Oncology
Statistical & Data
Management Center
@DownTownBufTech



Rebecca Previs, MD
Duke University
@BeccaPrevisMD

NRG Oncology General Session

Friday, July 19, 2019
1:00 pm - 2:00 pm
Salon EF/5th Floor



Join us at the
NRG Oncology
Welcome Reception



Friday, July 19, 2019
6 pm - 8 pm
Salon EF (5th floor)

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Workshop Agendas (CME/Non-CME)

NRG Scientific Committees

Brain Tumor Workshop

Date: Friday, July 19 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	152/360	Vogelbaum; 53 from NRG
2	BN 001	Hypofractionated Dose escalated Photon IMRT or PBT vs Conventional Photon Irradiation with Concomitant and Adjuvant Temozolomide	nGBM	10/14	Photon: 302/288; 41/30 for advanced imaging Proton: 148/288	IIR: Mehta/Gondi; photon arm accrued. Proton arm projected to close Mar 2023
3	NRG 1119	Phase IIR RT+/- Lapatinib	BM Breast	7/12	140/143	Kim; expected closure Jun 2019

	STUDY	NAME	DX	START	N	COMMENTS
4	CC 003	Phase II/III PCI WBRT +/- HA	SCLC PCI	12/15	172/172 and 3/132	Gondi: P2 accrued; P3 accruing
5	Alliance A071401	Meningioma targeted agents, 3 arms (SMO, AKT, NF2)	Menin	8/15	40/56	Brastianos; 3 from NRG
6	BN 003	Meningioma RT vs Obs	Menin	6/17	45/133	Rogers; Jun 2022 closure
7	BN 005	LGG Photons vs Protons	LGG	8/17	15/120	Grosshans; Sept 2025 closure

2. Closed Studies: None

3. Studies Activating soon:

	STUDY	NAME	DX	START	N	COMMENTS
1	BN 006	Phase II/III Toca511	GBM	10/19		Ahluwalia
2.	BN 1855	PII/III Ipi/Nivo	GBM	?		Lassman
3.	CCTG CE.7	PIII SRS vs. HA-WBRT, 5-15 BM	BM	?		Roberge/Gondi

Brain Core Agenda

Date: July 19, 2019
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: NSG
 - b. Rimas Lukas: IDO inhibition
 - c. Fabio Iwamoto: TMZ+Lomustine
 - d. Andy Lassman: Ipi+Nivo
2. Brain Mets
 - a. Paul Sperduto: Ipi/Nivo melanoma brain mets
 - b. Vinai Gondi: BM velocity: NSG
 - c. David Roberge: NCIC p3 randomized brain met trial
 - d. Vinai Gondi: NSCLC BM ICI +/- SRS
 - e. Stuart Burri: Pre vs Post-op SRS: NSG
3. PCNSL:
 - a. Christian Grommes: Ibrutinib

Breast Cancer Workshop

Date: Saturday, July 20, 2019
Start and End Time: 9:00 am – 12:00 pm
Chair: Eleftherios Mamounas, MD
Co-Chairs: Julia White, MD; Charles Geyer, MD; Matthew Ellis, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

9:00 – 10:00	Report from the Breast Working Group Meeting	Eleftherios Mamounas, MD Julia White, MD
10:00 – 10:30	Translational Proteogenomics	Matthew Ellis, MD
10:30 – 10:45	NRG BR-002 A Phase IIR/III Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer	Steve Chmura, MD, PhD
10:45 – 11:15	Immunotherapy Trials	
	NRG BR-004 A Randomized Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab/Placebo Compared to Paclitaxel/Trastuzumab/Pertuzumab/Atezolizumab in First Line HER2-Positive Metastatic Breast Cancer	Charles Geyer, Jr., MD
	NSABP-59/GBG 96 A Randomized, Double-Blind, Phase III Clinical Trial of Neoadjuvant Chemotherapy with Atezolizumab or Placebo in Patients with Triple-Negative Breast Cancer Followed by Adjuvant Continuation of Atezolizumab or Placebo	
	NRG BR-006 Phase III Trial to Evaluate Adjuvant Therapy of Pembrolizumab for TNBC with Residual Invasive Cancer or Positive Lymph Nodes After Neoadjuvant Chemotherapy	Eleftherios Mamounas, MD
11:15 – 11:25	NRG BR-003 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 Priya Rastogi MD

11:25 – 11:35	NRG BR-005 -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 De Los Santos, MD
11:35 – 11:45	NSABP B-51/RTOG 1304: 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
11:45 – 12:00	ECOG-ACRIN TMIST Breast Screening Study	Etta Pisano, MD

Breast Cancer Rare and Genetically Linked Subcommittee Workshop

Date: Friday, July 19, 2019
Start and End Time: 11:00 am – 1:00 pm
Chairs: Alexandra Thomas, Karen Daily

Learning Objectives:

Following this activity, participants will be better able to:

1. Identify and describe opportunities for trial concept development in rare and genetically-linked breast cancer
2. Understand genetics and therapeutics of hereditary breast cancer
3. Identify and describe opportunities to develop clinical trials in Phyllodes tumors and indolent rare breast tumors
4. Identify and describe mechanisms by which to assess trial proposals on rare breast cancers

WORKSHOP AGENDA

11:00- 11:05	Committee Updates Future speakers Update from Working Group	Alexandra Thomas, MD Karen Daily, DO
11:05- 12:00	Genetics and Therapeutics of Hereditary Breast Cancer: An Evolving Landscape	Payal D. Shah, MD
12:00 – 12:15	Gynecologic Oncology Rare Tumors Experience	Jubilee Brown, MD Allan Covens, MD
12:15 – 12:20	BR1901 Metaplastic Concept Update	Alexandra Thomas, MD
12:20- 12:55	Phyllodes/Indolent Rare Breast Tumors Concepts	Karen Daily, DO Simona Shaitelman, MD
12:55- 1:00	Committee Discussion <ul style="list-style-type: none">• Future speakers• Future directions	

NRG Protocol Workshop: NRG-BR003 NRG-BR004

Date: Friday, July 19, 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.

***Educational need** for the presentations is based on the discussion at the February 2019 NRG Oncology Meeting and the ongoing calls to the Clinical Coordinating Department (Pittsburgh Office) regarding the trials.*

WORKSHOP AGENDA

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

NRG Protocol NRG-BR005 Workshop - CANCELLED

Date: Saturday, July 20, 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	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

Date: Friday, July 19, 2019
Start and End Time: 2:30 pm – 4:30 pm
Chair: Lisa Kachnic, MD

Learning Objectives

Following this activity, participants will be better able to:

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

A. 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)
- **A211401:** Reducing Surgical Complication in Newly Diagnosed Lung Cancer Patients Who Smoke (S. Lo, NRG Study Champion)
- **EA1151:** Tomosynthesis Mammographic Imaging Screening Trial (TMIST) (E. Pisano)

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-CC008:** A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-Oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers [APSORB] (D. Levine)
- **NRG-CC1925:** Adaptive Intervention for Smoking Cessation in Women with Breast, Cervical, Endometrial and Vaginal Cancer prior to Radiation Therapy (T. Crane)
- **NRG-CC1928:** Utility of gonadotropin-releasing Hormone Agonists (GnRHa) to Protect Ovarian Reserve for Women Undergoing Chemotherapy (H. Burks, L. Landrum, J. Walker)
- **NRG-CC1741:** Surgery and chemotherapy vs. chemotherapy alone as primary treatment for older women with advanced staged epithelial ovarian, fallopian tube and primary peritoneal carcinomas (A. Ahmed)

D. Other Updates

- Lymphedema update – state of the science meeting with NCI to discuss the endpoints for two concepts (J. Walker)
- C. Xiao and K. Sturgeon – Pilot project update/report

Cancer Care Delivery Research (CCDR) Workshop Agenda

Date: Friday, July 19, 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. | 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 |
| D. | U01 Grant: The Implementation of Families Accelerating Cascade Testing Toolkit to Improve Cascade Genetic Testing through the NCORP/CCDR | Andrea Hagemann, MD |
| E. | NCI CCDR updates | |
| | a. Building a Foundation for CCDR Studies | Kate Castro, RN & Ann Geiger, MPH, PhD |
| F. | NRG-CC007CD: “Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy” Protocol Kick-off | Ron Chen, MD, MPH |

QUESTIONS / DISCUSSION

GYN Developmental Therapeutics/Phase I/Translational Science Workshop

Date: Thursday, July 18, 2019
Start and End Time: 2:00 PM – 4:00 PM
Chairs: Roisin O’Cearbhaill, MD (Developmental Therapeutics)
Michael Birrer, MD, PhD (Translational Science)
Translational Research Chair: Panagiotis Konstantinopoulos, MD, PhD (Developmental Therapeutics)
Co-Chairs: Floor Backes, MD (Phase II), Russell Schilder, MD (Phase I)
Stephanie Gaillard, MD, PhD (Phase I)

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

Thursday, July 18, 2019

Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

Discussion Topic - Current priorities of the Committee

2:00 PM – 2:05 PM	Introduction, Drs. O’Cearbhaill and Birrer. Welcome. Review of opportunities for new investigators.
2:05 PM – 2:15 PM	Updates on DT1907 Dr Backes, DT1910 Dr. Gogoi, PI1915 Dr. Moxley
2:15 PM – 3:45 PM	Review of new concepts <ul style="list-style-type: none">• 5-minute presentation of concept (by proposing investigator)• Review of concepts
3:45 PM – 4:00 PM	ComboMATCH study and discussion by committee of potential concepts, Dr. O’Cearbhaill (NRG Representative for the ComboMATCH study).

New Concepts:

- **DT1951** Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Martee Hensley)
- **DT1952** Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Martee Hensley)
- **DT1953** Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ uterine serous or clear cell carcinomas and in HER2+ ovarian cancer (Haider Mahdi)
- **DT1955** A Phase II study of N-803 and Durvalumab in recurrent epithelial ovarian, fallopian tube and primary peritoneal cancer. (Geller)
- **DT1957** A Phase II Study of Sapanisertib in Recurrent Ovarian Cancer. (Musa)

- **DT1958** Phase II study investigating the efficacy of rationale combination immunotherapy in recurrent endometrial cancer with deficient mismatch repair system post progression on anti-PD1 therapy (Haider Mahdi)
- **DT1959** Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Stephanie Gaillard)
- **PI1956** A Phase I Study of Sapanisertib in Combination with Olaparib in Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer (Musa)
- **PI1966** A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent *CCNE1* amplified ovarian and endometrial carcinomas (Simpkins)
- **PI1967** Phase I dose escalation study of the proteasome inhibitor bortezomib in combination with the histone deacetylase inhibitor belinostat for patients with recurrent ovarian cancers harboring oncogenic, mutated p53. (Hill)

QUESTIONS / DISCUSSION

GYN Developmental Therapeutics/Phase I Workshop

Date: Saturday, July 20, 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. Immune Therapy and Immune Modulation workshop will present an update from Thursday, July 18 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, July 20, 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, MD)

- 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
- New concepts

List of Studies

Under development:

- **NRG-GY022** Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Sarah Taylor/ Jan Beumer)
- **DT1907** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer (Backes)
- **DT1910** Phase II single arm trial of Visudyne in platinum resistant recurrent ovarian cancer (Gogoi)
- **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

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

Cervical Cancer Studies:

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

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

Ovarian Cancer and Endometrial cancer studies:

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

Ovarian Cancer Studies (prior safety lead-in):

- **NRG-GY007** A phase I/II study of ruxolitinib with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (R Burger) **Phase II** Active for accrual
- **NRG-GY009 (PTMA/CRDL)** A randomized, phase II/III study of pegylated liposomal doxorubicin and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab in platinum resistant ovarian cancer (R O’Cearbhaill) **Phase II** completed accrual May 2019

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) ASCO 2018
- **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 written

Ovarian Cancer Studies

- **9923** A phase I study of intravenous carboplatin/paclitaxel or intravenous and intraperitoneal paclitaxel/cisplatin in combination with continuous or intermittent, CTEP supplied agent ABT-888 and CTEP supplied agent bevacizumab, in newly diagnosed patients with previously untreated epithelial ovarian, fallopian tube or primary peritoneal cancer (K Moore) CTEP/CRDL. ASCO 2015
- **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) Gynecol Oncol 2018
- **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) DFCl. 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) Gynecol Oncol 2018
- **NRG-GY003** Phase II randomized trial of nivolumab with or without ipilimumab in patients with persistent or recurrent ovarian, primary peritoneal or fallopian tube cancer (B Burger) IGCS 2018

QUESTIONS/DISCUSSION/EVALUATION

Gastrointestinal Cancer Committee Workshop

Date: Saturday, July 20, 2019
Start and End Time: 12:30 pm – 2:30 pm
Colorectal Chair: Thomas George, MD, FACP
Colorectal Co-Chair: Scott Kopetz, MD, PhD
Non-colorectal Chair: Christopher Crane, MD
Non-colorectal Co-Chair: David Ilson, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

Time	Discussion/Study Information	Speaker
1:00PM	Introduction and Opening Remarks	Christopher Crane, MD Thomas George, MD
1:05PM	CRC SUBCOMMITTEE - Review of Upcoming Trials	
	SOLARIS Vitamin D supplementation in untreated mCRC	Christina Wu, MD
1:15PM	Active CRC Studies	
	NRG-GI002 TNT Trial	Thomas George, MD
	S0820 (PACES) Eflornithine & <i>Sulindac</i> for polyp prevention after CRC	Jenny Dorth, MD
	NRG-GI005 Use of cfDNA as a decision tool for stage II colon cancer treatment	Van Morris, MD
	A021502 (ATOMIC) MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab	Thomas George, MD
	NRG-GI004/S1610 (COMMIT) MSI-H mCRC 1L Immunotherapy Study	Caio Rocha Lima, MD
	S1613 HER2 Amplified mCRC Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan	Marwan Fakih, MD
2:00PM	NON-CRC SUBCOMMITTEE	
	Active Studies	
	RTOG 1112 Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma	Laura Dawson, MD
	NRG GI003 Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma	Ted Hong, MD
	EA2165 Nivolumab after Combined Modality Therapy in Treating Patients with High Risk Stage II-IIIIB Anal Cancer	Paul Romesser, MD
	S1815 A Phase III Randomized Trial of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers	Khalid Matin, MD
	NRG GI1426 Phase III Randomized Trial of Protons vs. Photons for Esophageal Carcinoma	Steven Lin, MD
	<u>NON-CRC Developing studies</u>	
	NRG 1824 Phase I trial of chemoradiation and telomolysin for inoperable esophageal and GEJ ACA	Geoff Ku, MD
	NRG GI1802 A Randomized Phase II of Local Treatment Targeted Sensitization in Locally Advanced Pancreatic cancer	Rich Tuli, MD Kyle Cuneo, MD

NRG Oncology Protocols GI004/GI002/GI005 Workshop

Date: Friday, July 19, 2019
Start and End Time: 2:00 pm – 3:00 pm

Presenters:

Thomas George, MD, FACP
Samuel Jacobs, MD
Van Morris, MD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

NRG-GI004/SWOG-S1610

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

and

NRG-GI002

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

and

NRG-GI005

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

11:30 am – 11:50 am	Overview of GI004/	Thomas George, MD
11:50 pm - 12:00 pm	GI002 Update	Thomas George, MD, FACP
12:00 pm - 12:20 pm	Overview of GI005	Van Morris, MD
12:20 pm - 12:30 pm	Question and Answer	

Genitourinary Cancer Workshop Agenda

Date: Saturday, July 20, 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	Felix Feng, 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
RTOG 3506	Randomized Phase II Trial of Salvage Radiotherapy With Std vs Enhanced ADT (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features	Edwin Posadas, MD Felix Feng, MD
SWOG/NRG 1806	Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer	Jason Efstathiou, MD
SWOG 1802	Local therapy for M1 prostate cancer, a SWOG study	Richard Valicenti, MD

8:45 – 9:35 Review of Pending Studies

NRG GU007	Phase I/II of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer	Dror Michaelson, MD, PhD
NRG GU008 (formerly GU1817)	Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial	Ronald Chen, MD, MPH
ECOG/NRG EA8185	Phase 2 Study of Bladder-Sparing Chemoradiation with Durvalumab in Clinical Stage 3, node Positive Urothelial Carcinoma (INSPIRE)	Abhishek Solanki, MD MS Jason Efstathiou, MD
NRG 1864 (developing concept)	Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with High Genomic Risk	Paul Nguyen, MD; Oliver Sartor, MD
Alliance/ NRG (concept # TBD)	Phase III Trial of Androgen Deprivation Therapy and Abiraterone/Prednisone Alone or with 177Lu-PSMA-617 in Castration Sensitive Metastatic Prostate Cancer (mCSPC)	Oliver Sartor, MD

9:35 – 9:55 Other issues

Translational Research
Medical Oncology Update
Urology Update
New Business

Phuoc Tran, MD PhD
Oliver Sartor, MD
Leonard G. Gomella, MD
Group

9:55 – 10:00 Closing Remarks

Cervix Workshop Agenda

Date: Friday, July 19, 2019
Start and End Time: 10:00am – 12:00 (Session I)

Date: Saturday, July 20, 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 July 19, 2019 (Scientific Developmental Focus) 10:00 am – 12:00 pm

- A. Introduction (10:00 – 10:10)
 - a. Welcome, committee membership and rotation plan and review of Feb 2019 minutes
- B. Scientific updates (10:10 – 10:45)
 - a. Chromosomal instability as a potential target in clinical trials and cervical cancer (Samuel Bakhoun, MD, PhD)
 - b. Cervical cancer T cell directed therapy (Christian Hinrichs, M.D.)
 - c. Non-CTEP Relevant Cervical Cancer Trials
 - a. GCIG (Dr. David Gaffney)
 - b. GOG Partners (Dr. Leslie Randall)
 - d. Previously committee approved/reviewed concepts – current updates and future directions
 - a. 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. **CV1922** P2 trial paclitaxel/bev/ CXCR4i/PARPi GOG-0240R (Salani Ritu)
- b. **CV1948** Evaluation of Minimally Invasive (Laparoscopic/Robotic) vs Open Surgery in Women with Early Stage Cervical Cancer (Davidson/Covens)
- c. **CV1962** FIGO 2018 stage 1B2 (≥ 2 cm - < 4 cm) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (**CoNteSSa**) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F) (Cobb/Covens)
- d. **CV1964** Incorporation of Immunotherapy into The Management of Locally Advanced Carcinoma of the Vulva. (Glaser)
- e. **GYN1963** A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

Session II: Saturday July 19, 2019 (Operational management of on-going NRG trials) 9:00– 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 (≤ 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 1st stage
 - iii. 2nd 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

QUESTIONS / DISCUSSION

Gynecologic Cancer Workshop

Date: Saturday, July 20, 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 February 2019
- C. Symposia (Alvarez)
- D. Report from Health Disparities Committee (Brown)
- E. Report from HRC (Creasman)
- F. Report from Scientific Publications Committee (Tewari)

II. Committee Descriptions

Gynecologic Cancer Committee

Cervix/Vulvar Cancer Subcommittee

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

Ovarian Cancer Subcommittee

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

Rare Tumor Subcommittee

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

Uterine Corpus Cancer Subcommittee

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

- Randomized phase II, Phase II/III, Phase III
- Gestational trophoblastic neoplasm (GTN)

GYN Developmental Therapeutics Committee

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

GYN Phase I Subcommittee

- Safety lead-ins
- Phase I

Other NCTN Group Trials & Study Champions

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

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

NRG Oncology Study Champion: Covens

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. **CV1948** Evaluation of Minimally Invasive (Laparoscopic/Robotic) vs Open Surgery in Women (A Covens, B Davidson, J Carter)
- b. **CV1962** FIGO 2018 stage 1B2 ($\geq 2\text{cm}$ - $< 4\text{ cm}$) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (CoNteSSa) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F) (Allan Covens/Lauren Cobb)
- c. **CV1964** Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (Scott Glaser)

Studies Under Development

- a. **CV1922**, A randomized phase II, 3 arm study of chemotherapy (paclitaxel/cisplatin or carboplatin) + bevacizumab, followed by randomization to maintenance with bevacizumab (control arm), CXCR4 inhibitor + bevacizumab or PARP inhibitor + bevacizumab (Ritu Salani)
- b. **PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley)

Active Studies:

- a. **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

Active Studies:

- 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:

IV. Ovarian Cancer Subcommittee

New Concepts

- a. **OV1954** Treatment of platinum sensitive recurrence in BRCA mutated patients with olaparib with or without cediranib maintenance after upfront treatment with olaparib maintenance therapy (John Nakayama)
- b. **OV1960** A phase III randomized, trial of heated intraperitoneal chemotherapy with cisplatin at the time of optimal interval cytoreductive surgery versus intravenous chemotherapy only followed by bevacizumab or olaparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer (Marta Crispens)
- c. **OV1961** OVHIPEC-2 Study

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. **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)
- c. **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)
- d. **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)
- e. **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)
- f. **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)

Active Studies:

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

New Concepts

- a. RT1965** A phase II study of Sapanisertib in recurrent Low Grade Endometrioid Ovarian Carcinoma and Low Grade Endometrioid Endometrial Carcinoma (Gina Mantia-Smaldone)
- b. RT1946** A Phase II trial of platinum based chemotherapy followed by olaparib and durvalumab in the treatment of Stage II-IV Ovarian, fallopian tube or primary peritoneal endometrioid ovarian Carcinoma (John Farley)
- c. RT1947** A randomized Phase II trial of hormonal maintenance therapy (HMT) versus observation in the treatment of Stage IC Ovarian or Fallopian tube Low grade serous or endometrioid ovarian Carcinoma (John Farley/Kosei Hasegawa)
- d. RT1949** A Phase II trial evaluation of alisertib (MLN 8237) in combination with carboplatin, paclitaxel, and followed by alisertib (MLN 8237) and sapanisertib (TAK-228) consolidation in the treatment of advanced Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma (John Farley/Kosei Hasegawa)
- e. RT1950** A Phase II trial evaluation of romidespin (FK228) and bortezomib (PS-341) in the treatment of Recurrent Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma (John Farley/Kosei Hasegawa)

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. RT1906**, A randomized phase II/III trial of chemotherapy versus chemo-radiation therapy in the treatment of Stage IC 2,3 and II ovarian or fallopian tube clear cell carcinoma. (John Farley)

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

New Concepts

- a. DT1955** A Phase II study of N-803 and Durvalumab in recurrent epithelial ovarian, fallopian tube and primary peritoneal cancer (Melissa Geller)
- b. DT1957** A Phase II Study of Sapanisertib in Recurrent Ovarian Cancer (Fernanda Musa)
- c. PI1956** A Phase I Study of Sapanisertib in Combination with Olaparib in Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer (Fernanda Musa)
- d. PI1966** A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Fiona Simpkins)
- e. PI1967** Phase I dose escalation study of the proteasome inhibitor bortezomib in combination with the histone deacetylase inhibitor belinostat for patients with recurrent ovarian cancers harboring oncogenic, mutated p53 (Mohammed Milhem/Emily Hill)

Studies Under Development

- 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)

Active Studies:

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

NCORP

Studies Under Development

- a. **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)

Closed Studies (Primary manuscript NOT published): 9923, 212, 255, 268, 273, 281, 283, GY003, GY004

Closed Studies (Primary manuscript published): 186H*, 213, 218, 239*, 252, 262

**patient on active treatment*

Terminations: 241

V. Uterine Corpus Cancer Subcommittee

New Concepts

a.

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)
- e. **UC1844**, Efficacy of immunotherapy with immune checkpoint inhibitors in patients with deficient mismatch repair system or POLE mutated advanced stage or recurrent endometrial carcinoma: A randomized phase II/III trial. (Haider Mahdi)
- f. **UC1926**, Randomized phase II trial of adjuvant therapy with either paclitaxel/carboplatin or everolimus/letrozole in stage III endometrial cancer with no residual disease. (Brian Slomovitz)

Active Studies:

- a. **GOG-0238**, A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus. (Jonathan Micha Feddock)
- b. **NRG-GY012**, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay)
New Arms: A Randomized Phase II Study Comparing Single Agent Cediranib,

Combination of Olaparib/Capivasertib, and Combination of Bevacizumab/
Capivasertib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer

GYN Developmental Therapeutics Committee - Endometrial Cancer

New Concepts

- a. DT1951** Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Martee Hensley)
- b. DT1952** Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Martee Hensley)
- c. DT1958** Phase II study investigating the efficacy of rationale combination immunotherapy in recurrent endometrial cancer with deficient mismatch repair system post progression on anti-PD1 therapy (Haider Mahdi)
- d. DT1959** Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Stephanie Gaillard)

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)

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

Closed Studies (TS): 210

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

*patient on active treatment

Terminations: 184

VI. Developmental Therapeutics Committee (O'Cearbhaill, Backes, Konstantinopoulos)

New Concepts

- a. DT1953** Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ uterine serous or clear cell carcinomas and in HER2+ ovarian cancer (Haider Mahdi)

Studies Under Development

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

VII. GYN Cancer Committee

New Concepts

- a. GYN1963** A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)

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

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

X. Translational Science Committee Report (Birrer, Lankes)

XI. Cancer Prevention and Control Committee Report (Walker)

Questions/Discussion

Ovarian Workshop Agenda

Date:	Friday, July 18, 2019	Saturday, July 19, 2019
Start and End Time:	8:00 am - 10:00 am	9:00 am - 10:00 am
Chair:	Kathleen Moore, MD	Kathleen Moore, MD
Co-Chair:	Robert Burger, MD	Robert Burger, MD
Translational Chair:	Elizabeth Swisher, MD	Elizabeth Swisher, MD
Translational Co-Chair:	Rebecca Arend, MD	Rebecca Arend, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Review the status of completed and ongoing NRG-GOG clinical trials on the treatment of ovarian cancer
2. Review the status of approved NRG-GOG concepts that are under development
3. Discuss 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)

- 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 biomarkers in Gyn cancers and how it could
 - PTMA/CTPM process, opportunities through the NCI (TBD)
-

C. Review of Closed Studies (not-terminated)

- GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
- GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman).
Accrual to surgical component completed and study closed JUN2017, NEJM article accepted and pending
- 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)
 - JCO publication 4/2019
- 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/manuscript submitted
- 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)

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 (Jubilee 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 12/17/2018
 - 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
 - Suspended at the end of phase 2 (May 2019)
- AGCT1531 (RT1205) Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, AI Covens NRG)
 - Activated group-wide 30MAY2017

- NRG-GY014 (DT1718) A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. (Ramez Eskander and David Hyman)
 - Activated 4/2019
- NRG-GY016 - phase 2 pembrolizumab + epacadostat (IDO inhibitor) in recurrent clear cell of the ovary (L Gien)
 - Activated Oct 2018/suspended for first phase accrual completion 4/2019

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. (S. Lee, A Kambadakone) ECOG-ACRIN Study Available to Alliance, NRG, SWOG

- NRG Oncology Study Champions: Mannel/Schilder
- N= 184
- Currently on hold

Ovarian Cancer Subcommittee

E. Review of Approved Concepts under Development

- **NRG-GY019 (RT1753)** A Phase III Randomized Three Arm trial of paclitaxel/carboplatin compared to paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV primary low-grade serous carcinoma of the ovary or peritoneum. (Amanda Nickles-Fader). 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
- **NRG-GY021** Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams). Approved by GCSC/ Protocol back to CTEP 5/2019; **CIMAC discussions/review started**
- **OV1741** Randomized evaluation of interval cytoreductive surgery in elderly patients receiving neoadjuvant chemotherapy. Coordinated development with Elderly Working Group. (Amina Ahmed, Amy Bregar, Helen Huang, et al.) Will be submitted to DCP, managed by NCORP.
- **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

RSCX 3/5/19

Telecon TBS with drug monitors (Doyle, Ivy) and Study team prior to submitting unsolicited LOI's

- **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

RSCX 3/5/19

For this and OV1839, Telecon TBS with drug monitors (Doyle, Ivy) and Study team prior to submitting unsolicited LOI's

- **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

- **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)
 - **OTF 4/26/19 RSC 5/8/19**
- **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)
 - **OTF 4/26/19**
 - **RSC 5/8/19**
- **NRG-GY022 (DT1833):** Assessment of carboplatin clearance predictors: PK protocol to allow for extra sample collection and collection of demographic data, laboratory values, and outcome data. (Liz Villaruz/Jan Beumer) GYN Cancer Committee: 7/14/18
 - RSC 11/1/18
 - LOI to PIO 10/12/18
 - CRC approved 11/27/18
 - Call conducted with CTEP 12/14/18
 Submitted to PRC 03/18/19. PRC reviewed 4/4/19. Reviewer's comments rec'd 4/15/19. TC 4/29/19. CRR UD, Call with Pharmacy Committee 5/6 aiming to submit response 5/10/19
- **DT1907:** Phase I/II study of lenvatinib, pembrolizumab and weekly paclitaxel for recurrent endometrial, epithelial ovarian, fallopian tube and primary peritoneal cancer- (Floor Backes)
 - **On hold until Merck review received. If approved by Merck, RSC July 20, 2019**
- **RT1841** A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien) #2 in queue behind RT1849
- **RT1849** A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus) LOI. RSC review Feb '19
 - **RSCX 3/5/19**
 - **Telecon TBS with drug monitors (Sharon, Ivy) and Study team prior to submitting unsolicited LOI's**
- **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)
 - **Administratively disapproved**
- **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)
- **TS1514** Immunoscore determination as predictive biomarkers for clinical outcomes in GOG-0262. Awaiting amendment of data sharing plan (Samir Khleif).
- **NRG-CC008 (CC1923) (NC1427) (CPC1206)** A non-randomized prospective clinical trial comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers (SOROC) (Doug Levine). Submitted for NCORP review. Submitted to DCP

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

- **HIPEC: report from the NRG HIPEC working group and presentation of the von Driel protocol**

- **OV1954** Treatment of platinum sensitive recurrence in BRCA mutated patients with olaparib with or without cediranib maintenance after upfront treatment with olaparib maintenance therapy. (Nakayama)
- **OV1960** A phase III randomized, trial of heated intraperitoneal chemotherapy with cisplatin at the time of optimal interval cytoreductive surgery versus intravenous chemotherapy only followed by bevacizumab or olaparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer. (Crispins)
- **PI1956** A Phase I Study of Sapanisertib in Combination with Olaparib in Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer (Musa)
- **PI1966** A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent *CCNE1* amplified ovarian and endometrial carcinomas (Simpkins)
- **PI1967** Phase I dose escalation study of the proteasome inhibitor bortezomib in combination with the histone deacetylase inhibitor belinostat for patients with recurrent ovarian cancers harboring oncogenic, mutated p53.
- **RT1946** A Phase II trial of platinum based chemotherapy followed by olaparib and durvalumab in the treatment of Stage II-IV Ovarian, fallopian tube or primary peritoneal endometrioid ovarian Carcinoma. (Farley)
- **RT1947** A randomized Phase II trial of hormonal maintenance therapy (HMT) versus observation in the treatment of Stage IC Ovarian or Fallopian tube Low grade serous or endometrioid ovarian Carcinoma. (Farley)
- **RT1949** A Phase II trial evaluation of alisertib (MLN 8237) in combination with carboplatin, paclitaxel, and followed by alisertib (MLN 8237) and sapanisertib (TAK-228) consolidation in the treatment of advanced Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma. (Farley)
- **RT1950** A phase II trial evaluation romidepsin (FK228) and bortezomib (PS-341) in the treatment of Recurrent Ovarian, peritoneal or fallopian tube clear cell carcinoma (Farley)

QUESTIONS / DISCUSSION

Rare Tumor Workshop

Date: Friday, July 19, 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

Session I

A. Closed Studies

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

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

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

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

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

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

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 281: 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: Jubilee Brown, MD

Low Grade Endometrioid Cancer of the Ovary. What do we know and where should we be Looking?

Clear Cell Carcinoma of the Ovary. What do we know and where should we be Looking?

C. Active Studies

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

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

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

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

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). **Opening Imminently**

D. Proposed Studies/in development

RT1849: A Phase II Trial of Durvalumab and Cediranib in Recurrent Ovarian Sex Cord Stromal Tumors (Vicus). Approved for development. Priority 1. **Awaiting teleconference call with Drug Monitor- Doyle, Ivy**

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

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

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 (Farley) **Administratively disapproved**

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 (Farley)

E. Discussion Topics:

- a) “Match” trial for rare tumors
- b) RFP: low grade endometrioid ovarian cancer. Both Adjuvant (stages II-IV), and for recurrent disease
- c) RFP: Clear Cell Ovarian Cancer. Both Adjuvant therapy for stages I-IV, and for recurrent disease

F. New Proposals

- a) **RT1965** A phase II study of Sapanisertib in recurrent Low Grade Endometrioid Ovarian Carcinoma and Low Grade Endometrioid Endometrial Carcinoma. (Mantia- Smaldone)
- b) **RT1946** A Phase II trial of platinum based chemotherapy followed by olaparib and durvalumab in the treatment of Stage II-IV Ovarian, fallopian tube or primary peritoneal endometrioid ovarian Carcinoma. (Farley)
- c) **RT1947** A randomized Phase II trial of hormonal maintenance therapy (HMT) versus observation in the treatment of Stage IC Ovarian or Fallopian tube Low grade serous or endometrioid ovarian Carcinoma. (Farley)
- d) **RT1949** A Phase II trial evaluation of alisertib (MLN 8237) in combination with carboplatin, paclitaxel, and followed by alisertib (MLN 8237) and sapanisertib (TAK-228) consolidation in the treatment of advanced Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma. (Farley)
- e) **RT1950** A phase II trial evaluation romidepsin (FK228) and bortezomib (PS-341) in the treatment of Recurrent Ovarian, peritoneal or fallopian tube clear cell carcinoma (Farley)

QUESTIONS / DISCUSSION

Uterine Corpus Workshop

Date: Friday, July 19, 2019
Start and End time: 2:30 pm – 4:30 pm (Session I)

Date: Saturday, July 20, 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 12:00-1:00 (Lead Neil Horowitz, MD)

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

Workshop Agenda

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

1. **GOG0188:** Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [*Gynecol Oncol* 120(2): 185-8, 2011]: **Dr Covens will contact Local PI to sort out drug availability for the one remaining patient.**
2. **GOG0209:** A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer (**David Scott Miller to discuss**) [*Gynecol Oncol* 125: 771-3, 2012] Submission Lancet Oncology
3. **GOG0210:** A Molecular Staging study of Endometrial Carcinoma (William T Creasman) : **Mutch in separate report**
4. **GOG0249:** Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy (**Bernard to discuss**) doi:10.1016/j.ygyno.2014.07.078: Accepted JCO Pending revisions.
5. **GOG0258:** A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma. (Daniela Matei) **Likely accepted for publication pending final revisions; (Miller to discuss)**

6. **GOG0261**: A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus (**Matthew A Powell to discuss**) ; **Presented ASCO 2019**;
7. **GOG0275** A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia (**Julian C Schink**)
8. **GOG0286B** A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (**Victoria L Bae-Jump to discuss**) ;
9. **NRG-GY008**: A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA and PIK3R1/R2 mutations (A Santin) ; **Manuscript in development; (Backes to discuss)**
10. **NRG-GY011** (UC1406): A Randomized Surgical Window Pilot Investigation of the Relationship of Short Term Medroxyprogesterone Acetate (NSC #26386) Compared to Medroxyprogesterone Acetate Plus Entinostat (NSC #706995) on the Morphologic, Biochemical, and Molecular Changes in Primary Endometrioid Adenocarcinoma of the Uterine Corpus (**Duska to discuss**)

C. Review of Active Studies

1. Endometrial Protocols:

- a. **GOG0238**: A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus (**Bernard to discuss**):
- b. **S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (**Schink to discuss**)
- c. **GY012**: A Randomized, Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer (**Mackay/Bender/Rimmel**) 32 of 120; Issue with BP cuff; Additional arms considered for this meeting.
- d. **GY018** (UC1710) Prospective randomized phase 3 trial of carboplatin and paclitaxel with or without pembrolizumab in the treatment of primary advanced stage (3 or 4) or recurrent endometrial cancer (**Eskander to discuss**)

D. Review of Approved Concepts/Protocols

1. GOG 210

- a. **UC0905**: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (**Mutch to discuss in 210 report**)
- b. **GOG-8032 (UC1102)**: A clinico-pathologic analysis of high-grade uterine carcinomas (grade 3 endometrioid, serous, and clear cell carcinoma) and carcinosarcomas from GOG-0210 (Richard Zaino/ Ian Hagemann):
- c. **GOG-8040 (UC1107)**: An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino/ Ian Hagemann):
2. **NRG TS008 (UC1601)**: Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black Women with Endometrioid Endometrial and Uterine Serous Cancer (**L. Maxwell to discuss**)

3. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (**Tanner to discuss**)
4. **UC1731** Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study (Jerzak/ Mackay/ **Duska to discuss**) **N: 120 Stat: Sill ; Await preliminary data from GY011 before submitting to GCSC**
5. **UC1844** Efficacy of immunotherapy with immune checkpoint inhibitors in patients with deficient mismatch repair system or POLE mutated advanced stage or recurrent endometrial carcinoma: A randomized phase II/III trial (Mahdi) (**Mahdi to discuss**) **To submit to RSC**
6. **GY020 (UC1805)** Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Backes) **N: 168 (2:1 randomization). Stat: Sill**
7. **GY022 (DT1833)** Assessment of carboplatin clearance predictors: a companion PK study to NCI-sponsored clinical trials or standard of care treatments using carboplatin (**Taylor/Beumer**) **N: 250 Stat: (Backes to discuss)**
8. **UC1926:** Randomized Phase II Trial of Adjuvant Therapy with either Carboplatin/Paclitaxel or Everolimus/Letrozole in Stage III Endometrial Cancer with No Residual Disease (Slomovitz)

E. Proposed studies :

DT1951 Phase II trial of venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma. (Hensley)

DT1952 Phase II study investigating the efficacy of rationale combination immunotherapy in recurrent endometrial cancer with deficient mismatch repair system post progression on anti-PD1 therapy. (Mahdi)

DT1953 Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ uterine serous or clear cell carcinomas and in HER2+ ovarian cancer (Mahdi)

DT1958 Phase II study of Alpelisib and Letrozole in *PIK3CA*-mutated endometrial cancers. (Gaillard)

DT1959 Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Hensley)

GYN1963 A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Chino)

F. Studies from Other Committees for Review:

PI1966 A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent *CCNE1* amplified ovarian and endometrial carcinomas (Simpkins)

G. New Business

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

Head and Neck Cancer Workshop

Date: Saturday, July 20, 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

10:00 – 10:10	Report on publications and protocol closed to active accrual	Quynh-Thu Le, MD
10:10 – 10:30	Review of Active Studies	
RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIIR)	Cristina Rodriguez, MD
RTOG 1216	RT-cisplatin vs. RT-Docetaxel + Cetuximab vs. cisplatin + Atezolizumab for “high risk” resected HNSCC (Phase IIIIR)	Julie Bauman, MD, MPH Paul Harari, MD David Rosenthal, MD
NRG HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III)	Nancy Lee, MD
NRG HN004	Phase II-IIIIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC	Loren Mell, MD
NRG HN005	Phase II-IIIIR 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
NRG HN006 (HN1854)	Phase III trial of cisplatin/gemcitabine chemo +/- anti PD1/PDL1 for first line recurrent/metastatic NPC	Quynh-Thu Le, MD
10:30-10:40	Review of recently completed study	

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	Quynh-Thu Le, MD
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)	Quynh-Thu Le, MD
10:40 – 11:30 Review of developing studies and ECOG studies		
NRG 1903	Clinically N0 Oral cavity cancer: ND vs. sentinel node biopsy	Stephen Lai, MD, PhD
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	Nabil Saba, MD
NRG 1937	Phase IIIR of HD vs. weekly cisplatin in intermediate/high risk locoregionally advanced HNSCC	Paul Harari, MD
NRG 1935	RT +/- PD1 for intermediate risk postop patients	Stuart Wong, MD
???	CRT +/-antimucositis agent	Beth Beadle, MD
ECOG trials	E3132 PORT +/- Cisplatin in intermediate risk pts with disruptive P53 mutation	Barbara Burtness, MD
	E3161: Intermediate risk HPV(+) HNSCC CRT +/- Nivo	Barbara Burtness, MD
	E3163 Sinonasal carcinoma	Nabil Saba, MD
11:30 – 12:00 Presentations & Updates		
Translational Research Program update		Quyn-Thu Lee, MD.
Surgical subcommittee update		Erich Sturgis, MD
HN Committee Membership update		Stuart Wong, MD
HNSC update		Quynh-Thu Lee, MD

Lung Cancer Workshop

Date: Saturday, July 20, 2019
Start and End Time: 1:00 pm – 3:00 pm
Chair: Jeffrey Bradley, MD / Kristin Higgins (for this meeting)
Co-Chairs: Jessica Donington, MD, PhD and Martin Edelman, MD

Learning Objectives:

Following this activity, participants will be better able to:

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

4. Active Studies:

a.)	Lung-MAP SWOG S-1400	Saiana Waqar, MD
b.)	ALCHEMIST Trial	Martin Edelman, MD
c.)	RTOG 1308: Protons vs photons for St III NSCLC	Xing Liao, MD
e.)	NRG CC003: Hippocampal avoidance brain	Vinai Gondi, MD
f.)	LU002: Phase III chemo +/- SBRT for Stage IV	Puneeth Iyengar, MD, PhD
g.)	NRG-LU003: NCI NRG ALK Master Protocol	Shakun Malik, MD
i.)	NRG LU004 Phase I/II anti-PD1 concurrent with RT	Steven Lin, MD, PhD
h.)	NRG/Alliance LU005 Limited-stage SCLC	Kristin Higgins, MD
j.)	NRG LU006 Phase IIR; Dose-painting IMRT for mesothelioma	Andreas Rimner, MD
k.)	RTOG 3515 SBRT +/- durva for medically-inoperable Stage I	Cliff Robinson, MD
l.)	SWOG S1914/NRG LU – SBRT +/- neoadjuvant atezo for Stage I	Charles Simone, MD
m.)	NRG LU1866 Phase II/III ES-SCLC; chemo + atezo +/- RT	Quynh Nguyen, MD
m.)	Alliance Trial: Reducing Surgical Complications in smokers	Simon Lo, MD

QUESTIONS / DISCUSSION

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

NRG Principal Investigators and Research Associates are cordially invited to a kick-off meeting to discuss

Date: Saturday, July 20, 2019

Start and End Time: 10:30 am – 11:30 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. Discuss the requirements for pathology review.
4. Overview of statistical design and treatment assignment.

Agenda

Welcome and Introductions – *Erica Field, NRG Oncology*

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

Blood Assay and Tissue Analysis – *Lynn Sullivan, Foundation of Medicine*

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

Registration and Data Entry – *Jeff Serianni, Data Management, NRG Oncology*

Question and Answer Session

Patient Centered Outcomes Research (PCOR) Workshop Agenda

Date: Thursday, July 18, 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

5:00 – 5:40	Comparative Effectiveness Subcommittee Update NRG PCOR Disease Site Liaisons Updates on Developing Concepts	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD Laura Havrilesky, MD Jason Efstathiou, MD
5:40 – 5:50	PCOR Compliance Update Comments/Audience Q & A	Ron Chen, MD
5:50 – 6:00	Other Business	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD

New GYN Proposals:

CV1962 FIGO 2018 stage 1B2 (≥ 2 cm - < 4 cm) Cervical Cancer Treated with Neadjuvant Chemotherapy Followed by Fertility Sparing Surgery (**CoNteSSa**) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F) (Cobb/Covens)

CV1948 Evaluation of Minimally Invasive (Laparoscopic/Robotic) vs Open Surgery in Women with Early Stage Cervical Cancer (Davidson/Covens)

CV1922 P2 trial paclitaxel/bev/ CXCR4i/PARPi (Salani Ritu)

OV1960 A phase III randomized, trial of heated intraperitoneal chemotherapy with cisplatin at the time of optimal interval cytoreductive surgery versus intravenous chemotherapy only followed by bevacizumab or olaparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer. (Crispins)

SARCOMA WORKING GROUP AGENDA

DIAN WANG, M.D, PH.D., CHAIR

Peter Houghton, Ph.D., TRP Liaison Friday, July 19 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. New concept:

Phase II trial of Grid sarcoma by JW Snider, Majid Mohiuddin and Rob Griffin

C. Developing Concepts:

1. Phase IIR Trial of Radiotherapy versus Surgery and Radiotherapy for Soft Tissue Sarcomas of the Extremities and Chestwall Following an Unplanned Excision (Wolfson) Oral Update only
2. Phase II trial to investigate the role of peri-operative RT in desmoid tumors harboring CTNNB1 S45 mutation (Pollock/Welliver) Oral Update only
3. Registry to evaluate the safety and feasibility of treating sarcomas of the trunk with permanently implantable LDR CivaSheet (Krisha Howell and Dian Wang): Oral Update only
4. Registry to evaluate the efficacy of SBRT in treating sarcoma oligomet (Yen-Lin Evelyn Chen): Oral Update only

CI. Sarcoma TRP

1. Exploiting the biological context of radiotherapy in sarcoma (Phil Wong)
2. Preclinical studies for Disulfiram clinical trial concept (updated by Xinhui Wang)
3. Preclinical studies for BMN673 clinical trial concept (updated by Meng Welliver and Brian Van Tine)

E: New Business

Translational Science Workshop Agenda

Date: Thursday, July 18, 2019
Start and End time: 4:00 pm– 5:30 pm
Chair: Michael Birrer, MD, PhD
Co-Chairs: Adam Dicker, MD, PhD
Matthew Ellis, MB, BCHIR, PhD

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

- 1 To understand the emerging radiomics approaches to human cancers
- 2 To identify, describe, and discuss the status of the new tumor banking organization.
- 3 To understanding the present translational research being conducted by the CPTAC grants.
- 4 To recognize critical aspects of developing translational endpoints for legacy GOG clinical trials.

WORKSHOP AGENDA

4:00 – 4:15	Opening Remarks and Introduction	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD
4:15 – 4:30	GBC update	Heather Lankes, PhD, MPH
4:30 – 4:45	CPTAC Update	Matthew Ellis, MB, BCHIR, PhD Michael Birrer, MD, PhD
4:45 – 5:00	Radiomics	Sanjay Aneja, MD
5:00 – 5:15	Artificial Intelligence Approaches in Glioblastoma	Gaurav Shukla, MD, PhD
5:15 – 5:30	Closing Remarks and Discussion	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD

Translational Science Brain Cancer Subcommittee and Low Grade Glioma Working Group

**Friday, July 19, 2019
Marriott Downtown Philadelphia
8:00-10:30am**

Low Grade Working Group & TS Subcommittee

Introduction

(Arnab Chakravarti, MD)

“NFKBIA Haploinsufficiency in Diffuse Glioma”

(Markus Bredel, MD, PhD)

“Updates on Comprehensive Profiling of Lower Grade Glioma NRG/RTOG Trials”

(Erica Bell, PhD)

“Prognostic RNA Biomarkers in Lower Grade Glioma: An Update on NRG Oncology/RTOG 9802, 9813, and 0424”

(Jessica Fleming, PhD)

“Understanding of Low-Grade Glioma Biology through Epigenome-Wide Association Studies NRG/RTOG 9802/9813/0424”

(Wei Meng, PhD)

“MGMT and CMET Updates in Glioblastomas”

(Aline Becker, MD, PhD)

“C2TA in GBM: More than Just an Immune Effect”

(Pierre Robe, MD)

“Mechanisms of Susceptibility and Resistance to BET-Bromodomain Inhibition in MYC-Amplified Medulloblastoma”

(Rameen Beroukhim, PhD, MD)

Translational Science GYN Workshop Agenda

Date: Friday, July 19, 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 science efforts of NRG Oncology. Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

4:00-4:15	Opening Remarks Biospecimen Bank/Translational Science Update	Michael Birrer, MD, PhD Heather Lankes, PhD, MPH
	GYN Subcommittee Translational Science Updates (Including Concept Review/Questions/Discussion)	
4:15-4:35	Cervix/Vulva Cancer Subcommittee	Dmitriy Zamarin, MD
4:35-4:55	Ovarian Cancer Subcommittee Rare Tumor Subcommittee	Rebecca Arend, MD Elizabeth Swisher, MD Gloria Huang, MD
4:55-5:15	Uterine Corpus Cancer Subcommittee 210 Subcommittee	Doug Levine, MD David Mutch, MD
5:15-5:25 MD, PhD	GYN Developmental Therapeutics	Panagiotis Konstantinopoulos
5:25-5:30	Closing Remarks	Michael Birrer, MD

New proposals:

DT1955 A Phase II study of N-803 and Durvalumab in recurrent epithelial ovarian, fallopian tube and primary peritoneal cancer (Geller)

DT1957 A Phase II Study of Sapanisertib in Recurrent Ovarian Cancer (Musa)

DT1951 Phase II trial of Venetoclax plus doxorubicin as second-line treatment of advanced, metastatic uterine leiomyosarcoma (Hensley)

DT1952 Phase II study investigating the efficacy of rationale combination immunotherapy in recurrent endometrial cancer with deficient mismatch repair system post progression on anti-PD1 therapy (Mahdi)

DT1953 Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ uterine serous or clear cell carcinomas and in HER2+ ovarian cancer (Mahdi)

DT1958 Phase II study of Alpelisib and Letrozole in *PIK3CA*-mutated endometrial cancers. (Gaillard)

DT1959 Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Hensley)

GYN1963 A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Chino)

OV1954 Treatment of platinum sensitive recurrence in BRCA mutated patients with olaparib with or without cediranib maintenance after upfront treatment with olaparib maintenance therapy. (Nakayama)

OV1960 A phase III randomized, trial of heated intraperitoneal chemotherapy with cisplatin at the time of optimal interval cytoreductive surgery versus intravenous chemotherapy only followed by bevacizumab or olaparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer. (Crispins)

PI1956 A Phase I Study of Sapanisertib in Combination with Olaparib in Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer (Musa)

PI1966 A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent *CCNE1* amplified ovarian and endometrial carcinomas (Simpkins)

PI1967 Phase I dose escalation study of the proteasome inhibitor bortezomib in combination with the histone deacetylase inhibitor belinostat for patients with recurrent ovarian cancers harboring oncogenic, mutated p53.
(Hill)

RT1965 A phase II study of Sapanisertib in recurrent Low Grade Endometrioid Ovarian Carcinoma and Low Grade Endometrioid Endometrial Carcinoma (Mantia-Smaldone)

RT1946 A Phase II trial of platinum based chemotherapy followed by olaparib and durvalumab in the treatment of Stage II-IV Ovarian, fallopian tube or primary peritoneal endometrioid ovarian Carcinoma.
(Farley)

RT1947 A randomized Phase II trial of hormonal maintenance therapy (HMT) versus observation in the treatment of Stage IC Ovarian or Fallopian tube Low grade serous or endometrioid ovarian Carcinoma.
(Farley)

RT1949 A Phase II trial evaluation of alisertib (MLN 8237) in combination with carboplatin, paclitaxel, and followed by alisertib (MLN 8237) and sapanisertib (TAK-228) consolidation in the treatment of advanced Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma. (Farley)

RT1950 A phase II trial evaluation romidepsin (FK228) and bortezomib (PS-341) in the treatment of Recurrent Ovarian, peritoneal or fallopian tube clear cell carcinoma (Farley)

CV1922 P2 trial paclitaxel/bev/ CXCR4i/PARPi GOG-0240R (Salani Ritu)

CV1948 Evaluation of Minimally Invasive (Laparoscopic/Robotic) vs Open Surgery in Women with Early Stage Cervical Cancer (Davidson/Covens)

CV1962 FIGO 2018 stage 1B2 (≥ 2 cm - < 4 cm) Cervical Cancer Treated with Neoadjuvant Chemotherapy Followed by Fertility Sparing Surgery (**CoNteSSa**) / Neo-Adjuvant Chemotherapy and Conservative Surgery in Cervical Cancer to Preserve Fertility (NeoCon-F) (Cobb/Covens)

CV1964 Incorporation of Immunotherapy into The Management of Locally Advanced Carcinoma of the Vulva. (Glaser)

Translational Science GU Cancer Subcommittee Agenda

Date: Friday, July 19, 2019

Time: 2:00 pm-4:00 pm

Chairs: Phuoc Tran, MD, PhD / Alan Pollack, MD, PhD

- | | |
|--------------------|--|
| 2:00 – 2:10 | Introduction and Welcome
Phuoc Tran, MD PhD / Alan Pollack, MD, PhD |
| 2:10 – 2:40 | “Circulating Stromal Cells as Universal Blood Based Biomarkers for the Real Time Monitoring of Progression/Recurrence in Solid Cancers” Daniel Adams (MicroTech) |
| 2:40 – 3:10 | “RTOG 0521: Why Docetaxel? Who Benefits? Is the Immune System Involved”
Ryan Phillips, MD, PhD (Johns Hopkins Medicine) |
| 3:10 – 3:40 | “Immune Related Tumor Microenvironment Profiling of Muscle Invasive Bladder Cancer Treated with Chemoradiation: an analysis of RTOG 0524 and 0712”
Matthew Deek, MD (Johns Hopkins Medicine) |
| 3:40 – 3:50 | “Project Updates”
Phuoc Tran, MD, PhD / Alan Pollack, MD, PhD |
| 3:50 – 4:00 | Closing Remarks and Discussion
Phuoc Tran, MD PhD / Alan Pollack, MD, PhD |

Translational Science Head & Neck Cancer Subcommittee Agenda

Date: Friday, July 19, 2019

Time: 2:00pm-3:00pm Neil

Chair: Hayes, MD, MPH

2:00 – 2:05 **Introduction/Overview**
Neil Hayes, MD, MPH

2:05 – 2:30 **“Patient Driven Clinical Trial Design: A Novel Approach to Answering Patient Centered Questions”**
Steven Chang, MD, FACS (Henry Ford Health System)

2:30 – 2:55 **“Supportive Care Trials to Optimize Swallowing Outcomes Along the Continuum of Care”**
Katherine Hutcheson, PhD (MD Anderson Cancer Center)

2:55 – 3:00 **Closing Remarks and Discussion**
Neil Hayes, MD, MPH

Translational Science Lung Cancer Workshop Agenda

Date: Friday, July 19, 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. Personalized Cancer Treatment for Lung Cancer: Biomarker Development through Clinical Trials
2. Thoracic Radiotoxicities: Genetic Predictors
3. Drug Development through Investigating Therapeutic Failures in Lung Cancer

WORKSHOP AGENDA

Intro/Overview: Bo Lu, MD, PhD

Speaker: Matthew Smith, PhD (Moffitt)
Presentation Title: "Signaling-Associated Complexes in Lung Cancer: From Biology to Biomarkers"

Speaker: Sarah Kerns, PhD, MPH (University of Rochester Medical Center)
Presentation Title: "Pan-Cancer Genetic Association Study of Acute Radiotoxicity"

Speaker: Steffan Ho, MD, PhD (Pfizer)
Presentation Title: "Understanding Clinical Mechanisms of Resistance in Lung Cancer to Inform Drug Development"

Speaker: Tianhong Li, MD, PhD (UC Davis Health)
Presentation Title: "Blood Based Biomarkers for Precision Lung Cancer Therapy"

QUESTIONS / DISCUSSION

Scientific Core Committees

Health Disparities Workshop

Date: Friday, July 19, 2019
Start and End Time: 10:00 am - 11:30 am
Chair: Kathie-Ann Joseph, MD, MPH

Learning Objectives:

Following this activity, participants will be better able to:

1. Understand that SGM populations are a designated NIH health disparity population
2. SGM populations are populations of interests for all NIMHD Funding Opportunity Announcements
3. Have a better understanding of the role of the Sexual and Gender Minority Research Office
4. Understand methods to removing barriers to planning, conducting and reporting NIH-supported research about SGM Health and Well-Being

WORKSHOP AGENDA

Session I

A. *Sexual and Gender Minority Related Activities at the National Institutes of Health*

Expanding the Knowledge Base of SGM Health and Well-Being through NIH Supported Research

In October 2016, the National Institute on Minority Health and Disparities (NIMHD) designated SGM populations as a health disparity population for the NIH, and subsequently, all NIMHD Funding Opportunity Announcements (FOAs) now identify SGM populations as a population of interest. The designation also impacts health disparities work across the other NIH ICs by including SGM populations in any work focused on health disparity populations. This includes the NIH Loan Repayment Program in health disparities research.

A second goal is to remove barriers to planning, conducting, and reporting NIH-supported research about SGM health and well-being. In addition to expanding research in SGM health, the NIH also must ensure that structural barriers to advancing SGM health research are addressed. The ever-improving coordination of SGM-related research activities across the NIH further highlights NIH's commitment to catalyze the growth of the field. The SGMRO is committed to building collaborations within the NIH to enhance the understanding of unique issues relevant to SGM research. SGMRO communicates with the extramural community about scientific areas of interest and connects researchers and scholars with appropriate contacts across the NIH.

Additional goals include strengthening the community of researchers and scholars who conduct research relevant SGM health and well-being by mentoring researchers conducting research on SGM populations, co-sponsoring the 2017 NIMHD Health Disparities Research Institute which supports the research career development of promising minority health disparities research scientists early in their careers.

Lastly, evaluating progress on advancing SGM research is the final goal.

This workshop will review the diverse health issues affecting the SGM communities and the need for support for research and training in this area, particularly as it pertains to oncology.

Introduction

Kathie-Ann Joseph, MD, MPH

Lecture

Karen L. Parker, PhD, MSW
Director, Sexual & Gender Minority Research Office
Division of Program Coordination, Planning, and Strategic Initiatives
Office of the Director, National Institutes of Health

Q&A-moderated by Post Assessment

Kathie -Ann Joseph, MD, MPH

Karen Parker promotional:

According to a recent article in Journal of Clinical Oncology (Jan 2019), most oncologists don't know enough about how to treat patients in the lesbian, gay, bisexual, transgender, and queer (LGBTQ) community. The good news is that most are interested in learning more.

Nearly 83% said they are comfortable treating transgender patients, but 37% said they knew enough to do so.

A 2012 Gallup poll found that great proportions of African Americans (AA), Hispanics and Asians identified as LGBT than non-Hispanic whites. Despite stereotypes of wealthy, white, LGBT individuals, the poll found that 35% of those who identified as LGBT reported incomes of less than \$24,000 a year versus \$24,000 a year versus 24% of the general population. Thus, the LGBT population is at a higher risk of poverty than the general population.

Screening rates tend to be lower in LGBT populations. For example, in California screening for gay and bisexual men were equivalent for prostate cancer compared with their heterosexual peers; however, AA gay/bisexual men had significantly lower prostate cancer screening rates compared with AA heterosexual men. Transgender patients are 70% less likely to be screened for breast cancer, 60 percent less likely to be screened for cervical cancer, and 50% for colorectal cancer.

Approximately 75% of cancer deaths in this country are linked to potentially avoidable lifestyle and environmental factors; thus emphasis has been placed on primary prevention and early detection of cancer. US federal and non-federal agencies acknowledge the existence of cancer disparities related to gender, age, race, ethnic origin, income, social class, disability/ability, and geographic location, but little focus and money have been devoted to assessing and understanding differences in the cancer burden associated with sexual orientation and gender identity.

This workshop will focus both on the diverse health issues affecting the Sexual and Gender minorities (SGM) communities and the need for support for research and training in this area, particularly as it pertains to cancer clinical trials.

Health Disparities Committee Meeting

Friday, July 19, 2019 - 3pm-5pm

Agenda

Chair: Kate Yeager, PhD, RN, MS

3:00-3:10 pm **Welcome/Announcements**
HDC Research Vice Chair, Chanita Hughes Halbert, PhD

3:10-3:20 pm **HDC Disease Site Liaisons-Committee- Liaisons**
- 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: Leon Hwang)
<u>Gyn-Ovarian</u>	Melissa Simon	(Alternate: Dana Chase)
<u>Gyn-Cervix</u>	Wendy Brewster	
<u>Gyn-Uterine</u>	Anuja Jhingran	(Alternate: Marianne Matzo, Kathleen Darcy)
<u>Head & 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, Anuja Jhingran |
| <u>Cancer Care Delivery (CCDR)</u>               | Lucy Gansauer              |
| <u>NCORP</u>                                     | Kate Yeager                |

Communications Committee/Patient Engagement Working Group  
Anuja Jhingran, Martha Duncan

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

**3:20 to 4:10 pm**      **Research concept review:**

*Breast Cancer (BC) Endocrine Therapy Adherence According to Race and Social Determinants of Health (BcETAARS) Principal Investigator:* Margaret Quinn Rosenzweig, PhD, CRNP-C, AOCN, FAAN, University of Pittsburgh School of Nursing

*A system-wide intervention for reducing the role of implicit bias in cancer patient outcomes*  
Principal Investigators: Jeffrey Stone, PhD, University of Arizona & Dana Chase, MD, Arizona Oncology/ Creighton University.



**4:10-4:40 pm**

**Community Engagement in NRG Oncology Trials**

- HDC Ad-hoc working group (Chanita Hughes-Halbert, Electra Paskett, Tiffany Elsea, Donna White)
- NRG Committee Involvement: (PSC, PAC, Other)
- Possible Efforts:
  - Training / Workshop for NRG members
  - Education/Information for community physicians/health care professionals
  - Other?

**4:40-4:50 pm**

**Working Group Updates- Leaders**

- **Education/training/mentorship**-*Kathie Ann Joseph*
  - HDC Workshop - July 2019
  - HDC Mentor Program
- **Clinical trial enrollment**-*William (Rusty) Robinson*
- **Health disparities research**-*Electra Paskett*
  - Alliance Pilot Study Update
- **Statistics/metrics**-*Reena Cecchini*
  - SDMC Reports

**4:50-4:55 pm**

**Future Plans/Transition: NCTN and NCORP grant updates – Kate Yeager**

- *Research proposals*
- *Committee changes*
- *Membership*
  - *Needed experience/expertise*
  - *Reapplication*
  - *Call for new members*

**Other Business / Discussion**

**5:00 pm**

**Adjournment**

***Future Meetings***

- Monthly Tri-Chair and Working Group Leader calls
- HDC Working Group(WG) Conference Call-As determined by WG Leaders
- Committee Conference Calls- At NRG semi-annual meetings and as needed
- Future NRG Oncology Meetings:

**January 9 - 11, 2020**

Marriott Marquis  
Houston, TX

**July 16 - 18, 2020**

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

## Imaging Committee Meeting Agenda

**Date:** Friday July 19, 2019  
**Start and End Time:** 11:00 am –1:00 pm  
**Chair** Daniel Pryma, MD  
**Co-Chairs** James Fink, MD, Amy Fowler, MD, PhD, Rathan Subramaniam, MD, PhD  
 Mark Rosen, MD, Ying Xiao, PhD, Feng-Ming (Spring) Kong, PhD, MD

### MEETING AGENDA

|                    |                                                           |                                                 |
|--------------------|-----------------------------------------------------------|-------------------------------------------------|
| <b>11:00-11:10</b> | <b>Opening Remarks</b>                                    | Dan Pryma, MD                                   |
| <b>11:10-11:15</b> | <b>Report from IROC on Imaging QA in NRG trials</b>       | Mark Rosen, MD                                  |
| <b>11:15-11:40</b> | <b>PET- directed Chemoradiation</b>                       | Geoffrey Ku, MD                                 |
| <b>11:40-12:00</b> | <b><u>Updates on Concepts near Development</u></b>        |                                                 |
| a.                 | H&N                                                       | Rathan Subramanian, MD/ Min Yao, MD             |
| b.                 | Brain                                                     | Tammy Benzinger, MD / Ashok Srinivasan, MD      |
| c.                 | Breast                                                    | Heidi Umphrey, MD / Mohammad Eghtedari, MD      |
| d.                 | Gyn                                                       | Katherine Maturen, MD / Aradhana Venkatesan, MD |
| e.                 | GI                                                        | Eric Tamm, MD                                   |
| f.                 | GU                                                        | Ashesh Jani MD / Bill Hall, MD                  |
| g.                 | Lung                                                      | Michelle Ginsberg, MD                           |
| h.                 | Sarcoma                                                   | Dan Pryma, MD                                   |
| <b>12:00-12:30</b> | <b>Update on TRT Workshop held Thursday July 18, 2019</b> | Ying Xiao, PhD                                  |
| <b>12:30-12:55</b> | <b>Questions, comments, concerns &amp; suggestions</b>    | Dan Pryma                                       |

## Medical Oncology Workshop Agenda

**Date:** Saturday July 20, 2019  
**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, PharmD                      |
|      | A. Update on Protocol Drug Information Database/Forms |                                           |
|      | 1. Critical post-ASCO updates                         | Corey Langer, MD<br>Deborah Armstrong, MD |
| III. | Other business                                        | Corey Langer, MD<br>Deborah Armstrong, MD |

### QUESTIONS / DISCUSSION

## Pharmacy Subcommittee Workshop

**Date:** Friday, July 19<sup>th</sup> 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. Contrast the generic and biosimilar medication development process.
2. Outline the biosimilar research requirements for FDA approval.
3. Address practical challenges of biosimilar use including interchangeability, formulary restrictions, prescribing, dispensing, and research
4. Understand the rationale and benefits of standardizing drug information for research protocols.
5. Explain the primary aspects for standardizing patient variables for dosing carboplatin.
6. Discuss the role of standardization of pre-medication components.

### WORKSHOP AGENDA

- I. Introduction **(2 min)**
  - a. Committee purpose and goals
- II. CE Presentation: “The Biosimilar Development Pathway and Challenges of Practical Integration ” **(25 min)**  
- Robin Lockhorst, PharmD BCOP
- III. Update on Protocol Review Process for Pharmacy Subcommittee **(3 min)**
- IV. Protocol Drug Information Update **(15 min)**
  - a. Approval of standardized pre-medications for chemotherapy templates
- V. Carboplatin Position Paper Update **(5 min)**
- VI. Updates for CTEP Pharmacy Team **(5 min)**
- VII. 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.
- VIII. Evaluation

## Immunotherapy and Immune Modulation Workshop

**Date:** Thursday, July 18, 2019  
**Start and End Time:** - 2:00 PM – 4:00 PM  
**Chair:** Samir N. Khleif, MD  
**Co-Chairs:** Mark Einstein, MD  
Arta Monjazeb, MD, PhD  
Stephen Shiao, MD, PhD  
Kristina Young, MD, PhD  
Harry Bear, MD, PhD  
Steven Finkelstein, MD, FACRO

### Learning Objectives:

Following this activity, participants will be better able to:

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

### Immunotherapy Studies (Active and Under Development):

#### Active Protocols

- **GOG 265:** ADXS11-011 in persistent/recurrent Cervical Cancer- PI W. Huh

**Dr. Huh or Leath to update**

**Study concluded- manuscript in process**

- **GOG-9929:** A Phase I Trial of Atezolizumab with Chemoradiation for the Primary Treatment of Patients with Stages IB2-IVA Cervical Cancer (PI Jyoti Mayadev, M.D.)

**Update:** Joyti Mayadev, M.D. [jmayadev@ucdavis.edu](mailto:jmayadev@ucdavis.edu) to present

- **NRG-GY002 (NCI LOI 9719):** A phase II evaluation of nivolumab (BMS-936558), a fully human antibody against PD-1, in the treatment of persistent or recurrent squamous or non squamous cell carcinoma of the cervix . (Alessandro D. Santin M.D., Michael Frumovitz, MD, MPH)

**Update:** Alessandro Santin, MD [alessandro.santin@yale.edu](mailto:alessandro.santin@yale.edu)

- **NRG-GY003:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent High-Grade Serous Adenocarcinoma of Ovarian, Primary Peritoneal, Fallopian Tube or Endometrial Origin. (Robert A. Burger, MD)

**Update: Robert Burger, MD**

Update on manuscript

#### **Recently Reviewed Immunotherapy Concepts:**

- **LU1704:** Limited stage small cell lung cancer: A phase II/III randomized study of chemoradiation versus chemoradiation plus anti PD-1 immunotherapy (Kristin Higgins, MD and Helen Ross, MD)

**Update: Kristin Higgins, MD**

**CTEP approved and the NRG number is now LU005. Need update on activation**

- **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 (Ramez N. Eskander, MD & Amanda N. Fader, MD)

**Update: Ramez Eskander, MD or Amada Fader to present update where in CTEP process and activation**

#### **Concepts/Protocols in varying degrees of development**

- **NRG GY017-** Anti PD-L1 (Atezolizumab) as an Immune Primer and Concurrently with Extended Field Chemoradiotherapy for Node Positive Locally Advanced Cervical Cancer

**Update Joyti Mayadev, MD to present. Where in CTEP process and activation.**

- **GU1604-** Phase 2 trial of radiation therapy combined with immunotherapy in metastatic renal cell carcinoma (Dror Michaelson, MD)

**Update: Dror Michaelson to update where in CTEP process and activation**

- **NRG-CR1556/ NRG-G1004-** A randomized phase 3 study of FOLFOX/Bevacizumab combination chemotherapy with or without Atezolizumab in the first line treatment of patients with microsatellite instability high (MSI-H) metastatic colorectal cancer (James Lee, MD)

**Update: James Lee, MD**

- **GY-016:** Phase 2 trial of pembro + epacadostat for recurrent clear cell ovary (PI Lilian Gien)

**Update: Dr Gien where in CTEP process and opening**

- **RT1626:** A phase II trial of combined anti-PDL1(MSB0010718C immunotherapy (IT) with stereotactic ablative radiotherapy (SAbR) in recurrent ovarian clear cell cancer (ROCCC (**PI: Kevin Albuquerque**))

**Dr. Albuquerque to update**

**BN1638:** Radiation Therapy and an anti-PD-1 antibody for Recurrent Glioblastoma (PI: Shahed Nicolas Badiyan) --- **PREVIOUSLY ON HOLD**

- **RT1632:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Cell Carcinoma of the Ovary, Peritoneum or Fallopian Tube (PI John Farley)

**Update: John Farley, MD**

- **BR004:** A Randomized Phase III Trial of Nab-paclitaxel/Trastuzumab/Pertuzumab Compared to Nab-paclitaxel/Trastuzumab/Pertuzumab/MEDI4736 in First Line HER2-Positive Metastatic Breast Cancer (PI: Charles E. Geyer, Jr., MD)—(Co-I: Harrigan, Haw, Luck)

**Update: Charles Geyer, MD where in CTEP approval and activation**

**OV1821:** A randomized phase II trial of olaparib + tremelimumab vs platinum-based physician choice chemotherapy in HRD+ and HRD- platinum sensitive recurrent ovarian cancer (PI: Sarah Adams, MD)

**Update: Sarah Adams, MD where in CTEP approval and activation**

- **NRG- UC1740:** Phase II Single Agent PD1 Inhibitor in Chemo-refractory Gestational Trophoblastic Disease (PI: Marilyn Huang)
- **ES-SCLC:** Phase II/III Trial of Consolidation XRT + Immunotherapy for ES-SCLC (PI: James Welsh, MD)

**Update: James Welsh, MD where in CTEP approval and activation**

Recently reviewed concepts:

**BN1855:** Randomized Phase III Open Label Study of Ipilimumab and Nivolumab vs Temozolomide in Patients with Newly Unmethylated MGMT (Tumor O-6-methylguanine DNA Methyltransferase) Glioblastoma. (PI: Andrew Lassman) —**need update regarding CTEP submission**

**BN1856/Sperduto:** A Phase II/III Trial of Dual Immune Checkpoint Inhibition (ICI) Alone vs Dual ICI and Stereotactic Radiosurgery (SRS) for Melanoma Patients with < 10 Brain Metastases. Need update regarding CTEP submission

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

**DT1831 A Phase II study of combination pegylated liposomal doxorubicin with durvalumab in women with microsatellite stable recurrent endometrial cancer (PI: Bradley Corr MD)**—Need update regarding CTEP submission

**UC1844 Efficacy of second line immunotherapy with dual checkpoint inhibitors (CPI) vs. monotherapy in patients with deficient mismatch repair system or POLE mutated recurrent endometrial carcinoma: A randomized phase II trial (PI: Haider Mahdi, MD, MPH)**- need update regarding CTEP approval

**NRG- HN1801:** Randomized, 3-arm, phase 2 trial of DNA-PK inhibition or cisplatin with PD-L1 checkpoint blockade vs cisplatin and IMRT in stage 3-4 local-regionally advanced HPV-neg HNSCC

**New Concepts for Review and discussion:**

**NRG RT1849 (PI Danielle Vicus [danielle.vicus@sunnybrook.ca](mailto:danielle.vicus@sunnybrook.ca))** A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors.

**Reviewers: Joe Lucci, Yvonne Lin, Whitney Graybill**

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

**Reviewers: Mark Einstein, Brad Monk, Joe Lucci**

**NRG-DT1911 (PI Dmitriy Zamarin [zamarind@mskcc.org](mailto:zamarind@mskcc.org)) 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.**

**Reviewers: Robert Berger, Robert Edward, Sarah Bernstein**

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

**Reviewers: Michael Bookman, Paul Sabatini, Haider Mahdi**

**NRG-RT1906 (PI John Farley [John.farley@dignityhealth.org](mailto:John.farley@dignityhealth.org)) 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**

**Reviewers: Harry Bear, Robert Edward, Paul Sabatini**



## Immunotherapy and Immune Modulation Workshop

**Date:** Friday, July 19, 2019  
**Start and End Time:** 11:00 am - 12:30 pm  
**Chair:** Samir Khleif, MD  
**Co-Chairs:** Harry Bear, MD  
Mark Einstein, MD  
Steven Finkelstein, MD  
Arta Monjazebl, MD, PhD  
Stephen Shiao, MD, PhD  
Kristina Young, MD, PhD

**Learning Objectives: Integrating patient and tumor specific biomarkers for comprehensive immunologic monitoring.**

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

1. Define how obesity influences baseline tumor immunity and response to immune checkpoint blockade.
2. Utilize CIBERSORT algorithms to distinguish tumor infiltrating immune populations from RNAseq.
3. Test the function of single-cell populations using the Isoplexis platform.

### WORKSHOP AGENDA

Session I: Interrogating T cell function using clinical data, RNAseq, and single-cell cytokine production.

- 1) Arta Monjazebl, MD, PhD. UC Davis Comprehensive Cancer Center
  - a. Paradoxical effects of obesity on T cell function during tumor progression and PD-1 checkpoint blockade.
- 2) Felix Feng, MD. UCSF Helen Diller Family Comprehensive Cancer Center
  - a. CIBERSORT (title TBD).
- 3) Will Singleterry, PhD - Isoplexis
  - a. Single-cell multiplex cytokine platform (title TBD)

A. Discussion Topic - Current priorities of the Committee; Background, status, and significance of major projects.

### QUESTIONS / DISCUSSION

**Protocol Support Committee Workshop**  
**Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session** (Breakfast and Lunch provided)

**Date:** Thursday, July 18, 2019  
**Start and End Time:** 8:00 am – 1:00 pm  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Program Facilitator:** Sally Brown RN, BSN, MGA, Melinda Weiblen, BS

**Learning Objectives**

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

1. Explain three methods to increase oral adherence
2. Describe standard treatment of rectal cancer
3. List two advances in the treatment of rectal cancer
4. Provide one example of misconduct in research
5. Describe when IROC must be contacted
6. Explain how to apply to be mentored

**AGENDA**

| <u>Time</u>       | <u>Topic</u>                                     | <u>Speakers</u>                                                                                                                                                                                                            |
|-------------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:00am-8:10am     | Introduction                                     | Sally Brown, RN, BSN, MGA,                                                                                                                                                                                                 |
| 8:10am- 8:30am    | Update on Institution Performance reports        | Mimi Passarello, MBA                                                                                                                                                                                                       |
| 8:30am- 9:00am    | Update from CTSU                                 | Jenny Hopkins BSN, RN<br>Assistant Project Director, CTSU                                                                                                                                                                  |
| 9:00am-9:15am     | IROC: The Big Picture                            | Denise Manfredi, ES, RT(T)<br>Jessica Lowenstein, MS, DABR                                                                                                                                                                 |
| 9:15am – 9:45am   | Adherence to Oral Therapies                      | Joan Cahill, RN, BSN, OCN, CCRP                                                                                                                                                                                            |
| 9:45am-10:10am    | Panel Discussion                                 | Rebecca Kramer, RN, BSN, CCRC<br>Karen Holeva, BS, Joan Cahill, RN, BSN, OCN, CCRP                                                                                                                                         |
| 10:10am-10:25am   | Break                                            |                                                                                                                                                                                                                            |
| 10:25 am-11:15am  | Overview of Rectal Cancer                        | Thomas George, MD, FACP<br>Associate Director of Clinical Investigations<br>Medical Director, GI Program<br>Associate Professor<br>Director, UFHCC Experimental Therapeutics<br>Incubator Program, UF Health Cancer Center |
| 11:15am – 11:30am | Mentor Program                                   | Nancy Fusco, RN, BSN                                                                                                                                                                                                       |
| 11:30am-11:50am   | Break & Lunch Pick Up                            |                                                                                                                                                                                                                            |
| 11:50am-12:00pm   | Welcome                                          | Katie Stoermer, MBA, Executive<br>Director, NRG Oncology                                                                                                                                                                   |
| 12:00pm-12:10pm   | PSC Committee Membership<br>Speaker Introduction | Susan Nolte CRNP, PhD<br>Chair PSC                                                                                                                                                                                         |
| 12:10 pm – 1:00   | Research Misconduct                              | Doreen Kornrumpf , JD<br>Associate Counsel, Privacy Officer<br>Thomas Jefferson University<br>Philadelphia, PA                                                                                                             |

## Protocol Support Committee Workshop CTN/CRA Educational Session- Roundtables

**Date:** Thursday, July 18, 2019  
**Start and End Time:** 1:30 pm – 4:30 pm  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Program Facilitator:** Sally Brown RN, BSN, MGA, Melinda Weiblen, BS

### Learning Objectives

Following this activity, participants will be better able to:

1. Describe how the information obtained during round table discussions will impact the work process at your institution
2. Identify how the best practices from the experts will improve quality of protocol reporting
3. Explain how utilizing resources from the experts at NRG Oncology will improve conducting clinical trials

### AGENDA

| Topic                                                     | Speakers                                                                                                |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Brain Protocols                                           | Liz Wise CCRC, Sylvia Solokov MS, RN, Denise Manfredi, BS, RT (T)                                       |
| *Breast (BR002)                                           | Deborah Washington, RN, MSN, Susan McNulty, CMD, BS (R) (T)                                             |
| *GI Non Colorectal Protocols                              | Deborah Washington, RN, MSN, Susan McNulty, CMD, BS (R) (T),<br>Wendy Bergantz RN                       |
| Breast Topics (BR005/BR004/BR003)                         | Lynne Suhayda, RN, MEd, Kristen Kotsko, RN, BSN, Elaina Harper                                          |
| GI (GI002/GI004/GI005)                                    | Martha Duncan RN, MSN, Mary Pat Matisko, RN, BSN                                                        |
| GU Protocols                                              | Elaine Motyka-Welsh, RN, MSN, CCRP, Margaret Kennish, AS, CCRC, Joanne Hunter, BS, RT (R) (T)           |
| Head & Neck Protocols                                     | Vanita Patel, MS, Nancy Linnemann BS, RT (R) (T), Marsha Raddeb BS, RT, (R) (T)                         |
| Lung Protocols                                            | Jeffrey Serrianni BS, Jennifer Presley, RT (R) (M) (T),<br>Joe Bauza, RT                                |
| NCOR & QOL                                                | Roseann Bonanni, CTR, CCRP, Tiffany Small RN                                                            |
| Neurocognitive Testing                                    | Catherine Sullaway BS                                                                                   |
| Gyn Protocols- Ovarian                                    | Chrisann Winslow RN, MSN                                                                                |
| Gyn Protocols – Cervix, Uterine Corpus                    | Izabela Frak, Mphil, Dolly Kirschner, MPH, BS, BA                                                       |
| NRG Oncology Membership/Payments                          | Mimi Passarello, MBA, Julie Kardell, Yuliya Hayes                                                       |
| NRG Oncology Audit                                        | Mimi Passarello, MBA, Tamara McLaughlin MHA, MPH, Jerry Koss RN, BSN<br>Kelly Dunn, Rachel San Pedro    |
| NRG Oncology Biospecimen Bank                             | Sandy DeVries, MA, Melanie Finnigan, BS, Lisa Beaverson, BA, CCRP, Heather Lankes, PhD, MPH             |
| CTCAE Version 5, AE/SAE Reporting                         | Sara McCartney, MS, RN                                                                                  |
| *CTSU Topics                                              | Meghan Blackburn, Jenny Hopkins, BSN, RN, Orlan Santos, BA                                              |
| CIRB                                                      | Renee Green, Jacquie Steenbakker                                                                        |
| IROC RT                                                   | Jessica Lowenstein, MS, DABR, George Ballinger RT (R) (T)                                               |
| IROC DI                                                   | Michael Boss                                                                                            |
| PMB                                                       | Tali Johnson, Pharm D, BCOP                                                                             |
| Best practices for study<br>implementation and management | Cynthia Licavoli, RN, BSN, MA, HeeSun Kim-Suh, RN, BSN, OCN<br>Tiffany Elsea, BA, CCRP, Karen Holeva BS |
| NRG Legacy data submission                                | Nick Barror, Charleen Davis, Laura Hall, AS                                                             |
| Vision Tree                                               | Martin Pellinat, CEO & Founder, Vision Tree, Sheena Gagh, Client Services<br>Manager, Vision Tree       |

**\*Denotes Session is from 1:30 – 3:00**

QUESTIONS/DISCUSSION

EVALUATION

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

|                                  |                                                      |
|----------------------------------|------------------------------------------------------|
| <b>Date:</b>                     | <b>Thursday, July 18, 2019</b>                       |
| <b>Start and End Time:</b>       | <b>4:30 pm – 6:00 pm</b>                             |
| <b>Chair:</b>                    | <b>Susan Nolte, PhD, CRNP</b>                        |
| <b>Co-Chairs:</b>                | <b>Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC</b>  |
| <b>Working Group Facilitator</b> | <b>Sally Brown RN, BSN, MGA, Melinda Weiblen, BS</b> |

**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 2020 meetings

**WORKSHOP AGENDA**

1. Welcome
2. Announcements of open positions
3. Update on potential for providing educational session online
  - a. Ellen Perme
4. Discuss plans for winter 2020 winter meeting
  - a. Sub working group
5. Suggestions for summer 2021 summer meeting
  - a. Sub working group

QUESTIONS/DISCUSSION

EVALUATIONS

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

**Date:** Thursday, July 18, 2019  
**Start and End Time:** 4:30 pm – 6:00 pm  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Working Group Facilitator** Nancy Fusco RN, BSN  
**Working Group Co-Facilitator** Sue Eaton CCRP

### **Learning Objectives**

Following this activity, participants will be better able to:

1. Identify potential new topics for the Introductory Materials
2. Discuss the development of mentor program tools
3. Review the effectiveness of the mentor program

### **WORKSHOP AGENDA:**

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

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

#### **\*\* 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 Clinical Trials Coordinators:
    - i. Annual review : Due in January
    - ii. Discuss new topics to include
  - b. Mentor working group documents:
    - i. Annual review of mentor documents
  - c. Mentor program
    - i. Development of Mentorship program tools: New tools as needed
    - ii. Lead/Second Lead mentor report
    - iii. New updates regarding the program
8. Meeting Plan: Monthly conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

QUESTIONS/DISCUSSION  
EVALUATIONS

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

**Date:** Thursday, July 18, 2019  
**Start and End Time:** 4:30 pm – 6:00 pm  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**Working Group Facilitator** Terry Thomas MS, CCRC  
**Working Group Co-Facilitator** 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 topics for review at future meeting with CTSU, protocol development and CIRB

### **WORKSHOP AGENDA**

1. Call to order
2. Intro new members
3. Circulate roster for approval and protocol review sheet
4. Intro guests
5. Review current Protocol review process
6. Update from the Protocol Development team;
  - a. Protocol template
  - b. Protocol team discussion
  - c. Development of standard protocol guidelines across NRG Oncology protocols
7. CIRB update
8. CTSU update
9. NRG regulatory
10. Update from Quality Control representative
11. Other business

### **QUESTIONS/DISCUSSION**

### **EVALUATION**

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

**Date:** Thursday, July 18, 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 Facilitator** Joyce Neading RHIT, CTR  
**Working Group Co-Facilitator** Michele Lacy RN, BSN

### **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 February ,2019 meeting
2. Introductions/Welcome
3. Quality Assurance /Audit Team Liaison report/discussion
4. Vacancy: Quality Control Working Group Liaison to Mentorship Working Group
5. Working Group Liaisons report
  - a. Protocol Review Working Group – Donna White
  - b. Education and Training Working Group – Robin Burgess
6. Suggestions for new projects for Quality Control Working Group
7. Other Business

QUESTIONS/DISCUSSION

EVALUATION

**Protocol Support Committee Workshop  
Clinical Trial Nurse Subcommittee (Open for first hour only)**

**Date:** Friday, July 19, 2019  
**Start and End Time:** 7:00am – 9:00am  
**PSC Chair:** Susan Nolte, PhD, CRNP  
**PSC Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC  
**CTN Chair:** Cindy Licavoli RN, BSN, MA,  
**CTN Co Chairs:** Nancy Fusco RN, BSN, Hee Sun Kim-Suh, RN, BSN

**Learning Objectives**

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

1. Identify, describe and discuss updates and needs for the PSC Working Groups
2. Identify, describe and discuss the purpose and expectations of individual appointments to committees/working groups
3. Identify, describe and discuss the primary goals and objectives of the CTN Sub Committee and membership guidelines
4. Identify and discuss educational needs of both new and experienced CRAs/Nurses
5. Discuss the current activities of NRG Committees by CTN representatives

**WORKSHOP AGENDA:**

1. Working Group Reports
  - a. Protocol Review
  - b. Education and Training
  - c. Quality Control
  - d. Mentorship
2. Discuss and review goals, objectives and membership guidelines for CTN Sub Committee members
3. Discuss roles, responsibilities and reporting methods for appointments to NRG Oncology disease site and modality committees
4. Review Meeting Programs
5. Discuss meeting schedules and future educational needs
6. Discuss Newsletter article topics
7. Other business

QUESTIONS/DISCUSSION  
EVALUATION



**Protocol Support Committee Workshop  
Clinical Research Associate Subcommittee (Open for first hour only)**

**Date:** Friday, July 19, 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  
**CRA Chair:** Sharon Stockman BA, C-CRP  
**CRA Co-Chairs:** Sally Brown RN, BSN, MGA, Joyce Neading RHIT, CTR

**Learning Objectives**

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

1. Discuss the functions and current activities of the Protocol Support Committee Working Groups
2. Describe the responsibilities and objectives of the CRA Subcommittee membership
3. Identify the responsibilities of CRAs appointed to Site and Modality Committees
4. Identify educational needs of both new and experienced CRAs
5. Discuss current activities and future goals of the CRA Subcommittee

**WORKSHOP AGENDA**

1. Working Group Reports
  - a. Protocol Review
  - b. Education and Training
  - c. Quality Control
  - d. Mentorship
2. CRA Subcommittee membership guidelines and objectives
3. Site and Modality Committee appointments and responsibilities
4. Meeting Schedule
5. Educational Needs
6. Projects and Goals
7. Other Business

QUESTIONS/DISCUSSION

EVALUATION

**Protocol Support Committee Workshop  
PSC Business Meeting (Closed)**

**Date:** Saturday, July 20, 2019  
**Start and End Time:** 7:00 am – 9:30 am  
**Chair:** Susan Nolte, PhD, CRNP  
**Co-Chairs:** Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC

**WORKSHOP AGENDA**

1. Meeting Summary
2. Reports from PSC Disease Site Committee representatives
3. Report from CTN Subcommittee
4. Report from CRA Subcommittee
5. Update on appointment of CRA/CTN to protocols and committee appointments
6. PSC Mailbox
7. New business

QUESTIONS/DISCUSSION  
EVALUATION

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

|                                  |                                                      |
|----------------------------------|------------------------------------------------------|
| <b>Date:</b>                     | <b>Thursday, July 18, 2019</b>                       |
| <b>Start and End Time:</b>       | <b>4:30pm – 6:00pm</b>                               |
| <b>Chair:</b>                    | <b>Susan Nolte, PhD, CRNP</b>                        |
| <b>Co-Chairs:</b>                | <b>Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC</b>  |
| <b>Working Group Facilitator</b> | <b>Sally Brown RN, BSN, MGA, Melinda Weiblen, BS</b> |

**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 2020 meetings

**WORKSHOP AGENDA**

1. Welcome
2. Announcements of open positions
3. Update on potential for providing educational session online
  - a. Ellen Perme
4. Discuss plans for winter 2020 meeting
  - a. Sub working group
5. Suggestions for summer 2021 meeting
  - a. Sub working group

QUESTIONS/DISCUSSION  
EVALUATIONS

## Radiation Oncology Committee Meeting

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

**Date:** Friday, July 19, 2019  
**Start and End Time:** 2:00 pm – 4:00 pm  
**Chair:** Jeff Michalski, MD  
**Co-Chairs:** Ivy Petersen, MD and Evan Wuthrick, MD

#### MEETING AGENDA

|                    |                                                                                                            |                                           |
|--------------------|------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>2:00 – 2:05</b> | <b>Welcome / Introduction</b>                                                                              | Wuthrick /Michalski<br>Petersen           |
| <b>2:05 – 2:20</b> | <b>Update on NCTN Cooperative Groups</b>                                                                   | Jeff Michalski                            |
|                    | a. NRG Oncology Group Update                                                                               |                                           |
|                    | - Planning underway: mini -symposium to be held at the Jan 2019 Mtg                                        |                                           |
|                    | - Submit suggestion to Betty O’Meara: <a href="mailto:OMearaE@NRGOncology.org">OMearaE@NRGOncology.org</a> |                                           |
|                    | b. Imaging and Radiation Oncology Core (IROC) RT Update                                                    | David Followill<br>Denise Manfredi        |
|                    | c. Imaging and Radiation Oncology Core (IROC) Imaging Update                                               | Mark Rosen                                |
| <b>2:20– 2:30</b>  | <b>Overview of Medical Physics</b>                                                                         |                                           |
|                    | a. TRT Workshop Update                                                                                     | Ying Xiao                                 |
| <b>2:30 - 2:40</b> | <b>Imaging Committee Update</b>                                                                            | Dan Pryma                                 |
| <b>2:40 - 2:50</b> | <b>NCI Update</b>                                                                                          | Ceferino Obcemea                          |
| <b>2:50 – 3:50</b> | <b>Disease Site Liaisons Reports</b>                                                                       |                                           |
|                    | a. H&N                                                                                                     | Sue Yom, MD / Min Yao, MD                 |
|                    | b. Brain                                                                                                   | Christina Tsien, MD / Tony Wang, MD       |
|                    | c. Breast                                                                                                  | Steven Chmura, MD / Simona Shaitelman, MD |
|                    | d. Gyn                                                                                                     | Sushil Beriwal, MD / Ann Klopp, MD        |
|                    | e. GI                                                                                                      | Evan Wuthrick, MD / Eugene Koay, MD       |
|                    | f. GU                                                                                                      | Dan Krauss, MD / Hiram Gay, MD            |
|                    | g. Lung                                                                                                    | Greg Videtic, MD / Charles Simone, MD     |
|                    | h. Sarcoma                                                                                                 | Philip Wong, MD                           |
| <b>3:50 – 3:55</b> | <b>Other Business</b>                                                                                      |                                           |
| <b>3:55 –4:00</b>  | <b>Q &amp; A Discussion</b>                                                                                |                                           |

**Save the Date Next Meeting: January 9 - 11, 2020 Marriott Marquis in Houston, TX!**

## Radiation Development Therapeutics Workshop

**Date:** Saturday July 20, 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, MD and Steven Lin, M.D., PhD

#### II. Scientific Talk:

#### III. Disease Site Committee Updates

##### a. Head & Neck (Committee Liaison: Neil Hayes, MD)

- 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. Genitourinary (Committee Liaison: Open)

##### c. Brain (Committee Liaison: Vinay Puduvalli, MD)

##### d. Breast (Committee Liaison: Stephen Chmura, MD)

##### e. Lung (Committee Liaison: Steven Lin, MD, PhD)

- 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)

##### f. GI-non colorectal (Committee Liaison: Terence Williams, MD)

- 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

##### g. GI-colorectal (Committee Liaison: Theodore Hong, MD)

- i. NRG-GI002: A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer (safety lead in)

##### h. GYN (Committee Liaison: Jyoti Mayadev, MD)

- 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

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

**Date:** Friday, July 19, 2019  
**Start and End Time:** 7:00 am – 9:00 am  
**Chair:** Ying Xiao, PhD  
**Co-Chair:** Stanley Benedict, PhD

**WORKSHOP AGENDA**

|                    |                                                                                                                                                                  |                                                                                                                              |  |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|--|
| <b>7:00 – 7:05</b> | <b>Introductions / Subcommittee Updates</b>                                                                                                                      | Ying Xiao   Stan Benedict                                                                                                    |  |
| <b>7:05 – 7:10</b> | <b>NCI Communications/NCTN Medical Physics</b>                                                                                                                   | Ceferino Obcemea                                                                                                             |  |
| <b>7:10 – 7:20</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>Denise Manfredi<br>Mark Rosen, MD                                                                        |  |
| <b>7:20 – 7:50</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> <li>Other/NCORP</li> </ul> | Fangfang Yin<br>Jean Moran<br>Adam Yock<br>Russell Ruo<br>Hayeon Kim<br>Nataliya Kovalchuk<br>Martha Matuszak<br>Yimei Huang |  |
|                    |                                                                                                                                                                  | Cecilia Lee                                                                                                                  |  |
|                    |                                                                                                                                                                  | Ping Xia                                                                                                                     |  |
|                    |                                                                                                                                                                  | Tim Solberg                                                                                                                  |  |
|                    |                                                                                                                                                                  | Tian Lu                                                                                                                      |  |
| <b>7:50 – 8:15</b> | <b>Modality Technology Reports</b>                                                                                                                               |                                                                                                                              |  |
|                    | <ul style="list-style-type: none"> <li>Notable technologies <ul style="list-style-type: none"> <li>MC Work Group Updates</li> </ul> </li> </ul>                  | Zoufeng Li<br>Liyong Lin                                                                                                     |  |
| <b>8:15 – 8:40</b> | <b>Working Group and Other Updates</b>                                                                                                                           |                                                                                                                              |  |
|                    | <ul style="list-style-type: none"> <li>Adaptive QA</li> <li>Deformable QA</li> <li>SBRT Practice Survey</li> <li>TRT Updates</li> </ul>                          | Carrie Glide-Hurst<br>Stan Benedict<br>Jason Sohn<br>Jacek Capala   Stan Benedict                                            |  |
| <b>8:40 – 8:50</b> | <b>Other Business</b>                                                                                                                                            |                                                                                                                              |  |
| <b>8:50 – 9:00</b> | <b>Questions/Discussions</b>                                                                                                                                     |                                                                                                                              |  |

## Proton Working Group Agenda

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

**Date:** Saturday, July 20, 2019  
**Start and End Time:** 7:00 am – 8:30 am  
**Chair:** Tom DeLaney, MD  
**Co-Chair:** Ted Hong, MD

#### WORKSHOP AGENDA

|             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                         |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| 7:00 – 7:05 | Welcome/Introduction/ Moderator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Tom DeLaney, MD                         |
| 7:05 - 7:15 | Update on Proton Center Credentialing by IROC Houston                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Paige Taylor, PhD                       |
| 7:15 – 7:30 | 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         |
| 7:30 – 7:50 | 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                        |
| 7:50—8:00   | <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                                                                                                                                                                                                                                                                                                                                                                              | Zhong Xing Liao, MD<br>Jeff Bradley, MD |
| 8:00 – 8:10 | <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       |
| 8:10 – 8:15 | <u>GI 006</u> : Ph III Randomized Protons vs. IMRT Photon for Esophageal CA                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Steven Lin, MD                          |
| 8:15– 8:20  | PCORI (Patient-Centered Outcomes Research Institute) RADCOMP Breast<br>Randomized Trial of Photons versus Protons                                                                                                                                                                                                                                                                                                                                                                                                                                       | Neil Taunk, MD                          |
| 8:20– 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 Workshop**

**Date:** Saturday, July 20, 2019  
**Start and End Time:** 7:00 am – 8:00 am  
**Chair:** Drew Ridge, M.D., Ph.D.  
**Co-Chairs:** Nick Spirtos, M.D., Thomas Julian, 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, integration into trials, and incorporation of immunotherapy
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 /Approval of Minutes
- 7:05 - 7:15 Medical Oncology Update
- 7:15 – 7:25 Radiation Oncology Committee Update
- 7:25 – 7:55 Disease Site Liaisons Reports (very brief update on developments—with attention to incorporation of immunotherapy)\*
- a. Brain
  - b. Breast
  - c. GI
  - d. Gynecology
  - e. Head and Neck
  - f. Lung
  - g. Urology
- \*Liaison to provide a 5 minute update on latest surgical advancement
- 7:55 –8:00 Questions/Discussion



# Administrative Committees

## Clinical Trials 101

### New Investigator Educational Session Agenda

**Date:** Thursday, July 18, 2019  
**Start and End Time:** 4:00pm – 5:15pm, Brief Reception to Follow  
**Co-Chairs:** Elizabeth Gore, MD; Priya Rastogi, MD Angeles Secord, MD

|                 |                                                        |                            |
|-----------------|--------------------------------------------------------|----------------------------|
| 4:00pm – 4:05pm | Introductory Remarks                                   | Committee Co-Chairs        |
| 4:05pm – 4:20pm | An Introduction to NRG Oncology and Ancillary Projects | Mitchell Machtay, MD       |
| 4:20pm – 4:35pm | Protocol Development Process                           | Nancy Soto                 |
| 4:35pm – 4:50pm | Statistics at NRG Oncology                             | James Dignam, PhD          |
| 4:50pm – 5:05pm | New Investigator Experience: Pacific 4                 | Clifford Robinson, MD      |
| 5:05pm – 5:15pm | Questions and Closing                                  |                            |
| 5:15pm – 6:00pm | New Investigator Reception                             | To follow in the same room |

## Canadian Members Meeting Workshop

**Date:** Saturday, July 20, 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:** Erica Field (back-up representatives: Judy Langer and Kate Wiser)

### Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing NRG Oncology clinical trials available in Canada
2. 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 (January – June 2019)  
*Discussion lead - NRG Oncology Regulatory*
- III. Optimizing accrual in Canada
  - a. Discuss best practices for and barriers to optimizing accrual among Canadian sites  
*Discussion lead - Canadian Members Co-Chairs*
- IV. New concepts and protocols
  - a. NRG-GU007: Randomized Phase II Trial of Niraparib With Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer (With Initial Phase I) – Z. Zumsteg, MD
  - b. 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) – J-M. Lee, MD
- V. New Business, General Questions, Discussion, Next Meeting  
*Discussion lead by NRG Oncology Staff*
- VI. Evaluation

## International Members Workshop

**Date:** Friday, July 19, 2019  
**Start and End Time:** 10:00 am – 11:00 am EST  
**Chairs:** Ben Corn, MD; Stephan Bodis, MD  
**NRG Operations:** Erica Field, Melissa French

### 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. NRG Proton Trials open to accrual – *Thomas DeLaney, MD*

#### III. Status of NRG trials open to accrual – *Erica Field*

#### IV. News from NRG for intl. members – *NRG Membership*

#### V. Optimizing accrual - Discuss best practices for optimizing accrual among International sites – *Ben Corn and Stephan Bodis*

- 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

#### VI. New concepts and protocols

- a. Presentation of concepts developed by International PI(s)

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

- a. Goals and milestones
- b. Input from international members

#### VIII. Evaluation

## NCORP PI & ADMINISTRATORS MEETING

### Agenda

**SATURDAY, July 20, 2019**

**8:00 – 10:00 AM**

**Philadelphia, PA**

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|           |                                            |                                  |
|-----------|--------------------------------------------|----------------------------------|
| 8:00 a.m. | Welcome                                    | J. Walker, MD                    |
| 8:05 a.m. | NCI NCORP Report                           | S. Russo, MD                     |
| 8:15 a.m. | NCI CCDD Report                            | K. Castro, RN, MS                |
| 8:25 a.m. | NRG-CC004 update                           | Deb Barton, PhD, RN              |
| 8:55 a.m. | Cancer Prevention and Control<br>Committee | L. Kachnic, MD                   |
| 9:05 a.m. | Cancer Care Delivery<br>Research Group     | M. Hudson, PhD, MPH              |
| 9:15 a.m. | Health Disparities Update                  | K. Yeager, RN, PhD               |
| 9:25 a.m. | PCOR Committee                             | Lari Wenzel, PhD                 |
| 9:35 a.m. | NCORP developing concept                   | Margaret Rosenzweig, PhD, CRNP-C |
| 9:45 a.m. | Q&A – Open Discussion                      |                                  |

# Institutional Accrual

**Accrual from 6/1/2018 to 5/31/2019**

| <b>Accrual For Agenda Book from 6/1/2018 to 5/31/2019    Run Date: 6/13/2019</b> |                |                                                   |                                                            |              |
|----------------------------------------------------------------------------------|----------------|---------------------------------------------------|------------------------------------------------------------|--------------|
| <b>NRG Main Member (Network)</b>                                                 | <b>CTEP ID</b> | <b>Accrued to NRG Studies and Credited to NRG</b> | <b>Accrued to Non-NRG NCTN Studies and Credited to NRG</b> | <b>Total</b> |
| AdventHealth Orlando                                                             | FL086          | 2                                                 | 0                                                          | 2            |
| Allan Blair Cancer Centre                                                        | 11076          | 8                                                 | 0                                                          | 8            |
| Allegheny General Hospital                                                       | PA009          | 16                                                | 110                                                        | 126          |
| AMITA Health Alexian Brothers Medical Center                                     | IL280          | 6                                                 | 4                                                          | 10           |
| Arizona Center for Cancer Care-Peoria                                            | AZ127          | 12                                                | 3                                                          | 15           |
| Aultman Health Foundation                                                        | OH100          | 4                                                 | 149                                                        | 153          |
| Aurora NCI Community Oncology Research Program                                   | AURORA         | 22                                                | 14                                                         | 36           |
| Avera Cancer Institute                                                           | SD021          | 5                                                 | 24                                                         | 29           |
| Banner University Medical Center - Tucson                                        | AZ017          | 7                                                 | 4                                                          | 11           |
| Baptist Health Cancer Research Network                                           | BHCRN          | 3                                                 | 51                                                         | 54           |
| Bay Area Tumor Institute NCORP                                                   | BATI           | 4                                                 | 2                                                          | 6            |
| Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center              | TX041          | 0                                                 | 12                                                         | 12           |
| Baystate Medical Center                                                          | MA004          | 21                                                | 6                                                          | 27           |
| Beaumont NCI Community Oncology Research Program                                 | BEAUMONT       | 13                                                | 7                                                          | 20           |
| Berkshire Medical Center - Cancer Center                                         | MA125          | 1                                                 | 2                                                          | 3            |
| Boston Medical Center                                                            | MA043          | 1                                                 | 145                                                        | 146          |
| Cancer Research Consortium of West Michigan NCORP                                | CRCWM          | 29                                                | 3                                                          | 32           |
| Cancer Research for the Ozarks NCORP                                             | OZARKS         | 14                                                | 1                                                          | 15           |
| Cancer Trials Ireland                                                            | ICORG          | 7                                                 | 0                                                          | 7            |
| Carle Cancer Center NCI Community Oncology Research Program                      | CARLE          | 13                                                | 43                                                         | 56           |
| Carolinas Medical Center/Levine Cancer Institute                                 | NC042          | 16                                                | 4                                                          | 20           |
| Catholic Health Initiatives NCORP                                                | CORA           | 23                                                | 50                                                         | 73           |
| Cedars-Sinai Medical Center                                                      | CA016          | 2                                                 | 0                                                          | 2            |
| Centre Hospitalier Universitaire de Sherbrooke-Fleurimont                        | 11065          | 10                                                | 0                                                          | 10           |
| Chinese University of Hong Kong-Prince of Wales Hospital                         | 34003          | 15                                                | 0                                                          | 15           |
| CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)                                       | 11073          | 21                                                | 0                                                          | 21           |
| CHUM - Centre Hospitalier de l'Universite de Montreal                            | 11062          | 19                                                | 0                                                          | 19           |
| City of Hope Comprehensive Cancer Center                                         | CA043          | 7                                                 | 6                                                          | 13           |
| CIUSSEMTL-Hopital Maisonneuve-Rosemont                                           | 11060          | 2                                                 | 0                                                          | 2            |
| Colorado Cancer Research Program NCORP                                           | CCRP           | 3                                                 | 29                                                         | 32           |
| Columbia Saint Mary's Water Tower Medical Commons                                | WI161          | 3                                                 | 17                                                         | 20           |
| Columbia University Minority Underserved NCORP                                   | COLUMBIA       | 6                                                 | 24                                                         | 30           |
| Columbus NCI Community Oncology Research Program                                 | COLUMBUS       | 13                                                | 8                                                          | 21           |
| Community Cancer Center North                                                    | IN006          | 2                                                 | 22                                                         | 24           |
| Cooper Hospital University Medical Center                                        | NJ036          | 4                                                 | 10                                                         | 14           |
| Covenant Medical Center-Lakeside                                                 | TX054          | 0                                                 | 5                                                          | 5            |
| Cross Cancer Institute                                                           | 11132          | 5                                                 | 0                                                          | 5            |
| CWRU Case Comprehensive Cancer Center LAPS                                       | LAPS-OH029     | 92                                                | 37                                                         | 129          |
| Dana-Farber / Partners CancerCare LAPS                                           | LAPS-MA036     | 26                                                | 8                                                          | 34           |
| Danbury Hospital                                                                 | CT030          | 1                                                 | 0                                                          | 1            |

**Accrual from 6/1/2018 to 5/31/2019**

|                                                                    |            |    |     |     |
|--------------------------------------------------------------------|------------|----|-----|-----|
| Dartmouth College - Norris Cotton Cancer Center LAPS               | LAPS-NH012 | 19 | 6   | 25  |
| Dayton NCI Community Oncology Research Program                     | DAYTON     | 4  | 10  | 14  |
| Delaware/Christiana Care NCI Community Oncology Research Program   | CHRISTIANA | 31 | 7   | 38  |
| Dell Seton Medical Center at The University of Texas               | TX063      | 0  | 12  | 12  |
| Duke University - Duke Cancer Institute LAPS                       | LAPS-NC010 | 10 | 0   | 10  |
| Edward Hospital/Cancer Center                                      | IL104      | 3  | 17  | 20  |
| Einstein Medical Center Philadelphia                               | PA094      | 0  | 1   | 1   |
| Emory University - Winship Cancer Institute LAPS                   | LAPS-GA005 | 34 | 21  | 55  |
| Essentia Health NCI Community Oncology Research Program            | ESSENTIA   | 3  | 14  | 17  |
| Fox Chase Cancer Center                                            | PA086      | 11 | 34  | 45  |
| Fred Hutchinson Cancer Research Center LAPS                        | LAPS-WA008 | 10 | 10  | 20  |
| Froedtert and the Medical College of Wisconsin LAPS                | LAPS-WI013 | 18 | 5   | 23  |
| Geisinger Cancer Institute NCI Community Oncology Research Program | GEISINGER  | 7  | 27  | 34  |
| Georgia Cares Minority Underserved NCORP                           | GRU        | 12 | 18  | 30  |
| Georgia NCI Community Oncology Research Program                    | GEORGIA    | 21 | 20  | 41  |
| Greater Baltimore Medical Center                                   | MD018      | 2  | 9   | 11  |
| Gulf South Minority Underserved NCORP                              | GULFSOUTH  | 20 | 2   | 22  |
| Hackensack University Medical Center                               | NJ022      | 0  | 7   | 7   |
| Hartford Hospital                                                  | CT009      | 2  | 4   | 6   |
| Hawaii Minority Underserved NCORP                                  | HAWAII     | 10 | 13  | 23  |
| Heartland Cancer Research NCORP                                    | HEARTLAND  | 36 | 4   | 40  |
| Henry Ford Hospital                                                | MI026      | 12 | 2   | 14  |
| Indiana University/Melvin and Bren Simon Cancer Center             | IN007      | 13 | 0   | 13  |
| Iowa-Wide Oncology Research Coalition NCORP                        | IWORC      | 8  | 30  | 38  |
| James A. Haley Veterans Affairs Hospital                           | FL064      | 0  | 0   | 0   |
| Jewish General Hospital                                            | 11116      | 4  | 0   | 4   |
| JHU Sidney Kimmel Comprehensive Cancer Center LAPS                 | LAPS-MD017 | 10 | 1   | 11  |
| Juravinski Cancer Centre at Hamilton Health Sciences               | 11183      | 1  | 0   | 1   |
| Kaiser Permanente NCI Community Oncology Research Program          | KAISER     | 80 | 129 | 209 |
| Kaiser Permanente-Gaithersburg Medical Center                      | MD198      | 0  | 17  | 17  |
| Kansas City NCI Community Oncology Research Program                | KANSASCITY | 2  | 0   | 2   |
| Kantonsspital Aarau                                                | 67029      | 16 | 0   | 16  |
| Lahey Hospital and Medical Center                                  | MA017      | 5  | 25  | 30  |
| Legacy Good Samaritan Hospital and Medical Center                  | OR013      | 13 | 2   | 15  |
| London Regional Cancer Program                                     | 11137      | 3  | 0   | 3   |
| Loyola University Medical Center                                   | IL017      | 23 | 0   | 23  |
| Main Line Health NCORP                                             | MAINLINE   | 12 | 4   | 16  |
| Maine Medical Center- Scarborough Campus                           | ME018      | 15 | 11  | 26  |
| Mayo Clinic LAPS                                                   | LAPS-MN026 | 34 | 1   | 35  |
| Medical University of South Carolina Minority Underserved NCORP    | MUSC       | 14 | 0   | 14  |
| MedStar Franklin Square Medical Center/Weinberg Cancer Institute   | MD029      | 1  | 12  | 13  |
| Memorial Sloan-Kettering Cancer Center LAPS                        | LAPS-NY016 | 50 | 3   | 53  |
| Mercy Cancer Center - Sacramento                                   | CA729      | 10 | 10  | 20  |
| Metro Minnesota Community Oncology Research Consortium             | METROMIN   | 29 | 17  | 46  |
| Michigan Cancer Research Consortium NCORP                          | MCRC       | 21 | 1   | 22  |
| Michigan State University Clinical Center                          | MI038      | 0  | 4   | 4   |
| Moffitt Cancer Center                                              | FL065      | 6  | 33  | 39  |
| Montana Cancer Consortium NCORP                                    | MONTANA    | 18 | 0   | 18  |
| Montefiore Minority Underserved NCORP                              | MONTEFIORE | 14 | 3   | 17  |



**Accrual from 6/1/2018 to 5/31/2019**

|                                                                           |            |    |    |    |
|---------------------------------------------------------------------------|------------|----|----|----|
| Mount Sinai Hospital                                                      | NY021      | 13 | 14 | 27 |
| National Cancer Centre Singapore                                          | 47005      | 5  | 0  | 5  |
| National Institutes of Health Clinical Center                             | MD004      | 0  | 0  | 0  |
| NCORP of the Carolinas (Greenville Health System NCORP)                   | GREENVILLE | 9  | 17 | 26 |
| Nevada Cancer Research Foundation NCORP                                   | NCRF       | 5  | 1  | 6  |
| New Mexico Minority Underserved NCORP                                     | NEWMEXICO  | 31 | 26 | 57 |
| New York-Presbyterian/Brooklyn Methodist Hospital                         | NY075      | 21 | 4  | 25 |
| NorthShore University HealthSystem-Evanston Hospital                      | IL018      | 3  | 5  | 8  |
| Northwell Health NCORP                                                    | NORTHSHOR  | 9  | 3  | 12 |
| Northwest NCI Community Oncology Research Program                         | NORTHWEST  | 22 | 0  | 22 |
| Northwestern Medicine Cancer Center Warrenville                           | IL387      | 15 | 25 | 40 |
| Northwestern University LAPS                                              | LAPS-IL036 | 17 | 7  | 24 |
| Norton Hospital Pavilion and Medical Campus                               | KY049      | 6  | 0  | 6  |
| NRG Oncology Foundation, Inc                                              | NRG        | 0  | 0  | 0  |
| Ochsner NCI Community Oncology Research Program                           | OCHSNER    | 18 | 10 | 28 |
| Odette Cancer Centre- Sunnybrook Health Sciences Centre                   | 11118      | 9  | 0  | 9  |
| Ohio State University Comprehensive Cancer Center LAPS                    | LAPS-OH007 | 38 | 6  | 44 |
| Ottawa Hospital and Cancer Center-General Campus                          | 11025      | 4  | 0  | 4  |
| Pacific Cancer Research Consortium NCORP                                  | PCRC       | 22 | 1  | 23 |
| Parkview Regional Medical Center                                          | IN181      | 3  | 11 | 14 |
| Peter MacCallum Cancer Centre                                             | 3003       | 0  | 0  | 0  |
| Piedmont Hospital                                                         | GA027      | 2  | 12 | 14 |
| ProMedica Flower Hospital                                                 | OH012      | 5  | 10 | 15 |
| Puerto Rico Minority Underserved NCORP                                    | SANJUAN    | 7  | 1  | 8  |
| Rabin Medical Center                                                      | 40021      | 0  | 1  | 1  |
| Reading Hospital                                                          | PA107      | 8  | 8  | 16 |
| Rhode Island Hospital                                                     | RI005      | 4  | 6  | 10 |
| Roswell Park Cancer Institute LAPS                                        | LAPS-NY158 | 15 | 2  | 17 |
| Rush University Medical Center                                            | IL043      | 11 | 16 | 27 |
| Rutgers Cancer Institute of New Jersey                                    | NJ066      | 6  | 31 | 37 |
| Saint Joseph Hospital - Orange                                            | CA087      | 2  | 13 | 15 |
| Saint Joseph's Hospital and Medical Center                                | AZ009      | 10 | 13 | 23 |
| Saitama Medical University International Medical Center                   | 42061      | 17 | 0  | 17 |
| Sanford NCI Community Oncology Research Program of the North Central Plai | SANFORD    | 16 | 0  | 16 |
| Saskatoon Cancer Centre                                                   | 11120      | 16 | 0  | 16 |
| Seoul National University Hospital                                        | 43002      | 59 | 0  | 59 |
| Southeast Clinical Oncology Research (SCOR) Consortium NCORP              | SCCC       | 48 | 26 | 74 |
| Stanford Cancer Institute Palo Alto                                       | CA141      | 8  | 1  | 9  |
| State University of New York Downstate Medical Center                     | NY178      | 0  | 6  | 6  |
| Staten Island University Hospital                                         | NY035      | 0  | 3  | 3  |
| Stony Brook University Medical Center                                     | NY184      | 0  | 7  | 7  |
| Stroger Hospital of Cook County Minority Underserved NCORP                | STROGER    | 12 | 3  | 15 |
| Summa Akron City Hospital/Cooper Cancer Center                            | OH055      | 10 | 7  | 17 |
| Sun Yat-sen University Cancer Center                                      | 60021      | 27 | 0  | 27 |
| Sutter Cancer Research Consortium                                         | SUTTER     | 15 | 27 | 42 |
| Technical Resources International                                         | CTTRI      | 0  | 0  | 0  |
| Tel Aviv Sourasky Medical Center                                          | 40019      | 0  | 0  | 0  |
| The Community Hospital                                                    | IN044      | 0  | 8  | 8  |
| The James Graham Brown Cancer Center at University of Louisville          | KY002      | 3  | 8  | 11 |

**Accrual from 6/1/2018 to 5/31/2019**

|                                                                          |            |    |     |     |
|--------------------------------------------------------------------------|------------|----|-----|-----|
| The Methodist Hospital System                                            | TX036      | 2  | 6   | 8   |
| The Research Institute of the McGill University Health Centre (MUHC)     | 11318      | 10 | 0   | 10  |
| The US Oncology Network                                                  | USONC      | 26 | 3   | 29  |
| Thomas Jefferson University Hospital LAPS                                | LAPS-PA121 | 51 | 3   | 54  |
| Thompson Cancer Survival Center                                          | TN038      | 2  | 1   | 3   |
| Tibor Rubin VA Medical Center                                            | CA041      | 4  | 0   | 4   |
| Tom Baker Cancer Centre                                                  | 11134      | 7  | 0   | 7   |
| Trinity Cancer Care Center                                               | ND026      | 1  | 5   | 6   |
| Tulane University Health Sciences Center                                 | LA001      | 0  | 2   | 2   |
| UC Davis Comprehensive Cancer Center LAPS                                | LAPS-CA189 | 15 | 0   | 15  |
| UC Irvine Health/Chao Family Comprehensive Cancer Center                 | CA088      | 9  | 21  | 30  |
| UC San Diego Moores Cancer Center                                        | CA249      | 15 | 5   | 20  |
| UCLA / Jonsson Comprehensive Cancer Center                               | CA006      | 0  | 0   | 0   |
| UCSF Medical Center-Mount Zion                                           | CA136      | 18 | 10  | 28  |
| UF Cancer Center at Orlando Health                                       | FL020      | 2  | 7   | 9   |
| UNC Lineberger Comprehensive Cancer Center LAPS                          | LAPS-NC007 | 6  | 75  | 81  |
| University Health Network-Princess Margaret Hospital                     | 11030      | 28 | 0   | 28  |
| University of Alabama at Birmingham / Deep South Research Consortum LAPS | LAPS-AL002 | 6  | 1   | 7   |
| University of Arkansas for Medical Sciences                              | AR006      | 14 | 5   | 19  |
| University of Chicago Comprehensive Cancer Center LAPS                   | LAPS-IL057 | 10 | 9   | 19  |
| University of Cincinnati/Barrett Cancer Center                           | OH070      | 14 | 338 | 352 |
| University of Colorado Cancer Center LAPS                                | LAPS-CO070 | 27 | 33  | 60  |
| University of Connecticut                                                | CT002      | 0  | 1   | 1   |
| University of Florida Health Science Center - Gainesville                | FL015      | 10 | 52  | 62  |
| University of Illinois                                                   | IL040      | 5  | 5   | 10  |
| University of Iowa/Holden Comprehensive Cancer Center                    | IA018      | 19 | 3   | 22  |
| University of Kansas Cancer Center                                       | KS004      | 26 | 0   | 26  |
| University of Kentucky/Markey Cancer Center                              | KY010      | 1  | 0   | 1   |
| University of Maryland/Greenebaum Cancer Center                          | MD015      | 19 | 7   | 26  |
| University of Massachusetts Memorial Health Care                         | MA009      | 0  | 0   | 0   |
| University of Miami Miller School of Medicine-Sylvester Cancer Center    | FL028      | 16 | 4   | 20  |
| University of Michigan Comprehensive Cancer Center LAPS                  | LAPS-MI014 | 39 | 4   | 43  |
| University of Minnesota/Masonic Cancer Center                            | MN022      | 0  | 0   | 0   |
| University of Mississippi Medical Center                                 | MS005      | 1  | 1   | 2   |
| University of Nebraska Medical Center                                    | NE003      | 4  | 5   | 9   |
| University of Oklahoma Health Sciences Center LAPS                       | LAPS-OK003 | 80 | 92  | 172 |
| University of Pennsylvania/Abramson Cancer Center                        | PA075      | 13 | 2   | 15  |
| University of Pittsburgh Cancer Institute LAPS                           | LAPS-PA015 | 24 | 11  | 35  |
| University of Rochester LAPS                                             | LAPS-NY167 | 15 | 11  | 26  |
| University of South Alabama Mitchell Cancer Institute                    | AL068      | 1  | 2   | 3   |
| University of Tennessee - Knoxville                                      | TN021      | 2  | 8   | 10  |
| University of Tennessee Health Science Center                            | TN030      | 3  | 6   | 9   |
| University of Texas Health Science Center at San Antonio                 | TX059      | 11 | 7   | 18  |
| University of Texas MD Anderson Cancer Center LAPS                       | LAPS-TX035 | 38 | 23  | 61  |
| University of Texas Medical Branch                                       | TX045      | 2  | 3   | 5   |
| University of Texas Southwestern Medical Center LAPS                     | LAPS-TX011 | 42 | 1   | 43  |
| University of Utah - Huntsman Cancer Institute LAPS                      | LAPS-UT003 | 7  | 7   | 14  |
| University of Vermont and State Agricultural College                     | VT004      | 11 | 4   | 15  |
| University of Virginia Cancer Center                                     | VA009      | 22 | 2   | 24  |

**Accrual from 6/1/2018 to 5/31/2019**

|                                                         |            |    |    |    |
|---------------------------------------------------------|------------|----|----|----|
| University of Wisconsin Carbone Cancer Center LAPS      | LAPS-WI020 | 20 | 21 | 41 |
| USC Norris Comprehensive Cancer Center LAPS             | LAPS-CA011 | 15 | 6  | 21 |
| Vanderbilt University - Ingram Cancer Center LAPS       | LAPS-TN008 | 6  | 5  | 11 |
| Vassar Brothers Medical Center                          | NY131      | 3  | 7  | 10 |
| VCU Massey Cancer Center Minority Underserved NCORP     | VCU        | 7  | 8  | 15 |
| Wake Forest University Health Sciences                  | NC002      | 4  | 2  | 6  |
| Walter Reed National Military Medical Center            | MD001      | 1  | 0  | 1  |
| Washington University - Siteman Cancer Center LAPS      | LAPS-MO011 | 77 | 0  | 77 |
| Wayne State University - Karmanos Cancer Institute LAPS | LAPS-MI020 | 56 | 27 | 83 |
| WellSpan Health-York Hospital                           | PA047      | 7  | 8  | 15 |
| West Virginia University Charleston Division            | WV004      | 5  | 15 | 20 |
| West Virginia University Healthcare                     | WV025      | 8  | 22 | 30 |
| Wichita NCI Community Oncology Research Program         | WICHITA    | 16 | 1  | 17 |
| Wisconsin NCI Community Oncology Research Program       | WINCORP    | 8  | 7  | 15 |
| Women and Infants Hospital                              | RI012      | 35 | 16 | 51 |
| Women's Cancer Center of Nevada                         | NV049      | 14 | 0  | 14 |
| Yale University - Yale Cancer Center LAPS               | LAPS-CT018 | 4  | 7  | 11 |
| Yonsei University Health System-Severance Hospital      | 43027      | 17 | 0  | 17 |

# NRG Oncology Summer 2019 Exhibitor Companies

NRG Oncology wishes to acknowledge the following exhibitors:

ASTRAZENECA  
BEST MEDICAL INTERNATIONAL  
CANCER TRIALS SUPPORT UNIT (CTSU)  
CARIS LIFE SCIENCES  
CONVEY  
FOUNDATION MEDICINE  
GENENTECH, A MEMBER OF THE ROCHE GROUP  
IROC GROUP  
MERCK & CO., INC.  
NCI CIRB  
NOVOCURE INC.  
PRELUDE DX  
SEATTLE GENETICS/GENMAB  
SOCIETY OF GYNECOLOGIC ONCOLOGY/FOUNDATION FOR WOMEN'S CANCER

Please take the time to visit the exhibit booths located in:

**Franklin Hall Foyer (4th Floor)**

## Exhibit hours are:

**Friday, July 19, 2019 - 7:00 am - 5:00 pm**

**Saturday, July 20, 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.

## **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**

Best Medical International now encompasses a family of trusted companies and organizations with a proven track record of innovation, quality and service in external beam radiation therapy, brachytherapy and vascular brachytherapy solutions.

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

The CTSU is a service of the NCI, providing information to qualified CTSU members at clinical sites and facilitating their access to NCI funded clinical trials.

## **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).  
Foundation Medicine, Inc.

Foundation Medicine is a world-leading molecular insights company, connecting physicians and their patients to the latest cancer treatments approaches and making medicine a reality for thousands.

## **Merck & Co., Inc.**

For more than a century, Merck has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Today, Merck continues to be at the forefront of research to deliver innovative health solutions and advance the prevention and treatment of diseases around the world.

## **Novocure Inc.**

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

## **Prelude Dx**

PreludeDx was founded with the goal of providing better decision-making tools to breast cancer patients and physicians. Founded in 2009 with technology licensed from University of California San Francisco, PreludeDx has focused on developing breast cancer tools that will impact a patient's treatment decision. Our mission is to provide tools that improve patient outcomes in breast cancer and reduce the overall cost burden to the healthcare system. Patient Focused: We realize that every sample that comes through our laboratory has a patient behind it and it is our job to ensure that we handle each sample with care and provide results back to the patient and physician in a timely manner. PreludeDx exists to take care of the needs of our patients.

Quality First: We will put quality systems and processes first and foremost as we provide the highest quality results to our patients and physicians.

Driving Innovation: PreludeDx will strive to find new innovative tools and processes that assist patients and physicians for the better management of cancer.

DCISionRT is the only test capable of predicting an individual patient's benefit from radiation therapy. Using DCISionRT provides you with 10-year Total and Invasive Recurrence Risk after breast conserving surgery as well as surgery with radiation therapy. No other test can do this.

## **Society of Gynecologic Oncology/Foundation for Women's Cancer**

The Society of Gynecologic Oncology (SGO) is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. As a 501 (c) (6) organization, the SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members and collaborating with other domestic and international organizations. SGO's foundation, the Foundation for Women's Cancer, provides over \$600,000 a year in research grants, prizes and career development awards.

## Seattle Genetics & Genmab

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

## Genmab

### 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).

*Save the Date!*



**NRG ONCOLOGY SEMIANNUAL MEETING**  
**January 9 - 11, 2020**  
**Marriott Marquis - Houston, Texas**

## Notes

[illegible]



## Notes

[illegible]

## Notes

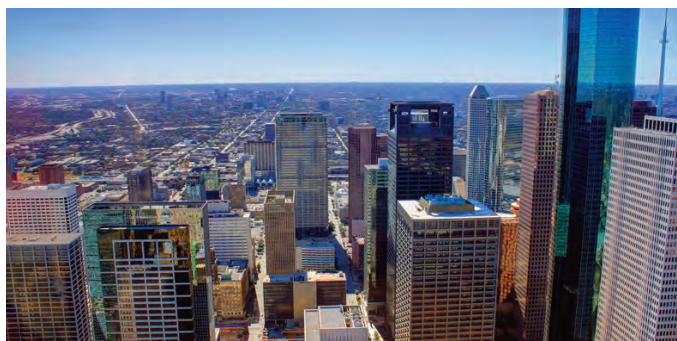
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# Future NRG Oncology Semiannual Meetings

SAVE THE DATES



**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