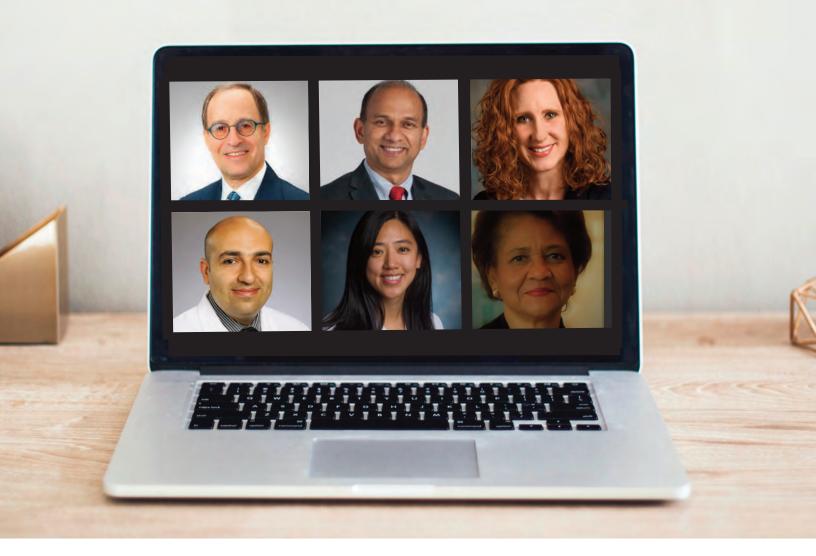


Program Book







NRG Oncology Semiannual Virtual Meeting - July 16-18, 2020

In accordance with the ACCME Accreditation Criteria, 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. Members of the Program Committee were required to disclose all financial relationships and speakers were required to disclose any financial relationship as it pertains to the content of the presentations. A "commercial interest" as any entity producing, marketing, re-selling, or distributing health proprietary entity producing health care goods or services consumed by or used on patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests. "Relevant" financial relationships are financial transactions (in any amount) occurring within the past 12 months that may create a conflict of interest.

All program committee members and speakers were contacted and the conflicts listed below have been managed to our satisfaction. However, if you perceive a bias during a session, please report the circumstances on the session evaluation form.

Please note we have advised the speakers that it is their responsibility to disclose at the start of their presentation if they will be describing the use of a device, product, or drug that is not FDA approved or the off-label use of an approved device, product, or drug or unapproved usage.

The requirement for disclosure is not intended to imply any impropriety of such relationships, but simply to identify such relationships through full disclosure, and to allow the audience to form its own judgments regarding the presentation.

All Committee members were contacted for Disclosure forms, only Committee Members with a potential conflict of interest are listed below.

NAME		Nothing To Disclose	DISCLOSURE <company &="" role=""></company>
Planning Disclosures			
Aghajanian, Carol, MD	Chair - GYN		Advisory Board/Honorarium: AbbVie; Roche; Mersana
Arend, Rebecca, MD	Translational Co- Chair - Ovarian		Advisory Committee/Consulting Fee: Leap Therapeutics; AstraZeneca; Tesaro; Merck; Caris Life Sciences Steering Committee/Consulting Fee: VBL Therapeutics
Backes, Floor, MD	Co-Chair – DT (phase I)		Advisory Board/Consulting Fee: Merck; GSK/Tesaro; Eisai; Genentech; AstraZeneca Teaching/Honorarium: OncLive; ECE Oncology
Barton, Debra, PhD	Co-Chair - CPC	Х	
Bauman, Julie, MD	Head & Neck Co-Chair - CPC		Advisory Board/Consultant/Honorarium: Cue Biopharma
Birrer, Michael, MD, PhD	Chair - DT		Advisory Board: Clovis; AstraZeneca; GSK
Bradley, Jeffrey, MD	Chair - Lung		Scientific Advisory Board/Honorarium: AstraZeneca; Mevion Medical Systems Consulting/Fee: Genentech; Varian
Cooley, Mary, PhD, RN	Co-Chair - CCDR	Х	
DiSilvestro, Paul, MD	Co-Chair - GYN		Consultant/Consulting Fee: AbbVie; AstraZeneca
Edelman, Martin, MD	Co-Chair -Lung		DSMB/Honorarium: AstraZenecaTakeda DSMB Research/Honorarium: GSK Scientific Advisor/Stock Options: Biomarker Strategies; Flame Biosciences Investigator/Research Funding: Nektar; Apexigen; Revolutions Medicine; Mersana
Efstathiou, Jason, MD	PCOR Co-Chair GU		Consulting/Consulting Fee: Blue Earth Diagnostic; Boston Scientific; AstraZeneca Scientific Advisory Board/Honorarium: Boviant Pharma
Feng, Felix, MD	Chair - GU		Consultant/Fee: Janssen; Roivant; Myovant; Astellas
Fusco, Nancy, RN, BSN	Co-Chair - PSC	Х	

Gaffney, David, MD, PhD	Cervix Co-Chair - GYN	Х	
Gaillard, Stephanie, MD, PhD	Co-Chair – DT (phase II)		Speaker/Honorarium: PRIME Author/Royalties: UpToDate Advisory Committee/Consulting Fee: Sermonix Pharmaceuticals; Rigel Advisory Committee/Honorarium: Curio Science
Ganz, Patricia, MD	Co-Chair - PCOR	Х	
George, Thomas, MD, FACP	Chair – Gl colorectal		Research Funding: Bristol-Myers Squibb; Merck; AstraZeneca/MedImmune; Eli Lilly; Bayer; Incyte; Tesaro; Pharmacyclics; Ipsen; Seattle Genetics; Newlink Genetics
Geyer, Charles, MD	Co-Chair - Breast		Speaker/Travel: Genentech/Roche Research/Travel: Daiichi Sankyo
Hensley, Martee, MD	Med Onc Co-Chair - Corpus		Spouse/Employee/Salary: Sanofi Advisory Board/Honorarium: GSK; Tesaro Author/Royalties: UpToDate
Hong, Ted, MD	Chair – GI non- colorectal		DSMB/Honorarium: Novacure Consulting/Honorarium: Synthetic Biologic; Merck
Hudson, Matthew, PhD, MPH	Co-Chair - CCDR	Х	
Ilson, David, MD	Co-Chair – GI non- colorectal		Consulting/Consulting Fee: Roche; AstraZeneca; Merck; Bristol-Myers Squibb; Pieris; Eli Lilly; Bayer; Taiho; Astellas
Kachnic, Lisa, MD	FORTE Co-Chair - CPC	Х	
Klopp Ann, MD	Rad Onc Co-Chair - Corpus	Х	
Konstantinopoulos, Panagiotis, MD	Chair – (Trans. Research) -DT		Advisory Board/Scientific Advisory Committee: Consulting Fee: AstraZeneca; Alkermer Advisory Board/Consulting Fee: Bayer; GSK
Kopetz, Scott, MD, PhD	Chair – GI colorectal		Ownership: MolecularMatch; Navire Advisory Role: Roche; Genentech; EMD Serono; Merck; Karyopharm Therapeutics; Amal Therapeutics; Navire; Symphogen; Holy Stone; Biocartis; Amgen; Novartis; Eli Lilly; Boehringer Ingelheim; Boston Biomedical; AstraZeneca/MedImmune; Bayer Health; Pierre Fabre; Redx Research Funding: Amgen; Sanofi; Biocartis; Guardian Health; Array BioPharma; Genentech/Roche; EMD Serono; Medimmune; Novartis; Eli Lilly
Lankes, Heather, PhD, MPH	Translational Science Co-Chair - GYN	Х	
Le, Quynh- Thu, MD	Chair - Head & Neck		Research/Honorarium: Amgen Consulting/Travel Expenses: Merck; Varian; Pfizer; Genentech Consulting/Travel Expenses/Honorarium: Grail
Leath, Charles, III, MD	Chair - Cervix		Advisory Board/Honorarium: AbbVie; Clovis; Eisai Contracted Research/Support to Institution: AstraZeneca; Celsion; Tesaro (GSK); Roche/Genentech; AbbVie; Syros; Agenus; Immunogen; Seattle Genetics Speaker/Honorarium: PeerView CME
Levine, Doug, MD	FORTE CPC – Chair Translational Co- Chair - Corpus	Х	
Licavoli, Cynthia, RN, BSN	Co-Chair - PSC	Х	
Liu, Joyce, MD	Co-Chair - Ovarian	Х	
Mamounas, Eleftherios, MD	Chair - Breast		Advisory Board/Speakers Bureau; Honorarium: Consulting Fees: Genentech/Roche; Exact Sciences Advisory Board/Consulting: Biotheranostics; Dachii Sankyo Consulting/Fees: Merck
Mayadev, Joyti, MD	Co-Chair - Cervix		Consulting/Honorarium: AstraZeneca Co-Chair Cervix Comm./Grant Fees: NRG
Moore, Kathleen, MD	Chair - Ovarian		Consulting/Honorarium: Aravive; AstraZeneca; AbbVie; Eisai; Immunogen; GSK/Tesaro; Genentech/Roche; Mersana; Merck; Tarveda; VBL Therapeutics; Vavotar; Myrid; Perthera Study PI/Research Support to Institution: PTC Therapeutics' Eli Lilly; Genentech; Merck
Morgan, Todd, MD	Co-Chair - GU	Х	
Movsas, Benjamin, MD	Co-Chair - PCOR		Co-Investigator/Research Support: Varian; ViewRay; Philips
O'Cearbhaill, Rosin, MD	Chair - DT		Advisory Committee/Honorarium: Regeneron
	Chair - Corpus		Consulting/Fee: Merck; AstraZeneca; Tesaro; Easai; Clovis; GOG Foundation
Powell, Matthew, MD	0.14.11		j

			Editorial Advisor/Consulting Fee: Caribon Publishing
Sartor, Oliver, MD	Co-Chair - GU		Advisory/Consulting/Research/Grant Funding: Advanced Accelerator Applications; AstraZeneca; Bayer; Constellation;
			Dendreon; Janssen; Progenics; Sanofi
			Advisory/Consulting: Blue Earth Diagnostics, Inc.; Bavarian Nordic; Bristol-Myers
			Squibb; Clarity Pharmaceuticals; EMD Serono; Fusion; Myovant; Myriad; Noria
			Therapeutics, Inc.; Novartis; Noxopharm; POINT Biopharma; Pfizer; Tenebio; Telix; Theragnostics
			Research Grant/Funding: Endocyte; Innocrin; Invitae; Merck; SOTIO
Schilder, Russell, MD	Co-Chair – DT		Consultant/Consulting Fee: Incyte; Flatiron
	(phase II)		Chair/DSMB/Consulting Fee: Celsion
Swisher, Elizabeth, MD	Translational Chair	Х	Ad Board/Honorarium: Clovis; Immunogen
Swisher, Elizabeth, MD	- Ovarian	^	
Sturgis, Erich, MD, MPH	Co-Chair - Head & Neck		PI/ Research Award: Roche Diagnostics, Inc.
Thomas, Terry, MS, CCRC	Chair - PSC		Founder/Consultant/Consulting Fee/Ownership Interest: GammaTile; GT MedTech
Wenzel, Lari, MD	Co-Chair - PCOR	Х	
White, Julia, MD	Co-Chair - Breast	Х	
Wong, Stuart, MD	Co-Chair - Head & Neck		Research Support: Merck; GSK; Hoopika
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Alvarez, Ronald, MD	GYN		Consultant/Honorarium: Unleash
			Ad Board/Honorarium: Vaccitech; Genentech; AbbVie; Eisai DSMB Consultant/Honorarium: Papivax
Backes, Floor, MD	DT		Advisory Board/Consulting Fee: Merck; GSK/Tesaro; Eisai;
			Genentech; AstraZeneca Teaching/Honorarium: OncLive; ECE Oncology
Bandos, Hanna, PhD	FORTE	Х	reaching, nonoranum. Onetive, Let oncology
Barton, Debra, PhD	Co-Chair - CPC	Х	
Bauman, Julie, MD	Head & Neck		Advisory Board/Consultant/Honorarium: Cue Biopharma
	Co-Chair - CPC		
Berlin, Ale, MD, PhD	GU	X	
Blackburn, Megan	PSC	Х	Danks and set with selection of Committee of
Borges, Virginia, MD	Breast	Х	Protocol study chair/Advisory Committee/Consulting Fee: Seattle Genetics
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Chen, Ron, MD, MPH	CCDR PCOR GU		Consultant/Consulting Fee: AbbVie; Accuray; Blue Earth Diagnostics
Chung, Christine, MD	Head & Neck		Advisory Board/Honorarium: Sanofi
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Cooley, Mary, PhD, RN	Co-Chair - CCDR	Х	
Corley, Doug, MD, PhD	FORTE		Contracted Research/Support: Pfizer; Medial Research
Creasman, William, MD	GYN	Х	
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Dawson Laura MD	GI - non		Vice Chair, Rectal Anal Task Force: Honorarium: NCI Co-Inventor/Licensing Fee: RaySearch
Dawson, Laura, MD	GU GU		PI/Research Funding/Consulting Fee: Boston Scientific
Desai, Nail, MD	GI	Х	- 17 Nessearch Funding/ consulting Fee. Doston scientific
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Dicker, Adam, MD	PCON		Foundation Challenge Grant Advisory: Roche; Janssen; Self Care Catalysts; Oncohost; Varian; Accordant;
Dill, Jennifer, BS, CCRP	PSC	х	Envisino Health Partners

DiSilvestro, Paul, MD	Co-Chair - GYN		Consultant/Consulting Fee: AbbVie; AstraZeneca
Dorth, Jenny, MD	GI	Х	
Dueker, Jeffrey, MD	FORTE	Х	
Edelman, Martin, MD	Co-Chair -Lung		DSMB/Honorarium: AstraZenecaTakeda DSMB Research/Honorarium: GSK Scientific Advisor/Stock Options: Biomarker Strategies; Flame Biosciences Investigator/Research Funding: Nektar; Apexigen; Revolutions Medicine; Mersana
Efstathiou, Jason, MD	PCOR Co-Chair GU		Consulting/Consulting Fee: Blue Earth Diagnostic; Boston Scientific; AstraZeneca Scientific Advisory Board/Honorarium: Boviant Pharma
Ellis, Rod, MD	GU		Research/Fees: Boston Scientific
Fakih, Marwan, MD	GI		Speaker/Consultant/Honorarium/Consulting Fee: Amgen Consulting/Advisory/Consulting Fee: Pfizer; Bayer; Array Speaker/Honorarium: Guardant360
Feng, Felix, MD	Chair - GU		Consultant/Fee: Janssen; Roivant; Myovant; Astellas
Gaffney, David, MD, PhD	Cervix Co-Chair - GYN	Х	
Ganz, Patricia, MD	PCOR	Х	
Gay, Hiram, MD	GU	Х	
George, Thomas, MD, FACP	Chair – GI colorectal		Research Funding: Bristol-Myers Squibb; Merck; AstraZeneca/MedImmune; Eli Lilly; Bayer; Incyte; Tesaro; Pharmacyclics; Ipsen; Seattle Genetics; Newlink Genetics
Geyer, Charles, MD	Co-Chair - Breast		Speaker/Travel: Genentech/Roche Research/Travel: Daiichi Sankyo
Gillison, Maura, MD	Head & Neck		Consulting: Merck; Roche; Roche Dianostics GmbH; EMD serono; Bayer Healthcare; BioNTech; Kura Oncology; Shatucks Lab; Bristol-Myers Squibb; Genocea Biosciences
Goldstein, Jay, MD	FORTE	Х	
Gondi, Vinai, MD	Lung PCOR	Х	
Grossman, Sadie, MS	PSC	Х	
Harari, Paul, MD	Head & Neck	Х	
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Higgins, Kristin, MD	Lung		Consultant/Advisory Board: AstraZeneca
Hinrichs, Christian, MD, PhD	Cervix		Cooperative Research Agreement/Research Funding: Kite Pharma; T Cure Biosciences Inventor/Patents/Royalties: NIH
Ho, Alan, MD	Head & Neck		Consultant/Consulting Fee: McGivney Global Advisors Advisory Board/Consulting Fee: Prelude Therapeutics; Kura Oncology
Holeva, Karen, MS	PSC	Х	
Hong, Ted, MD	Chair – GI non- colorectal		DSMB/Honorarium: Novacure Consulting/Honorarium: Synthetic Biologic; Merck
Hudson, Matthew, PhD, MPH	Co-Chair - CCDR	X	
Hurwitz, Mark, MD	GU	Х	Control No. Contro
Ilson, David, MD	Co-Chair – GI non- colorectal	х	Consulting/Consulting Fee: Roche; AstraZeneca; Merck; Bristol-Myers Squibb; Pieris; Eli Lilly; Bayer; Taiho; Astellas
Iyengar, Puneeth, MD, PhD	Lung	X	
Jacobsen, Paul, PhD	Head & neck		
Jordan, Richard, MD Kachnic, Lisa, MD	FORTE Co-Chair - CPC	X	
Koh, Wui-Jin, MD	Cervix	Х	
Kopetz, Scott, MD, PhD	Chair – GI colorectal		Ownership: MolecularMatch; Navire Advisory Role: Roche; Genentech; EMD Serono; Merck; Karyopharm Therapeutics; Amal Therapeutics; Navire; Symphogen; Holy Stone; Biocartis; Amgen; Novartis; Eli Lilly; Boehringer Ingelheim; Boston Biomedical; AstraZeneca/Medlmmune; Bayer Health; Pierre Fabre; Redx Research Funding: Amgen; Sanofi; Biocartis; Guardian Health; Array BioPharma; Genentech/Roche; EMD Serono; Medimmune; Novartis; Eli Lilly
Koyfman, Shlomo, MD	Head and Neck		Advisory Board/Consulting: Merck Investigator/Research: Merck; Bristol-Myers Squibb Autor/Honorarium: UpToDate

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Lankes, Heather, PhD, MPH	Translational Science Co-Chair - GYN	х	
Le, Quynh- Thu, MD	Chair - Head & Neck		Research/Honorarium: Amgen Consulting/Travel Expenses: Merck; Varian; Pfizer; Genentech Consulting/Travel Expenses/Honorarium: Grail
Leath, Charles, III, MD	Chair - Cervix		Advisory Board/Honorarium: AbbVie; Clovis; Eisai Contracted Research/Support to Institution: AstraZeneca; Celsion; Tesaro (GSK); Roche/Genentech; AbbVie; Syros; Agenus; Immunogen; Seattle Genetics Speaker/Honorarium: PeerView CME
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Liang, Margaret, MD	CCDR	Х	
Liao, Xing, MD	Lung	Х	
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Lima, Caio Roche, MD	GI		Honoraria/Eisai; Consulting Fee/Consultant: Incyte, AGOS
Lin, Steven, MD, PhD	Lung GI - non		PI/Grant Funding: Hitachi Chemical Diagnostics, Inc; Beyond Spring Pharmaceuticals, Inc PI/Licensing/Advisory Board: STCube Pharmaceuticals Speaker/Board Member/Advisory Board Fees: AstraZeneca Speaker: Varian Medical Systems
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Mamounas, Eleftherios, MD	Chair - Breast		Advisory Board/Speakers Bureau; Honorarium: Consulting Fees: Genentech/Roche; Exact Sciences Advisory Board/Consulting: Biotheranostics; Dachii Sankyo Consulting/Fees: Merck
Matin, Khalid, MD	GI - non		Consulting/Fee: MedTrend Intl. LLC
Mayadev, Joyti, MD	Co-Chair - Cervix		Consulting/Honorarium: AstraZeneca Co-Chair Cervix Comm./Grant Fees: NRG
Mell, Loren, MD	Head & Neck	Х	
Michaelson, Dror, MD, PhD	GU	Х	
Morgan, Todd, MD	Co-Chair - GU	Х	
Morris, Van Karlyle, MD	GI		Advisory Board/Research/Salary/Honorarium: Array Biopharma Data Safety Monitoring/Fee: Incyte Research/Salary: Bristol Myers Squibb; EMD Serano: AstraZeneca
Movsas, Benjamin, MD	Co-Chair - PCOR		Co-Investigator/Research Support: Varian; ViewRay; Philips
Nguyen, Paul, MD	GU		Consulting; Trial Steering Committee; Consulting Fee: Janssen Advisory Board/Consulting Fee: Bayer Consulting/ Consulting Fee: Cota; Augmenix; Boston Scientific Grant to Support Investigator Initiated Trials/ Grant to Institution: Janssen; Astellas; Bayer
Nguyen, Quyna, MD	Lung	Х	
O'Cearbhaill, Rosin, MD	Chair - DT		Advisory Committee/Honorarium: Regeneron
Ogunsanya, Cherita, MBA	PSC	Х	
Passarello, Mimi, MBA	PSC	Х	
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Rimner, Andreas, MD	Lung		Independent Contractor/Research/Research Grant: Merck; Pfizer PI/Grant to Institution/Research Grant: Varian Medical Systems; Boehringer Ingelheim; Pfizer; AstraZeneca; Merck
			Consultant/Consulting Fee: Nore Health
Robinson, Cliff, MD	Lung		Consulting/Consulting Fee/Grants to Institution: Varian
neamach, chin, ma			Consulting/Consulting Fee/Stock Options: Radiaolgica
			Grants to Institution: Merck
			Consulting/Consulting Fees: EMD Serono; AstraZeneca
Rodriguez, Cristina, MD	Head & Neck		Advisory Board Member/Consulting Fee: Cue Biopharma CME Faculty/Honorarium: Clinical Care Options
Romesser, Paul, MD	GI – non GI		Contracted Research/Consulting/Consulting Fee/Research Funding: EMD Serono
Rosenthal, David, MD	Head & Neck		Scientific Advisory Board/Honorarium: Merck
Russo, Sandra, MD	CPC	Х	
Saba, Nabil, MD	Head & Neck	Х	
Salem, Mohamed, MD	GI - non		Speaker/Consulting/Honorarium: Taiho Oncology; Merck; Bristol-Myers Squibb
Salem, Monamed, MD	G		Travel Support: Caris Life Science
Samuels, Michael, MD	Head & Neck	Х	
Sandler, Howard, MD	Co-Chair - GU		Member, Trial Steering Committee; Consulting Fee: Janssen
			Advisory/Stock: Radiogel
C I Oli MAD	Co-Chair - GU		Editorial Advisor/Consulting Fee: Caribon Publishing Advisory/Consulting/Research/Grant Funding:
Sartor, Oliver, MD	CO-CHAII - GO		Advanced Accelerator Applications; AstraZeneca; Bayer; Constellation; Dendreon; Janssen; Progenics; Sanofi
			Advisory/Consulting: Blue Earth Diagnostics, Inc.; Bavarian Nordic; Bristol-Myers
			Squibb; Clarity Pharmaceuticals; EMD Serono; Fusion; Myovant; Myriad; Noria Therapeutics, Inc.; Novartis; Noxopharm; POINT Biopharma; Pfizer; Tenebio;
			Telix; Theragnostics
			Research Grant/Funding: Endocyte; Innocrin; Invitae; Merck; SOTIO
Schoen, Robert, MD, MPH	FORTE	Х	
Shaib, Walid, MD	GI		Consultant/Honorarium: Ipsen; Bristol-Myers Squibb; Mylan
			Consultant/Consulting Fees: Lexicon; Blueprint Medicines; Natera; Exelexis
Sherman, Eric, MD	Head & Neck		Advisory Committee/Honorarium: Regeneron; Loxo Oncology/Eli Lilly; Eisai
Siddiqui, Farzan, MD	PCOR		Speaker/Honorarium: Varian Medical Systems
Simone, Charles, MD	Lung	Х	
Sly, Amanda, MS, CIP	PSC	Х	
Soares, Heloisa, MD	GI		Advisory Board/Honorarium: Ipsen; Advanced Accelerator Applications; Exelixis; QED Therapeutics; Lexicon; Natera
Solanki, Adhishek, MD	GU	Х	QED THE apealog, Ecklosh, Natera
Sturgis, Erich, MD, MPH	Co-Chair - Head &		PI/ Research Award: Roche Diagnostics, Inc.
Temkin, Sarah, MD	Neck CCDR		Advisory Committee/Honorarium: GSK/Tesaro
Terrikiri, Sarari, IVID	CCDIK		Expert Opinion/Consulting Fee: Cancer Expert Now
Tran, Phuoc, MD, PhD	GU		PI/Grant: Bayer; Astellas; Reflexon
			Consultant/Ad Board: lanssen/Taris; Noxopharm; Myovant
Truong, Minh Tam, MD	PCOR		ABR Examiner Oral Boards/Travel: American Board of Radiology Editorial Board Member/Honorarium: NCI PDQ Editorial Board
Valicenti, Richard, MD	GU	Х	
Waqar, Saima, MD	Lung	Х	
Weiblen, Melinda, BS	PSC	Х	
Wenzel, Lari, MD	PCOR	Х	
White, Julia, MD	Co-Chair - Breast	Х	
Winslow, Chrisann, RN, MSN	PSC		Ad Board/Honorarium: Seattle Genetics
Wong, Stuart, MD	Co-Chair - Head & Neck		Research Support: Merck; GSK; Hoopika
Wu, Christina, MD	GI		Consultant on Advisory Committee/Honorarium: Signatera; Array
Yom, Sue, MD	Head & Neck		PI/Grant – clinical trial: Bristol-Myers Squibb; Merck; Genentech; BioMimetix
			Author/Royalties: UpToDate; Springer
Zamarin, Dmitriy, MD, PhD	Translational Co- Chair - Cervix		Consultant/Consulting Fee: Agenus; Western Oncolytics Investigator on Clinical Trial/Payment to Institution: Genentech
Zumsteg, Zach, MD	GU	Х	

LAS 07/15/2020

NRG Oncology Virtual Summer Meeting

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Welcome

To The NRG Oncology Virtual Summer Meeting



Our semiannual meetings are so much more than a time to focus on the work of NRG Oncology. It is a time to see old friends, make new ones, and establish connections. Those connections and friendships are the hallmark of NRG Oncology - team science and innovation.

It is impossible to fully translate the in-person experience using a virtual platform, however we are delighted that this temporary circumstance created opportunities for broader engagement. With over 2100 registrants, we are pleased to welcome many first time meeting attendees.

In addition to joining our many sessions, please join the Town Halls and General Session to learn more broadly about the activities and initiatives within NRG Oncology and the broader cancer research community. Also check out some of the on-demand videos that are intended to provide information about the structure and processes of NRG Oncology.

Importantly, we want to acknowledge the circumstances changing our world. From the unprecedented pandemic and its impact across NRG and at our member institutions to the heightened recognition and calls for change around ethnic and racial disparities, our world is very different from when we last met six months ago. The tremendous impact of world events within our community weighs heavily, and we constantly ask "How can NRG help?"

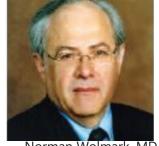
We hope this meeting will offer a small respite, a place to focus on our shared mission and enjoy camaraderie as we come together to focus on improving the lives of cancer patients through clinical cancer research. Coming to an NRG meeting has always been an event to look forward to, and while we'd prefer to shake your hand - we are glad to give a virtual wave and welcome you to the NRG Oncology Virtual Summer 2020 meeting.



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



Robert Mannel, MD NRG Oncology Group Chair



Norman Wolmark, MD NRG Oncology Group Chair

Molmals

Robert S. Mannel, MD

NRG Oncology Virtual Meeting - July 2020

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.



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

Instructions for Claiming CME Credits NEW!

- 1. Click on link the following link: https://www.xcdsystem.com/nrgoncology/credits/index.cfm?ID=pRx9ma
- 2. Enter your Credentials (email and password used for your registration profile)
- 3. Select Credit Type (physician or non-physician)
- 4. Enter your session code(s)
- After adding all your codes click start to complete overall evaluation to claim your CME credits (you must fill out the evaluation in order to claim your credits and receive certificate)
- 6. Submit Evaluation
- 7. To print your certificate click access certificate
- 8. To download/print certificate click email certificate



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.



Disclosure Information

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

Final Listing of Approved CME Credits

The following sessions/workshops have been approved to receive credits accredited by the GOG Foundation for the virtual meeting July 16-19, 2020

WORKSHOP AGENDAS	Thursday	Friday
Breast Cancer Committee		1.5
Cancer Prevention and Control Committee	2	
Cancer Care Delivery Research	2	
Cervix Cancer Subcommittee		1.5
FORTE Protocol Workshop	1.5	
Genitourinary Cancer Committee		1.5
GI Colorectal Cancer Subcommittee		2
GI Non Colorectal Cancer Subcommittee		2
Gynecologic Cancer Committee		1
GYN Developmental Therapeutics workshop/Phase I Committees		1.5
Head and Neck Cancer Committee		1.5
Lung Cancer Committee		1.5
Patient Centered Outcomes Research (PCOR) Committee	1.5	
Ovarian Cancer Subcommittee		2
Uterine Corpus Subcommittee		2
PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD's		
PSC-Clinical Trial Nurse/Clinical Reseach Assoc. Educational Session A Morning	2	
PSC-Clinical Trial Nurse/Clinical Reseach Assoc. Educational Session B Afternoon	1.5	

NRG Oncology Virtual Summer Meeting

Stay connected virtually with updates and announcements from the NRG Oncology Semiannual Meeting 2020 on Twitter and Facebook





Twitter

JOIN The Conversation On Twitter: @NRGONC #NRG2020



Facebook

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



Instagram @NRGOnc



LinkedIn

https://www.linkedin. com/company/nrg-oncology-foundation-inc/?viewAsMember=true







NRG Oncology Virtual Summer WHAT'S NEW!

- CME Credits -New sign in process instructions (see page 10)
- NRG Town Hall with Dr. Ned Sharpless, NCI Director
- Committee sessions will be offered via Zoom. Registered attendees will be provided access to the meeting landing page and webcasts.
 - -Times are Eastern Time (ET) (GMT -4) All Sessions 90 minutes unless otherwise noted-





NRG Oncology welcomes the NRG Membership and stakeholders to join our Virtual Summer 2020 meeting!

Our core goals for the meeting include

Advancing our research through the continuum from concept development to reporting results and engaging our membership in that process through the meeting.

Meetings are open to all members and special webcasts include

- NRG Town Hall with Dr. Ned Sharpless, NCI Director
- NRG General Session
- NCORP Town Hall
- Digital Health
 Symposium

Committee sessions will be offered via Zoom. Registered attendees will be provided access to the meeting landing page and webcasts.





NRG ONCOLOGY SUMMER 2020 OF TUAL MEETING

Times are Eastern Time (ET) (GMT -4)
All Sessions 90 minutes unless otherwise noted

Thurso	lay, July 16, 2020
10:00	Protocol Support Committee CTN/CRA Educational Workshop A (2 hours)
11:30	NRG NCORP FORTE Protocol Workshop
1:00	Protocol Support Committee CTN/CRA Educational Workshop B
1:00	Health Disparities Committee
2:45	Cancer Prevention and Control Committee
3:00	NRG Digital Health Symposium
4:30	Patient Centered Outcomes Research Committee
6:00	NRG NCORP RB Concept Review (NCORP Exec. Cmte. Only)

Friday, July 17, 2020

8:00 Developmental Therapuetics Committee

10:00 NRG Townhall with the NCI Director

11:15 Session 1 -

NRG NCORP Townhall Breast Cancer Committee Brain Tumor Committee Cervix Cancer Subcommittee Corpus Cancer Subcommittee

1:00 Session 2 -

GI Non-Colorectal Cancer Subcommittee Head and Neck Cancer Committee Ovarian Cancer Subcommittee Cancer Care Delivery Research Committee

2:45 Session 3 -

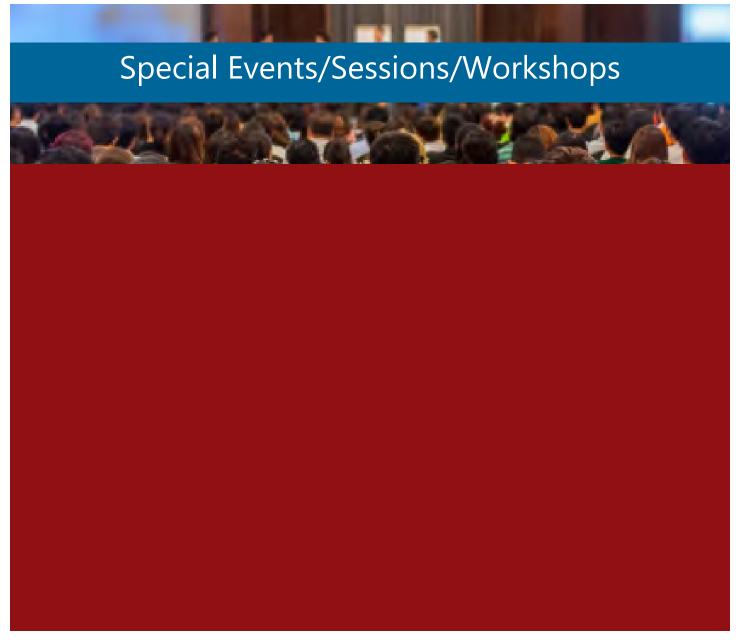
GI Colorectal Cancer Subcommittee Genitourinary Cancer Committee Lung Cancer Committee Gyncologic Cancer Committee

4:30 NRG General Session

Saturday, July 18

10:00 NRG Research Strategy Committee (Committee Members Only) 2 Hours

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NRG Oncology

Clinical Trial Nurse & Clinical Research Associate

Workshop - Educational Sessions

Held during the NRG Oncology Virtual Summer Meeting Thursday, July 16, 2020 - 10:00am-12:00pm ET, 1:00-2:30pm ET

Session 1 Speakers & Topics:

Karen Holeva, BS Megan Rossman Blackburn

Welcome Remarks CTSU

Mimi Passarello, MBA Amanda P. Sly, MS, CIP

Headquarters / Audits CIRB

Jennifer Dill, BS, CCRP

Best Practices for Remote Trial Coordination

day will teach participants about the nature and preparation needed for NCI-mandated Quality Assurance Audits, help attendees identify current procedures and approval with CTSU, Protocol Development, and CIRB, and will identify and discuss best practices for remote trial coordination and program management to integrate into practice. The second session will focus on dietary changes to alleviate stress and tension, mindfulness, medidation, and breathing techniques for stress and tension.

The first educational session of the

Session 2 Speakers & Topics:

Karen Holeva, BS Welcome Remarks

Cherita N. Ogunsanya, MBA, RD, LD

Diet and Nutrition

Sadie Grossman, MS Yoga Therapy, C-IAYT Mindfulness for the Provider Movement, Medidation and Mindfulness





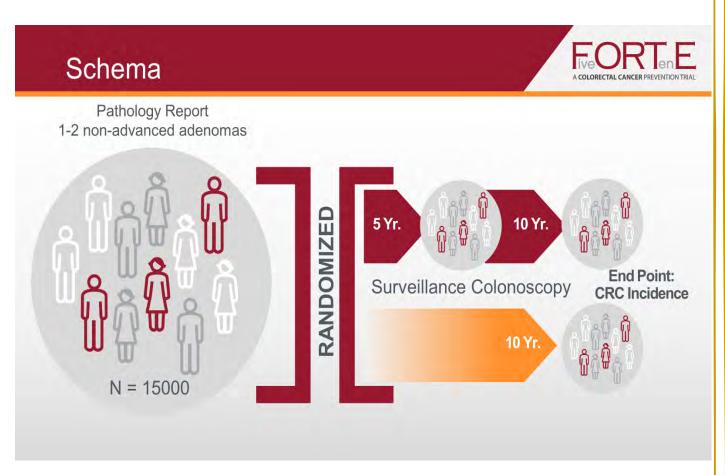
@NRGOnc





NRG Oncology FORTE Trial Kick-Off Workshop July 16, 2020 at 11:30 am EDT

What is the FORTE Trial? FORTE (Five or Ten Year Colonoscopy for 1-2 Non-Advanced Adenomatous Polyps) is a colorectal cancer prevention study to determine whether people with 1 or 2 benign polyps should have a repeat colonoscopy exam at 10 years or at 5 and at 10 years. The best timing for a repeat colonoscopy is not known. Do participants need an exam at 5 years? That is the question that needs answering. FORTE will randomize 15,000 participants to one of two schedules for repeat colonoscopy (5 and 10 years vs. 10 years). FORTE will measure and compare the colorectal cancer incidence rates in the two groups and see if the cancer rates are similar. If the cancer rates are non-inferior to each other, then in the future, a 5-year follow-up surveillance colonoscopy exam may not be necessary.



Please join us for the FORTE Trial Kick-Off Workshop at the NRG Oncology Virtual Summer Meeting. This workshop is for CRAs/CTNs, Pls and Gastroenterologists who want to learn more about this exciting trial.

Each person must pre-register to attend this workshop. Please go to the NRG Oncology website at www.nrgoncology.org to register for this workshop by July 7, 2020.



NRG Oncology **Digital Health Symposium**Workshop - Educational Sessions

Held during the NRG Oncology Virtual Summer Meeting Thursday, July 16, 2020 - 3:00pm ET

Speakers & Topics:

"Clinical Trials Digital Engagement in Adapative Phase"



Krishna Gunturu, MD
Program Director, Cancer Survivorship
Associate Research Director, Clinical
Cancer Research at Lahey Health Cancer
Institute
Assistant Professor at Tufts University

#NRG2020

Program Co-Chairs:



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



Sanjay Aneja, MD
Yale School of Medicine

"Hugo: Transforming Data Research by Connecting People and Data"



Leslie Krumholz, JD CEO at Hugo PHR



Dave Hutten *VP Product at Hugo PHR*













Session to be held during the NRG Oncology Virtual Summer Meeting on Friday, July 17, 2020 from 10:00-11:00am ET. Panelist questionaire to follow speakers.

Dr. Ned Sharpless is the Director of the National Cancer Institute and previously served as the Director of the University of North Carolina Lineberger Comprehensive Cancer Center as well as served for seven months as the Acting Commissioner for Food and Drugs at the US FDA. Dr. Sharpless is currently a member of the Association of American Physicians and the American Society for Clinical Investigation, has authored 160 original scientific papers, reviews, and book chapters, is an inventor on 10 patents, and cofounded two clinical-stage biotechnology companies: G1 Terapeautics and Sapere Bio.

Program Chair and Opening Remarks:



Walter J. Curran, Jr., MD

NRG Oncology Presiding Group Chair

Executive Director of the Winship Cancer Institute of Emory University













NRG Oncology Town Hall

Friday, July 17, 2020 10-11:00 AM ET

Opening/Brief Remarks Walter J. Curran, Jr., M.D.

NRG Oncology Presiding Group Chair

NCI Directors Update Norman "Ned" Sharpless, MD

Director, National Cancer Institute

Question & Answer Panelists - 3 Chairs, 2 NCORP PI



NRG Oncology NCORP Town Hall

Held during the NRG Oncology Virtual Summer Meeting Friday, July 17, 2020 - 11:15am-12:45pm ET

Speakers & Topics:



Robert Schoen, MD, MPH

NRG-CC005 Study Chair

"NRG-CC005: FORTE (Five or ten year colonoscopy for 1-2 non-advanced adenomatous polyps)"



Douglas Levine, MD

NRG-CC008 Study Chair

"NRG-CC008: A NonRandomized Prospective
Clinical Trial Comparing the
Non-Inferiority of
Salpingectomy to SalpingoOophorectomy to Reduce the
Risk of Ovarian Cancer
Among BRCA1 Carriers
[SOROCk]"

Program Chair:



Deb Bruner, PhD, RN NRG NCORP Prinicpal Investigator

"Welcome"
"NRG NCORP Updates"



Worta McCaskill-Stevens, MD Chief, Community Oncology & Prevention Trials Research Group "NCI NCORP Report"



Ann Geiger, PhD
Scientific Director of Cancer Care
Delivery Research in the NCI
NCORP

"Measuring Organizational Context in NCORP CCDR"











AGENDA NCORP TOWN HALL Friday July 17, 2020 11:15AM – 12:45PM EST

Welcome	Deb Bruner, PhD, RN, NRG NCORP PI
NRG NCORP Updates	
NRG-CC005: FORTE (Five or ten year colonoscopy for 1-	Robert Schoen, MD, MPH, NRG-CC005 Study
2 non-advanced adenomatous polyps	Chair
NRG-CC008: A Non-Randomized Prospective Clinical	Douglas Levine, MD, NRG-CC008 Study Chair
Trial Comparing the Non-Inferiority of Salpingectomy to	
Salpingo-Oophorectomy to Reduce the Risk of Ovarian	
Cancer Among BRCA1 Carriers [SOROCk]	
Q&A – Open Discussion	
NCI NCORP Report	Worta McCaskill-Stevens, MD, Chief,
	Community Oncology and Prevention Trials
	Research Group
Measuring Organizational Context in NCORP CCDR	Ann Geiger, PhD, Scientific Director of
	Cancer Care Delivery Research in the NCI
	Community Oncology Research Program
Q&A – Open Discussion	



NRG Oncology General Session

Held during the NRG Oncology Virtual Summer Meeting Friday, July 17, 2020 - 4:30-6:00pm ET

Program Chairs:



Walter J. Curran, Jr., MD

NRG Group Chair

Executive Director of Winship Cancer
Institute of Emory University



Robert Mannel, MD

NRG Group Chair

Director of the Stephenson Cancer

Center of the University of Oklahoma



Norman Wolmark, MD

NRG Group Chair

Director of the National Cancer

Institute Cooperative Group Clinical

Trials at University of Pittsburgh

Medical Center Hillman Cancer Center

Speakers & Topics:

NRG Research Center Mitch Machtay, MD NRG Deputy Group Chair, Research

NRG Statistics & Data Management Center James Dignam, PhD NRG Group Statistician

NRG NCORP Research Base Deborah Watkins-Bruner, RN, PhD, FAAN NRG NCORP Contact Pl

NRG Biobanking Richard Jordan, DDS, PhD NRG Biospecimen Bank Contact PI

NRG Top Accruing Institutions &
Membership Updates
David Miller, MD
NRG Deputy Group Chair, Membership

NRG Publications & Communications
Harry Bear, MD
NRG Deputy Group Chair, Publications &
Communications









NRG Oncology General Session Agenda

Friday, July 17, 2020 4:30 – 6:00pm ET

Opening Walter J. Curran, Jr., M.D.

NRG Oncology Presiding Group Chair

NRG Group Chairs Remarks Walter J. Curran, Jr., M.D.

Norman Wolmark, M.D. Robert Mannel, M.D.

NRG Research Center Mitch Machtay, M.D.

NRG Deputy Group Chair, Research

NRG Statistics and Data Management

Center

James Dignam, Ph.D.
NRG Group Statistician

NRG NCORP Research Base Deborah Watkins-Bruner, RN, Ph.D.,

FAAN

NRG NCORP RB Contact Principal Investigator

NRG Biobanking Richard Jordan, DDS, Ph.D.

NRG Biospecimen Bank Contact Principal

Investigator

Top Accruing Institutions & David Miller, M.D.

Membership Update Deputy Group Chair for Membership

NRG Publications & Harry Bear, M.D.

Communications Deputy Group Chair for Publications and

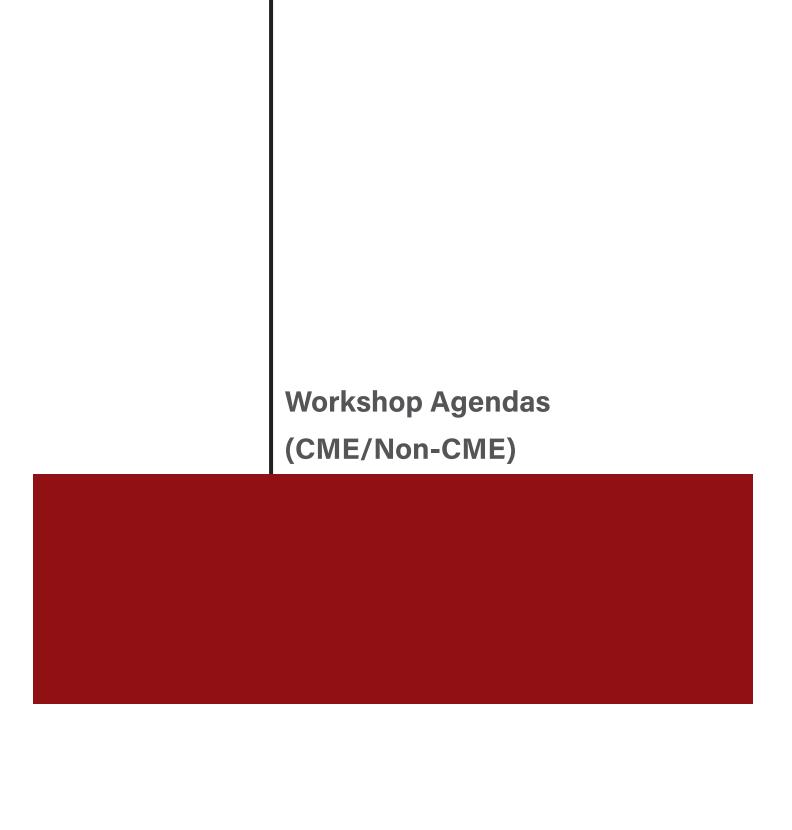
Communications

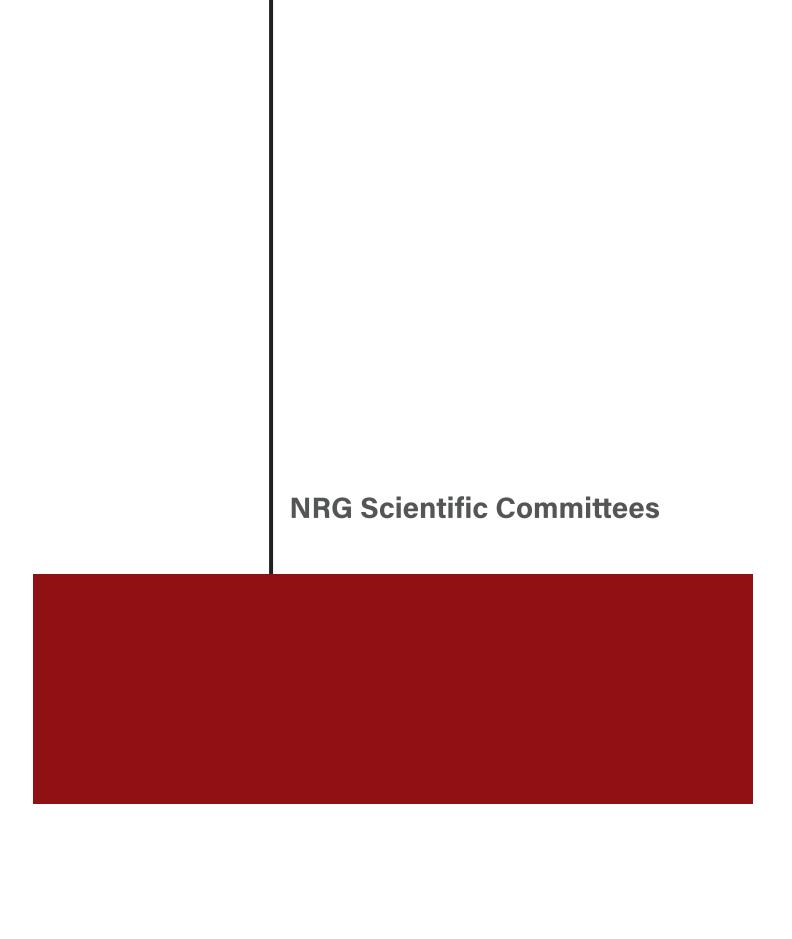
NRG Board of Directors Robert Mannel, M.D.

Chairman of the Board

Closing Remarks Walter J. Curran, Jr., M.D.

NRG Oncology Presiding Group Chair





Brain Tumor Committee Meeting Agenda

Date: Friday, July 17, 2020
Start and End Time: 11:15 AM – 12:45 pm EDT
Chair: Minesh P. Mehta, MD

- 1. Introduction: Clinical trials and NRG/COVID: Mehta 5 min
- 2. Burri: Pre-operative vs. post-operative SRS for brain metastases
 - a. Present finalized version to Brain Committee (5 min presentation, 5 min discussion)
 - b. Slated to go to Research Strategy at the July meeting
- 3. Sperduto/Kotecha: Ipilimumab/nivolumab + SRS vs. FSRT for melanoma brain metastases
 - a. Present finalized version to Brain Committee (5 min presentation, 5 min discussion)
 - b. Slated to go to Research Strategy at the July meeting
- 4. Puduvalli/Gondi: EORTC adult medulloblastoma concept
 - a. Present finalized version to Brain Committee (5 min presentation, 5 min discussion)
 - b. Slated to go to Research Strategy at the July meeting
- 5. Concepts (all 5 min presentation, 5 min discussion; 10 min total) for review: Review 4 concepts
 - a. Rimas: IDO inhibitor (discuss final design for later submission to RSC, not July)
 - b. Kim: Advanced imaging based GBM RT (discuss final design)
 - c. Riggins/Sengupta: Mebendazole for meningioma
 - d. Aulakh: Concept 1 from ABTC
 - e. Umemura: Concept 2 from ABTC
- 6. Wrap-up: 5 min

Breast Cancer Committee Agenda

Date: Friday, July 17, 2020
Start and End Time: 11:15 am – 12:45 pm EDT
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

11:15 – 11:30	Report from the Breast Working Group Meeting	Eleftherios Mamounas, MD Julia White, MD
11:30 – 11:40	ComboMATCH Phase 2 Trial of Fulvestrant and Binimetinib in Patients with HR-Positive Metastatic NF1 Lost Breast Cancer	Matthew Ellis, MD/Bora Lim, I
11:40 – 11:55	NSABP B-43- A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma In Situ Resected by Lumpectomy	Melody Cobleigh, MD
11:55 – 12:10	NRG BR-007: A Phase III Clinical Trial to Evaluate Omission of Post Lumpectomy Breast Radiation in Node-Negative Hormone Sensitive Breast Cancer with a Low Oncotype Recurrence Score	Julia White, MD
12:10 – 12:25	ALLIANCE A011801 COMPASS HER2 Trials Examining Escalating and De-Escalating Therapy in HER2-positive Breast Cancer: Optimizing Treatment in Residual Disease (COMPASS HER2 RD): A Double-Blinded, Phase III Randomized Trial	Virginia Borges, MD
	Immunotherapy Trials	
12:25 – 12:45	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	

MD

Cancer Prevention and Control Meeting

Date: Thursday, July 16, 2020 Start and End Time: 2:45 pm – 4:15 pm EST

Chairs Lisa Kachnic, MD; Douglas A. Levine, MD Vice Chairs Debra Barton, PhD; Julie Bauman, MD

Learning Objectives

Following this activity, participants will be better able to:

- 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
- 2:45pm 2:50pm: Opening Remarks Lisa Kachnic, MD; Douglas Levine, MD, Cancer Prevention and Control Chairs
- 2:50pm 3:05pm: Ceclia Lee, Dr. P.H.,R.N., Division of Cancer Prevention, National Cancer Institute

 Symptom management implementation priorities for community oncology/NCORP settings.
- 3:05pm 3:15pm: Sandra Russo, MD NCI/DCP Cancer Prevention and Control update
- 3:15pm 3:25pm: Question and Answer
- 3:25pm 3:30pm: Top Accruing sites to Cancer Control Studies Deb Barton, PhD, RN; Vice Chair, Cancer Control
- 3:30pm 3:40pm: Review of Open Studies NRG CPC Chairs and Co-Chairs
 - 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 [SOROCk]
 - GOG 0278: Before/after Non-radical Surgery Physical Function and QOL
 - NRG-CC003: Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC
 - 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) (NRG Study Champion)
 - EA1151: Tomosynthesis Mammographic Imaging Screening Trial (TMIST)
 - **\$1820:** A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC) (NRG Study Champion)

3:40pm - 4:05pm: Review of Approved Concepts & Protocols in Development - NRG CPC Chairs and Co-Chairs

- NRG-CC005: FORTE Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps
- NRG-CC009: Stereotactic Radiosurgery (SRS) Versus Hippocampal-avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer
- Gynecologic cancer therapy, the Vaginal Microbiome and Patient Symptom Experience
- Impact of Sentinel Lymph Node Mapping on Lymphedema Associated Impairment of Health Related Quality of Life in Endometrial Cancer
- NRG-CC1925: Adaptive Intervention for Smoking Cessation in Women with Breast, Cervical, Endometrial and Vaginal Cancer prior to Radiation Therapy
- CPC Pilot project funded

4:05pm - 4:15pm - Questions

Cancer Care Delivery Research (CCDR) Meeting Agenda

Date: Friday, July 17

Start and End Time: 1:00pm – 2:45pmEST

Co-Chair: Mary Cooley, PhD, RN

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

Learning Objectives

WORKSHOP AGENDA

Following this activity, participants will be better able to:

- 1. Discuss proposed and ongoing NRG cancer care delivery research trials.
- 2. Discuss proposed and ongoing NRG cancer care delivery research trials and cross-cutting aims with disparities.

SPEAKERS

- 3. Identify and prioritize areas of unmet need in cancer care delivery research
- 4. Apply procedures required to design, submit, and implement a research protocol for support by the NRG

1:00 – 1:10pm Welcome and Committee Updates/Information Mary Cooley, PhD; NRG CCDR Chair; Matthew Hudson, PhD; NRG CCDR Vice-Chair 1:10 - 1:20pm NCI CCDR updates Kate Castro, RN, MS, AOCN; Nurse Consultant/Program Director, Healthcare Delivery Research Program 1:20 – 1:35pm Health care delivery research priorities Paul Jacobsen, PhD; Associate Director, NCI Healthcare Delivery Research Program 1:35 - 1:45pm Q&A 1:45 – 1:55pm NRG-CC007CD: Increasing the Dose of Survivorship Ron Chen, MD, MPH; NRG-CC007CD Chair Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy 1:55 – 2:20pm Emerging Concepts Mary Cooley, PhD; Matthew Hudson, PhD Molecular classification-directed care in endometrial Sarah Temkin, MD carcinoma: an observational prospective cohort study Update on Financial Toxicity collaborators Margaret Liang, MD

QUESTIONS / DISCUSSION

Developmental Therapeutics Committee Agenda

Date: Friday, July 17, 2020 Start and End Time: 8:00 AM – 9:30 PM EDT

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 ComboMATCH Trial
- 4. Recommendations for action by the GYN Developmental Therapeutics committee will be summarized.
- 5. Participants will become familiar with the current status of phase I and phase II studies that are under development and activated for accrual.
- 6. Participants will become familiar with the Phase I Membership application and the Phase I Program Procedure Manual.

WORKSHOP AGENDA

COMBINED DT AND PHASE I WORKSHOP AGENDA

Friday, July 17, 2020

Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

Discussion Topic - Current priorities of the Committee

8:00 AM –8:05 AM Introduction, Drs. O'Cearbhaill. Welcome. Review of opportunities for new

investigators.

8:05 AM – 8:10 AM Update on concepts from last meeting, Dr Backes: PI1915 Dr. Moxley, DT 1959 Hensley, DT 1953 Mahdi,

DT1955 Geller, DT 1958 Gaillard, PI1966 Simpkins, DT 2006 Mahdi, Dt 2013 Doll, PI2014 Fuh.

8:10 AM – 9:20 AM Review of new concepts

5-minute presentation of concept (by proposing investigator)

Review of concepts

9:20 AM – 9:30 AM ComboMATCH study and discussion by committee of potential concepts, Dr. O'Cearbhaill (NRG

Representative for the ComboMATCH study).

Concepts Approved from last meeting:

- DT2006 Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer (Haider Mahdi)
- DT2007 A multicohort single-arm trial of DS-8201a, an anti-HER2 antibody-drug conjugate incorporating a DNA topoisomerase I inhibitor in patients with HER2-positive (Hasegawa) – contingent on PTMA outcome

- DT2013 CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer. (Corinne Doll)
- PI2014 Phase IB of AVB500 in combination with carboplatin and paclitaxel or carboplatin and pegylated liposomal doxorubicin (Katherine Fuh)

New Concepts from Rare Tumor Primary:

- RT2029 A Phase I Trial of the MDM2 Inhibitor, AMG-232, Alone and in Combination with Nivolumab in Advanced or Metastatic Extra-Renal Clear Cell Tumors (Eugenia Girda)
- RT2030 A Phase II Trial Evaluation of Pembrolizumab and Lenvatinib in the Treatment of Recurrent Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma (John Farley)
- RT2032 A Phase II Study of Nivolumab and Relatlimab in Recurrent Ovarian Clear Cell Carcinoma (Ken Lin)
- RT2036 A Phase II Trial of Cabozantinib in Combination with Atezolizumab in Patients with Recurrent Clear Cell Ovarian Carcinoma (Ramez Eskander)
- RT2039 A Phase II study of Durvalumab and Cediranib in Recurrent Ovarian Clear Cell Carcinoma (Mihaela Cristea)
- RT2041 Chemotherapy plus anti-PD-L1 and Ablative Radiation Followed by Maintenance anti-PD-L1 and Bevacizumab in Relapsed/Refractory or Locally Advanced Stage III/IV Clear Cell Ovarian Cancer (Brandon Dyer)
- RT2042 A Phase II Study Evaluating PARP-inhibitor in Recurrent Immature Teratoma of the Ovary (Lilian Gien)

QUESTIONS / DISCUSSION

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

List of Studies

Under development:

- **PI1966**, A phase IB study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Simpkins)
- **DT1959**, Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Hensley)
- DT1958, Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Gaillard)
- **DT1953/ComboMATCH EAY191-N1**, Phase II study investigating the efficacy of dual anti-HER2 therapy (T-DM1 and anti-HER2 TKI) with or without chemotherapy in HER2+ serous endometrial cancers (Mahdi)
- **DT2006** Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer (Haider Mahdi)
- DT2007 A multicohort single-arm trial of DS-8201a, an anti-HER2 antibody-drug conjugate incorporating a DNA topoisomerase I inhibitor in patients with HER2-positive (Hasegawa)
- **DT2013** CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer. (Corinne Doll)
- **PI2014** Phase IB of AVB500 in combination with carboplatin and paclitaxel or carboplatin and pegylated liposomal doxorubicin (Katherine Fuh)

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

 NRG-GY022 Assessment of Carboplatin Clearance Predictors: A PK Study to NCI-Sponsored Clinical Trials or Standard of Care Treatments Using Carboplatin (Taylor/ Beumer)

Cervical Cancer Studies:

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

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

Ovarian Cancer and Endometrial cancer studies:

- NRG-GY014 A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid/clear cell carcinoma of the ovary, and recurrent endometrioid endometrial adenocarcinoma (R Eskander) CTEP CRDL LOI. First stage completed accrual August 2019
- NRG- GY021 A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Adams) safety lead-in ongoing

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. Phase III planned to open.
- NRG-GY012, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay) Prior DT safety review

Closed DT/Phase I studies:

Cervical Cancer

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

Endometrial Cancer Studies:

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

Ovarian Cancer Studies

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

QUESTIONS/DISCUSSION/EVALUATION

GI Non-Colorectal Cancer SubCommittee Agenda

Date: Friday, July 17, 2020
Start and End Time: 1:00 pm – 2: pm
Non-Colorectal Chair: Ted Hong, MD David
Non-Colorectal Co-Chair: Ilson, MD, PhD

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

Discussion/Study Information

Meeting AGENDA

Introduction and Opening Remai	rks	Ted Hong, MD David Ilson, MD, PhD						
Review of New Concepts, Upcor	Review of New Concepts, Upcoming and Active Trials							
RTOG 1112	Phase III RCT of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in HCC	Laura Dawson, MD						
NRG GI003	Phase III RCT of Protons vs. Photons for HCC	Ted Hong, MD						
EA2165	Nivolumab after Combined Modality Therapy in Treating Patients with High Risk Stage II-IIIB Anal Cancer	Paul Romesser, MD						
S1815	A Phase III RCT of Gemcitabine, Cisplatin, and Nab-Paclitaxel Versus Gemcitabine and Cisplatin in Newly Diagnosed, Advanced Biliary Tract Cancers	Khalid Matin, MD						
EA2182	A Randomized Phase II Study of De-intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)	Prajnan Das, MD						
S1922	Phase II Study of Ramucirumab and Paclitaxel Versus FOLFIRI in Refractory Small Bowel Adenocarcinoma	Mohamed Salem, MD						
NRG GI006	Phase III RCT of Protons vs. Photons for Esophageal Carcinoma	Steven Lin, MD						
NRG GI007	Phase I trial of chemoradiation and telomolysin for inoperable esophageal and GEJ ACA	Geoff Ku, MD						
NRG GI1976	RPh II study of tislelizumab and chemoradiation followed by adjuvant tislelizumab in PET chemotherapy locally advanced esophageal squamous	Geoff Ku, MD						
NRG GI2022	Ablative RT +/- checkpoint inhibition in IHCC	Ted Hong, MD						

Speaker

GI Colorectal Cancer SubCommittee Agenda

Date: Friday, July 17, 2020

Start Time: 2:45pm

Colorectal Chair: Thomas George, MD, FACP
Colorectal Co-Chair: Scott Kopetz, MD, PhD

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

Discussion/Study Information

Meeting AGENDA

Introduction and Opening Remar	rks	Thomas George, MD Scott Kopetz, MD, PhD
Review of New Concepts, Upcon	ning and Active Trials	
	NCTN Portfolio of NET Studies	Heloisa Soares, MD
	New NET concept	Walid Shaib, MD
	New HIPEC concept	Edward Levine, MD
NRG-CR2003 (ERASure)	Update on Oligometastatic CRC Total Ablative Therapy Concept	Paul Romesser, MD
NRG-GI005	cfDNA as a decision tool for stage II colon cancer treatment	Kyle Van Morris, MD
S0820 (PACES)	Eflornithine & Sulindac for polyp prevention after CRC	Jenny Dorth, MD
NRG-CR1902 (CANCERID)	cfDNA as decision tool for stage III colon cancer treatment	Arvind Dasari, MD
A021502 (ATOMIC)	MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab	Asha Dhanarajan, MD
NRG-GI004/S1610 (COMMIT)	MSI-H mCRC 1L Immunotherapy Study	Caio Rocha Lima, MD
A021703 (SOLARIS)	Vitamin D supplementation in untreated mCRC	Christina Wu, MD
S1613	HER2 Amplified mCRC Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan	Marwan Fakih, MD
A021805/NRG-CR1861 (JANUS)	Non-operative rectal cancer study	William Hall, MD
NRG-GI002 (TNT)	TNT Trial and national rectal cancer studies	Thomas George, MD

Speaker

Genitourinary Cancer Workshop Agenda

Date: Friday, July 17, 2020
Start and End Time: 2:45 pm – 4:15 pm
Chair: Felix Feng, MD

Co-Chairs: Jason Efstathiou, MD; Todd Morgan, MD; Howard Sandler, MD, Oliver Sartor, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

2:45 – 2:50	Opening Remarks and Update	
2:50 – 3:50	Review of Active Trials	
NRG GU002	PhII-III Adjuvant RT Following Radical Prostatectomy \pm Adjuvant Docetaxel (RADD trial)	Mark Hurwitz, MD
NRG GU005	Phase III IGRT & SBRT vs. IGRT & Hypofrax IMRT localized prostate cancer	Rod Ellis, MD
NRG GU007	Phase I/IIR of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer	Dror Michaelson, MD, PhD Zach Zumsteg, MD
NRG GU008 (newly activated!)	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
RTOG 3506	Randomized Phase II Trial of Salvage Radiotherapy With Std vs Enhanced ADT (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features (STEEL trial)	Edwin Posadas, MD Hiram Gay, MD
SWOG/NRG 1806	Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer	Jason Efstathiou, MD

ECOG/NRG EA8185 (newly activated!)	Phase 2 Study of Bladder-SparIng ChemoradiatioN with Durvalumab in Clinical Stage 3, node PosItive URothElial Carcinoma (INSPIRE)	Abhishek Solanki, MD MS Jason Efstathiou, MD
SWOG 1802	Local therapy for M1 prostate cancer, a SWOG study	Richard Valicenti, MD
3:50-4:05	Review of Pending Studies	
NRG GU009 (PREDICT- RT). – activating Sept 2020	Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with High Genomic Risk (PREDICT-RT)	Paul Nguyen, MD; Oliver Sartor, MD
NRG GU1934 (GUIDANCE)	\underline{G} enomic-Risk Stratified \underline{U} nfavorable Intermediate Risk Prostate Cancer: \underline{D} eintensification \underline{a} nd Intensification Clinical Trial (GUIDANCE)	Neil Desai, MD; Ale Berlin, MD PhD
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
4:05 – 4:10	Other issues	

4:05 - 4:10 Other issues

Translational Research Medical Oncology Update **Urology Update New Business**

Phuoc Tran, MD PhD Oliver Sartor, MD Todd Morgan, MD Group

Closing Remarks 4:10 - 4:15

Cervix Committee Agenda

Date: Friday, July 17, 2020

Start and End Time: 11:15am – 12:45pm (via zoom)
Chair: Charles A. (Trey) Leath, III, MD, MSPH

Co-Chair: Jyoti Mayadev, MD
Translational Co-Chair: Dmitriy Zamarin, MD, PhD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

Scientific Developmental Focus

- A. Introduction / Announcements (11:00-11:20)
 - a. Welcome, committee membership and rotation plan and review of Jan 2020 minutes
 - b. New cervical cancer related appointments
 - i. Cervical Cancer Task Force Dana Chase (2nd Term), Katherine Moxley (1st Term)
 - ii. Cervical Cancer Task Force (Junior Investigator) Naresh Jegadeesh
- B. Scientific updates (11:20-12:00)
 - a. NCCN and Cervical Cancer Clinical Trials: Dr. Wui-Jin Koh, MD, Medical Director NCCN
 - b. Update on T cell therapy for Cervical Cancer: Dr. Christian Hinrichs, MD, PhD
 - c. Non-CTEP Relevant Cervical Cancer Trials
 - i. GCIG (Dr. David Gaffney)
 - ii. GOG Partners (Dr. Leslie Randall)
 - d. Previously committee approved/reviewed concepts current updates and future directions
 - CV1922 (Ritu Salani): PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer
 - Pending from GCSC
 - ii. CV1923 (Brian Slomovitz / Lillian Gien): GROINSS V3 GY0024
 - GCSC Approved
 - 2. United States Participation Appendix Finalizing Development
 - iii. CV1962 (Allan Covens / Lauren Cobb): FIGO 2018 stage 1B2 (≥2cm <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)</p>

- 1. Pending GCSC review
- iv. **CV1964** (Scott Glaser / Oladapo Yeku): Incorporation of Immunotherapy into The Management of Locally Advanced Carcinoma of the Vulva
- v. **UC1963** (Junzo Chino): A Randomized Phase II trial of ablative radiation therapy for women with oligometastatic gynecologic cancers
- vi. **PI1915** (Katherine Moxley): A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix **CTEP IND**
- vii. **DT2013** (Corrine Doll): CB-839 before and concurrent with chemoradiotherapy in patients with locally advanced, node positive cervical cancer

C. New proposed concepts CV/RT

- a. CV2040, Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARTACUS) II (Eric Leung)
- D. New proposed Concepts from other committees
 - a. **RT2033**, Topical 5% imiquimod cream compared with topical 0.4% sirolimus ointment for treatment of vulvar Paget's disease (William Bradley)
 - **b.** RT2044, Phase II open label evaluation of trastuzumab in HER2 positive unresectable, recurrent or persistent Paget's disease of the vulva (Jill Alldredge)

Operational management on-going NRG trials

E. Closed Studies

Protocols: 101, 120, 205, 222, 141, 173, 179, 204, 206, 240, 233, 9806

- F. Active / Recently Completed Trials
 - a. **GOG-0724/RTOG0724**: Phase III trial randomized study of concurrent chemotherapy and pelvic RT with or without adjuvant chemotherapy in high-risk patients with early stage cervical carcinoma following radical hysterectomy. (Heidi Gray, Anuja Jhingran)
 - i. Opened April 2009
 - ii. Accrual 215/285 (75.4%)
 - 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 325/360 (90.3%)
 - 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 (≤2cm) cervical cancer. (Al Covens)
 - i. Opened October 1, 2012
 - ii. PET imaging amendment approved July 2015
 - iii. Accrual 212/220 (96.4%)
- f. **GOG-0279**: A phase II trial evaluating cisplatin and gemcitabine concurrently with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva. (Neil S. Horowitz)
 - i. Opened July 2, 2012
 - ii. Temporarily Closed June 15,2015 after enrolling 28 in 1st stage
 - iii. 2nd stage re-opened July 2016
 - iv. Accrual completed
- g. NRG-GY006: A randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, stage II, IIIB, or IVA Cancer of the uterine cervix or Stage II-IVA vaginal cancer. (Trey Leath, Loren Mell)
 - i. Opened January 15, 2016
 - ii. Amendment to CTEP re: increase in accrual size and transition to Randomized phase 3
 - iii. Accrual 280/450 (62.2%)
- h. **NRG-GY017**: Phase I trial using anti PD-L1 (atezolizumab) as immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer. (Jyoti Mayadev)
 - i. Opened October 26, 2018
 - ii. Accrual: 40/40
 - iii. Temporarily Suspended to accrual pending amendment

Reports from Other Committees and Groups

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

G. Concluding Remarks and Wrap-up

Next Semi-Annual Meeting

QUESTIONS / DISCUSSION

Gynecologic Cancer Committee Agenda

Date: Friday, July 17, 2020
Start and End Time: 2:45 PM – 4:15 PM
Chair: Carol Aghajanian, MD

Co-Chairs: Paul DiSilvestro, MD & David Gaffney, MD, PhD

Translational Science Co-Chair: Heather Lankes, PhD, MPH

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

General Business

- A. Call to order
- B. Approval of minutes from January 2020
- C. Symposia (Alvarez)
- D. Report from HRC (Creasman)
- E. 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 III/III, Phase III

Ovarian Cancer Subcommittee

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

Rare Tumor Subcommittee

- Clear Cell Tumors
- Germ Cell Tumors
- Ovarian Low Grade Serous
- Ovarian Mucinous
- Ovarian Stromal Tumors

Uterine Corpus Cancer Subcommittee

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

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

GYN Developmental Therapeutics Committee

- Early phase trials (Phase I, Phase I/II, Phase II), Window of opportunity trials
 - Cervical cancer
 - Endometrial cancer
 - Ovarian cancer
 - Uterine sarcoma

GYN Phase I Subcommittee

- Safety lead-ins
- Phase I

Other NCTN Group Trials & Study Champions

\$1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors

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

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

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

III. <u>Cervix/Vulvar Cancer Subcommittee</u>

New Concepts

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

Studies Under Development

- **a. CV1922**, PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer (Ritu Salani)
- **b. CV1962**, FIGO 2018 stage 1B2 (≥2cm <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). Coordinating Center: Princess Margaret Consortium (PMHC). PI: Dr. Marie Plante
- **c. CV1964**, Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (Scott Glaser/Oladapo Yeku)
- **d. CV2020**, GROINSS-V III, Groningen International Study on Sentinel Nodes in Vulvar Cancer lii, A Prospective Phase II Treatment Trial

Active Studies:

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

Rare Tumor Subcommittee – Paget's

New Concepts

- **a. RT2033**, Topical 5% imiquimod cream compared with topical 0.4% sirolimus ointment for treatment of vulvar Paget's disease (William Bradley)
- **b. RT2044**, Phase II open label evaluation of trastuzumab in HER2 positive unresectable, recurrent or persistent Paget's disease of the vulva (Jill Alldredge)

Rare Tumor Subcommittee – Mucosal Melanoma

Studies Under Development

a. DT1822, A Randomized Phase II Trial of Adjuvant nivolumab with or without cabozantinib in patients with resected mucosal melanoma— Alliance lead group

<u>GYN Developmental Therapeutics Committee - Cervical Cancer</u> Studies Under Development

- **a. PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley)
- **b. DT2013**, CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corinne Doll)

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)

Closed Studies (Primary manuscript NOT published): 270 (GROINSS-V) (SGO 2020), THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174), 279

Terminations: 265

IV. Ovarian Cancer Subcommittee

New Concepts

- **a. OV2031**, A Randomized Phase II Trial of Maintenance after Prior PARP Inhibitor in Platinum Sensitive Ovarian Cancer with VEGF-inhibition and Olaparib based Therapy (PIVOT) (J Nakayama)
- **b. OV2035**, A Randomized, Open-label, Phase II Study of Talazoparib in Combination with Carboplatin and Paclitaxel versus Standard Chemotherapy in Patients with Recurrent Platinum Sensitive Ovarian Cancer who have been previously treated with PARPi (Elisavet Paplomata)
- **c. OV2037**, A Phase II/III Randomized study of anti-TGIT versus Placebo Administered in Combination with Carboplatin, Paclitaxel, Bevacizumab and Atezolizumab in Patients with newly diagnosed stage 3 or 4 Ovarian, Fallopian tube or Primary Peritoneal Cancer who are Homologous Recombination Proficient. (Ramez Eskander)
- **d. OV2038**, A Phase II/III randomized study of VIGIL versus placebo administered in combination with carboplatin, paclitaxel, bevacizumab and atezolizumab in patients with newly diagnosed stage 3 or 4 ovarian, fallopian tube or primary peritoneal cancer who are homologous recombination proficient (HRP). (Ramez Eskander)

Studies Under Development

- a. OV1838, A Randomized Phase II trial comparing the combination of PI3K inhibitor Copanlisib and PARP inhibitor Olaparib to standard chemotherapy in patients with recurrent, platinum sensitive or platinum resistant epithelial ovarian, fallopian tube or primary peritoneal cancer who have progressed through prior PARP inhibitor therapy (Panagiotis Konstantinopoulos)
- b. NRG-GY023, A Randomized Phase II Trial of Triplet Therapy (a PD-L1 Inhibitor Durvalumab in Combination with Olaparib and Cediranib) Compared to Olaparib and Cediranib or Durvalumab and Cediranib or Standard of Care Chemotherapy in Women with Platinum-Resistant Recurrent Epithelial Ovarian Cancer, Primary Peritoneal or Fallopian Cancer Who Have Received Prior Bevacizumab (Jung-Min Lee)
- c. OV1960, A phase III randomized trial of heated intraperitoneal chemotherapy (HIPEC) with cisplatin at the time of interval cytoreductive surgery versus intravenous chemotherapy only followed by niraparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer (Marta Crispins)
- **d. OV2008**, A Randomized Phase 2 trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)

Active Studies:

- a. NRG-GY005, A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS). (Jung-Min Lee)
- **b.** NRG-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)
- **c. NRG-GY021**, A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Sarah Adams)

Rare Tumor Subcommittee

New Concepts

- **a. RT2029**, A Phase I Trial of the MDM2 Inhibitor, AMG-232, Alone and in Combination with Nivolumab in Advanced or Metastatic Extra-Renal Clear Cell Tumors (Eugenia Girda)
- **b. RT2030**, A Phase II Trial Evaluation of Pembrolizumab and Lenvatinib in the Treatment of Recurrent Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma (John Farley)
- **c. RT2032**, A Phase II Study of Nivolumab and Relatlimab in Recurrent Ovarian Clear Cell Carcinoma (Ken Lin)
- **d. RT2036**, A Phase II Trial of Cabozantinib in Combination with Atezolizumab in Patients with Recurrent Clear Cell Ovarian Carcinoma (Ramez Eskander)
- **e. RT2039**, A Phase II study of Durvalumab and Cediranib in Recurrent Ovarian Clear Cell Carcinoma (Mihaela Cristea)
- f. RT2041, Chemotherapy plus anti-PD-L1 and Ablative Radiation Followed by Maintenance anti-PD-L1 and Bevacizumab in Relapsed/Refractory or Locally Advanced Stage III/IV Clear Cell Ovarian Cancer (Brandon Dyer)
- **g. RT2042**, A Phase II Study Evaluating PARP-inhibitor in Recurrent Immature Teratoma of the Ovary (Lilian Gien)

Active Studies:

- **a.** NRG-GY016, Randomized phase II evaluation pembrolizumab + epacadostat in recurrent clear cell carcinoma of the ovary (Lilian Gien)
- **b.** NRG-GY019, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Amanda Fader)

GYN Developmental Therapeutics Committee - Ovarian Cancer New Concepts

a.

Studies Under Development

a. P11966, A phase I study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Fiona Simpkins)

Active Studies:

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

Closed Studies (Primary manuscript NOT published): 212, 264, 268, 273, 281, 283, GY004 (ASCO 2020), GY007

Closed Studies (Primary manuscript published): 186H*, 213, 239*, 252, 262, GY003

*patient on active treatment Terminations:

V. <u>Uterine Corpus Cancer Subcommitee</u>

New Concepts

- **a. CV2040**, Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARTACUS) II (Eric Leung)
- **b. UC2034**, Endometrial cancer prevention in women with obesity with the levonorgestrel-releasing intrauterine system (Laurence Bernard)
- **c. UC2043**, A Pilot Study of Dactinomycin plus Avelumab as First line Treatment for Selected Patients with Gestational Trophoblastic Neoplasia (Lua Eiriksson)
- d. UC2045, A Phase III Randomized Trial of Radiation +/- MK-3475 (Pembrolizumab) for Newly Diagnosed Completely Resected Stage III Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer (Floor Backes)

Studies Under Development

- **a. UC1731**, Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study (Katarzyna Jerzak/Helen Mackay/Linda Duska)
- **b. UC1963**, A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)
- **c. UC1972**, A randomized phase III trial of paclitaxel/carboplatin alone or combined with either trastuzumab or trastuzumab/pertuzumab in HER2 Positive Stage I-IV uterine serous carcinoma and carcinosarcoma after primary surgery (Erikson, Fader, Santin)
- **d. UC2019**, A phase II/III randomized study of carboplatin, paclitaxel, atezolizumab, and ipatasertib plus ipatasertib and atezolizumab maintenance versus carboplatin, paclitaxel, ipatasertib and ipatasertib maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer (Debra Richardson)
- **e. UC2024**, Efficacy of immunotherapy with dual immune checkpoint inhibitors compared to anti-PD1 monotherapy in patients with deficient mismatch repair system recurrent endometrial carcinoma: A randomized phase II trial (Haider Mahdi)

Active Studies:

- **a. GOG-0238**, A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus (Jonathan Micha Feddock)
- **b.** NRG-GY012, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay)
- **c. NRG-GY018**, A randomized phase III Placebo-Controlled Study of Pembrolizumab in addition to Paclitaxel and Carboplatin for Measurable Stage III Or IVA, Stage IVB or Recurrent Endometrial Cancer. (Ramez Eskander)
- **d.** NRG-GY020, Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer. (Floor Backes)

Rare Tumor Subcommittee
New Concepts

a. RT

<u>GYN Developmental Therapeutics Committee – Uterine Corpus Cancer</u> New Concepts

a. DT

Studies Under Development

- **a. DT1958**, Phase 2 study of Alpelisib and Letrozole in PIK3CA-mutated endometrial cancers (Stephanie Gaillard)
- **b. DT1959**, Phase II trial of PARP inhibition for advanced, metastatic uterine leiomyosarcoma with a somatic BRCA mutation (Martee Hensley)
- **c. DT2006**, Efficacy of anti-CD47 therapy with Hu-F59 and atezolizumab in recurrent, persistent or metastatic endometrial cancer (Haider Mahdi)
- **d. DT2007**, A multicohort single-arm trial of DS-8201a, an anti-HER2 antibody-drug conjugate incorporating a DNA topoisomerase I inhibitor in patients with HER2-positive endometrial cancer (Kosei Hasegawa)

Active Studies:

a.

Closed Studies (Primary manuscript NOT published): 209, 261, 275, 286B (SGO 2020), GY011 Closed Studies (Primary manuscript published): 188*, 249, 258

*patient on active treatment

Terminations:

VI. <u>Developmental Therapeutics Committee</u> (O'Cearbhaill, Backes, Konstantinopoulos) New Concepts

Studies Under Development

a. MATCH COMBO

Approved:

- EAY191-N1, Tucatinib and T-DM1 in HER2 amplified malignancies (Haider Mahdi)
- EAY191-N2, Binimetinib and Fulvestrant for ER+ HER2-, NF1 deleted metastatic breast cancer (Matthew Ellis & Bora Lim)
- **EAY191-N3**, Phase IB trial of the combination of KRAS G12C inhibitor MRTX849 and CDK4/6 inhibitor palbociclib in patients with molecularly-selected advanced solid tumors (Timothy Yap)
- EAY191-N4, MEK inhibition combined with PARP inhibition in ovarian and endometrial cancer with RAS pathway mutation (Shannon Westin & Kathleen Moore)

Under review:

 AZD6738 (ATRi) & AZD1775 (Wee1i) (Simpkins, PI1966) - needs phase I with NRG Oncology then will be proposed to Match Combo as phase II

Active Studies:

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

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

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

- **a. OV1741**, Surgery and Chemotherapy vs. Chemotherapy Alone as Primary Treatment for Older Women with Advanced Stage Epithelial Ovarian Carcinomas (Amina Ahmed)
- **b.** NRG-CC1860, A Randomized Trial of IADL-adjusted Dosing- versus Standard of Care of Dosing of Pegylated Liposomal Doxorubicin (PLD) Every 28 Days with Bevacizumab 10 mg/kg Every 2 Weeks in Elderly Women with Recurrent Ovarian Cancer (Dana Chase)
- IX. Translational Science Committee Report (Birrer, Lankes)
- X. <u>Cancer Prevention and Control Committee Report</u> (Walker)

Studies Under Development

a. UC2034, Endometrial cancer prevention in women with obesity with the levonorgestrel-releasing intrauterine system (Laurence Bernard)

Active Studies:

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

QUESTIONS / DISCUSSION

Ovarian Workshop Agenda

Date: Friday, July 17, 2020
Start and End Time: 1:00 pm – 2:45 pm
Chair: Kathleen Moore, MD
Co-Chair: Joyce Liu, MD

Translational Chair: Elizabeth Swisher, MD
Translational Co-Chair: Rebecca Arend, MD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

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

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

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

- Presentation of NRG GY004 (J. Liu) ASCO 2020
- Discussion of NRG GY007 and new standard of care PARPi option

C. Review of Closed Studies (not-terminated)

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

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

D. Review of Active Studies (all metrics are as of 6/2020)

- GOG0264 RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advancedstage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Jubilee Brown)
 - o Activated 08FEB2010
 - Futility limits met, Study closed to accrual 6/12/2020
- NRG-GY004 Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Joyce Liu and Ursula Matulonis). Expanded overall accrual to 550 patients, closed to accrual 10-NOV-2017
 - o Presented ASCO 2020
- 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
- o Re-opened to phase 3 without monotherapy olaparib arm 12/17/2018
- o Reminder to sites regarding completion of scheduled QOL assessments
- o Enrollment 495/562
- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Postsurgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer. (Robert A Burger and Chip Landen)
 - Closed to accrual
- NRG-GY009 A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Roisin O'Cearbhaill, Carol Aghajanian).
 - Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
 - o Second-stage safety lead-in (all three arms) opened 14NOV2017
 - o Group-wide activation 6/18/2018
 - o Suspended at the end of phase 2 (May 2019) pending reopening 7/2020
- 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)
 - o Activated 4/2019
 - o Suspended 8/2019
- NRG-GY016 phase 2 pembrolizumab + epacadostat (IDO inhibitor) in recurrent clear cell of the ovary (L Gien)
 - Activated Oct 2018/suspended for first phase accrual completion 4/2019
- 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).
 - o Activated 8/26/19
 - 0 24/450
- NRG-GY021 Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams)
 - o Activated Oct, 12 2019
 - o Safety calls coordinated through DT committee
 - 0 24/170
- 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
 - o Activated 11/2019

- NRG-CC008 (CC1923) (NC1427) (CPC1206) A non-randomized prospective clinical trial comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers (SOROC) (Doug Levine).
 - Activated 6/2020
- AGCT1531 (RT1205) Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, Al Covens NRG)
 - o Activated group-wide 30MAY2017
 - o 254/1680

E. Review of Approved Concepts under Development

- OV1838 PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib vs Standard
 Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube,
 or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P.
 Konstantinopoulos) LOI submitted 10/2018
 - Submitted to OTF 11/20 for Dec review
 - Approved by GCSC 6/2/2020 pending approval of drug supply
- OV1913 (NRG-GY023) A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab
 in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) vs
 doublet therapy (durvalumab and cediranib) vs investigator choice chemo in women with
 platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer
 who have received prior bevacizumab (Jung Min Lee)
 - o Approved by GCSC 9/19; drug supply confirmed
 - Goal is activation prior to 10/2020
- OV1960 A phase III randomized trial of heated intraperitoneal chemotherapy (HIPEC) with cisplatin
 at the time of interval cytoreductive surgery versus intravenous chemotherapy only followed by
 niraparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary
 peritoneal, and fallopian tube cancer. (Crispens)
 - o Submitted to OTF 11/20 for 12/2019 meeting
 - o Resubmitted for OTF July 2020 meeting with revisions
- OV2008: A Randomized Phase II trial of PARP-inhibitor combinations in <u>PARP</u> inhibitor <u>Resistant</u>
 Ovarian Cancer (PaROC) (Joyce Liu/Angeles Second)
 - Submitting Back to OTF for second review
- P11966: Wee1 + ATRi in CCNE1 amplified ovarian and endometrial (Simpkins)
 - o RSC 10/29/19
 - o Phase I UD
- PI2014: A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)

- F. Review of **New Concepts** and Future Request for Proposals
 - 1. **OV1741**: Surgery and Chemotherapy vs. Chemotherapy Alone as Primary Treatment for Older Women with Advanced Stage Epithelial Ovarian Carcinomas (Amina Ahmed)
 - 2. OV2031: A Randomized Phase II Trial of Maintenance after Prior PARP Inhibitor in Platinum Sensitive Ovarian Cancer with VEGF-inhibition and Olaparib based Therapy (PIVOT) (J Nakayama) resubmission, previously withdrawn.
 - 3. OV2035: A Randomized, Open-label, Phase II Study of Talazoparib in Combination with Carboplatin and Paclitaxel versus Standard Chemotherapy in Patients with Recurrent Platinum Sensitive Ovarian Cancer who have been previously treated with PARPi (Elisavet Paplomata)
 - 4. OV2037: A Phase II/III Randomized study of anti-TGIT versus Placebo Administered in Combination with Carboplatin, Paclitaxel, Bevacizumab and Atezolizumab in Patients with newly diagnosed stage 3 or 4 Ovarian, Fallopian tube or Primary Peritoneal Cancer who are Homologous Recombination Proficient. (Ramez Eskander)
 - 5. OV2038: A Phase II/III randomized study of VIGIL versus placebo administered in combination with carboplatin, paclitaxel, bevacizumab and atezolizumab in patients with newly diagnosed stage 3 or 4 ovarian, fallopian tube or primary peritoneal cancer who are homologous recombination proficient (HRP). (Ramez Eskander)
 - 6. RT2029: A Phase I Trial of the MDM2 Inhibitor, AMG-232, Alone and in Combination with Nivolumab in Advanced or Metastatic Extra-Renal Clear Cell Tumors (Eugenia Girda)
 - 7. RT2030: A Phase II Trial Evaluation of Pembrolizumab and Lenvatinib in the Treatment of Recurrent Ovarian, peritoneal or fallopian tube Clear Cell Carcinoma. (John Farley)
 - 8. RT2032: A Phase II Study of Nivolumab and Relatlimab in Recurrent Ovarian Clear Cell Carcinoma (GY016R) (Ken Lin)
 - 9. RT2036: A Phase II Trial of Cabozantinib in Combination with Atezolizumab in Patients with Recurrent Clear Cell Ovarian Carcinoma. (Ramez Eskander)
 - 10. RT2039: A Phase II study of Durvalumab and Cediranib in Recurrent Ovarian Clear Cell Carcinoma. (Mihaela Cristea)
 - RT2041: Chemotherapy plus anti-PD-L1 and Ablative Radiation Followed by Maintenance anti-PD-L1 and Bevacizumab in Relapsed/Refractory or Locally Advanced Stage III/IV Clear Cell Ovarian Cancer. (Brandon Dyer)
 - 12. RT2042: A Phase II Study Evaluating PARP-inhibitor in Recurrent Immature Teratoma of the Ovary. (Lilian Gien)

QUESTIONS / DISCUSSION

Uterine Corpus Committee Agenda

Date: Friday July 17, 2020 Start and End time: 11:15 AM- 12:45 PM EDT

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.

Workshop Agenda

- A. Introduction (Powell):
- **B.** Review of Closed Studies
 - 1. <u>GOG0188</u>: Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [Gynecol Oncol 120(2): 185-8, 2011]:
 - 2. <u>GOG0209</u>: 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 Miller to discuss) [Gynecol Oncol 125: 771-3, 2012] Submission
 - 3. <u>GOG0210</u>: A Molecular Staging study of Endometrial Carcinoma (William T Creasman): Mutch in separate report
 - 4. GOG0249: Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy doi:10.1016/j.ygyno.2014.07.078: Accepted JCO Randall to discuss
 - 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) Mutch 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 (**Powell to Update**)
- GOG0275 A Phase III Randomized Trial of Pulse Actinomcyin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia (Horowitz to discuss)
- 8. GOG0286B A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (Victoria L Bae-Jump to discuss)
- 9. NRG-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 (Randall to discuss)
- **b. \$1609,** DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (Hororwitz 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/Rimel) Additional arms added (Rimel to discuss)
- d. GY018 (UC1710) Prospective randomized phase 3 trial of carboplatin and paclitaxel with or without pembrolizumab in the treatment of primary advanced stage (3 or 4) or recurrent endometrial cancer (Eskander to discuss)
- e. GY020 Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Backes) N: 168 (2:1 randomization). Stat: Sill (Backes to discuss)

D. Review of Approved Concepts/Protocols

1. GOG-0210

a. UC0905: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (Mutch to discuss in 210 report)

- b. **GOG-8032 (UC1102)**: A clinico-pathologic analysis of high-grade uterine carcinomas (grade 3 endometrioid, serous, and clear cell carcinoma) and carcinosarcomas from GOG-0210 (Richard Zaino/ Ian Hagemann):
- **c. GOG-8040 (UC1107):** An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino/ Ian Hagemann):
- UC1731, Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study (Katarzyna Jerzak/Helen Mackay/Linda Duska)
- 3. **UC1963**, A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)
- UC1972, A randomized phase III trial of paclitaxel/carboplatin alone or combined with either trastuzumab or trastuzumab/pertuzumab in HER2 Positive Stage I-IV uterine serous carcinoma and carcinosarcoma after primary surgery (Erikson, Fader, Santin)
- 5. **UC2019**, A phase II/III randomized study of carboplatin, paclitaxel, atezolizumab, and ipatasertib plus ipatasertib and atezolizumab maintenance versus carboplatin, paclitaxel, ipatasertib and ipatasertib maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer (Debra Richardson)
- 6. **UC2024**, Efficacy of immunotherapy with dual immune checkpoint inhibitors compared to anti-PD1 monotherapy in patients with deficient mismatch repair system recurrent endometrial carcinoma: A randomized phase II trial (Haider Mahdi)
- UC2045: A Phase III Randomized Trial of Radiation +/- MK-3475
 (Pembrolizumab) for Newly Diagnosed Completely Resected Stage III Mismatch Repair Deficient (dMMR) Endometrioid Endometrial Cancer (Backes to update)
- 8. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health- Related Quality of Life in Endometrial Cancer (**Tanner to Update**)
- 9. (CCRD study) Molecular classification-directed care in endometrial carcinoma: a prospective cohort study (Temkin to Update)

Proposed studies New Concepts:

- a. **CV2040**, Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARTACUS) II (Eric Leung)
- b. **UC2034**, Endometrial cancer prevention in women with obesity with the levonorgestrel-releasing intrauterine system (Laurence Bernard)
- c. **UC2043**, A Pilot Study of Dactinomycin plus Avelumab as First line Treatment for Selected Patients with Gestational Trophoblastic Neoplasia (Lua Eiriksson)

E. Studies from Other Committees for Review / New Concepts:

a. RT2029 Phase I of MDM2 Inhibitor, AMG-232, Alone and in Combination with Nivolumab in Advanced or Metastatic Extra-Renal Clear Cell Tumors (Girda)

G. New Business

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

Head and Neck Workshop

Date: Friday, July 17, 2020
Start and End Time: 1:00 – 2:30 PM ET
Chair: Quynh-Thu Le, MD

Co-Chair: Erich Sturgis, MD, MPH; Stuart Wong, MD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

A. Head and Neck portfolio overview Quynh-Thu Le, MD

B. Actively developing studies

• **HN007** Phase III Gem/cis vs. Gem/cis/Nivo in 1st line Rec/met NPC Brigette Ma, MD

• **HN008** Phase I RT + DNA-PK inhibitor + Avelumab in High risk LA HNSCC Maura Gillison, MD

Michael Samuels, MD

HN1937 Phase III HD vs. Weekly cisplatin in high risk LA HNSCC
 Paul Harari, MD

• HN2004: Phase II of T-DM1 +/- Atezo in metastatic HER2 amplified Alan Ho, MD

salivary duct cancer

HN2001: Phase II-III of placebo vs. adjuvant IO in LA NPC with
 Nancy Lee, MD

persistently detectable EBV DNA

HN1936 Phase II Chemo-immunotherapy selection to guide salvage surgery
 Nabil Saba, MD

in rHNSCC enriched for PD1

C. Review on active studies

Actively accruing trials

RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR)	Cristina Rodriguez
RTOG 1216	RT-cisplatin vs. RT-Docetaxel + Cetuximab vs. cisplatin + Atezolizumab for "high risk" resected HNSCC (Phase IIIR)	Julie Bauman Paul Harari David Rosenthal
NRG HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III)	Nancy Lee
NRG HN004	Phase II-IIIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC	Loren Mell
NRG HN005	Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer	Sue Yom

NRG HN006	Phase II-III SLN Biopsy vs. END in T1-2N0 oral cavity cancer	Stephen Lai
RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong

D. Report on publications and protocols closed to active accrual

Quynh-Thu Le, MD

Recently completed trials

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

E. ECOG trials

EA3132	PORT +/- Cisplatin in intermediate risk pts with disruptive P53 mutation	Christine Chung
EA3161	Intermediate risk HPV(+) HNSCC CRT +/- Nivo	Nabil Saba
EA3163	Sinonasal carcinoma	Nabil Saba

F. NCI Head and Neck Steering Committee update

Sue Yom, MD

G. NRG Biobank/Navigator update

Richard Jordan, DDS, PhD

H. NCI COVID-19 Trial Registry

Quynh-Thu Le, MD Stuart Wong, MD

I. New Investigator Resources/Closing Remarks

Quynh-Thu Le, MD

QUESTIONS / DISCUSSION

Lung Cancer Committee Agenda

Date Friday, July 17, 2020
Time: pm – (EDT)
Chair: Jeffrey Bradley, MD

Co-Chairs: Jessica Donington, MD PhD and Martin Edelman, MD

1) Learning Objectives

Following this activity, participants will be better able to:

a) Learn about ongoing clinical trials within the lung cancer committee.

b) Participate in feedback about ongoing and prospective trials.

c) Develop strategies to participate in these trials at your home institution.

2) Active Studies

a) Lung-MAP SWOG S-1400 Saiama Waqar, MD b) ALCHEMIST Trial Saima Waquar, MD c) RTOG 1308: Protons vs photons for St III NSCLC Xing Liao, MD d) NRG CC003: Hippocampal avoidance brain Vinai Gondi, MD e) LU002: Phase III chemo +/- SBRT for Stage IV Puneeth Iyengar, MD PhD f) NRG-LU003: NCI NRG ALK Master Protocol Shakun Malik, MD g) NRG LU004: Phase I/II anti-PD1 concurrent with RT Steven Lin, MD PhD h) NRG/Alliance LU005: Limited-stage SCLC Kristin Higgins, MD

i) NRG LU006: Phase IIR; Dose-painting IMRT for mesothelioma Andreas Rimner, MD
 j) RTOG 3515: SBRT +/- durva for medically-inoperable Stage I Cliff Robinson, MD
 k) SWOG S1914/NRG LU – SBRT +/- neoadjuvant atezo for Stage I Charles Simone, MD

I) NRG LU007: Phase II/III ES-SCLC; chemo + atezo +/- RT Quynh Nguyen, MD

m) NRG CC1974: SCLC Brain mets; SRS vs HA-WBI Vinai Gondi, MD

QUESTIONS / DISCUSSION

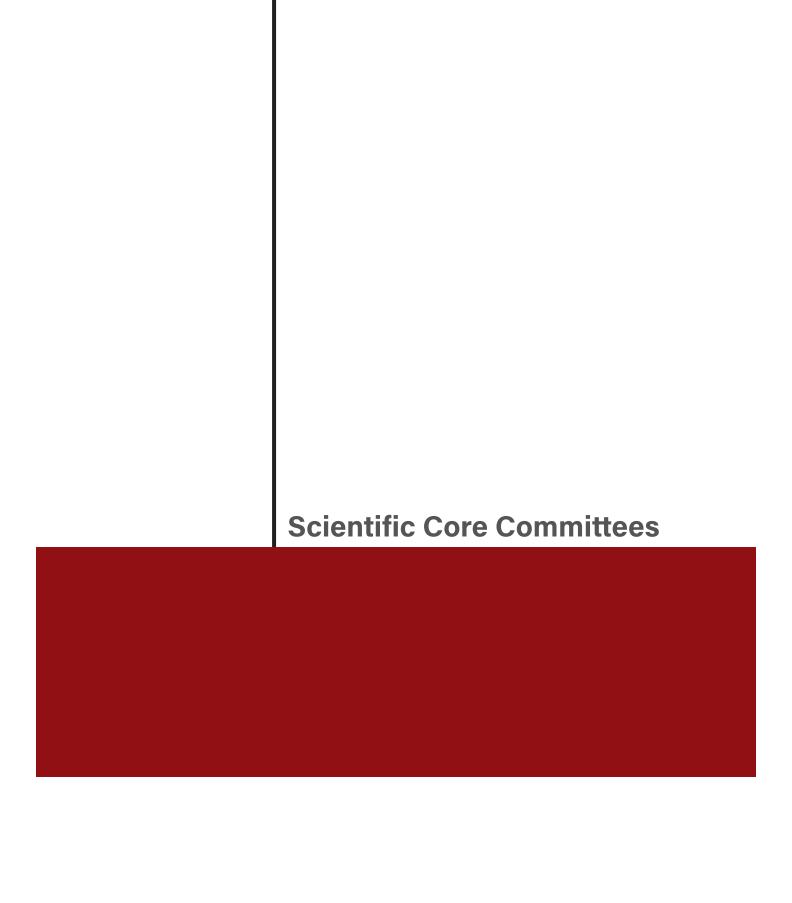
Patient Centered Outcomes Research (PCOR) Committee Agenda

Date: Thursday, July 16, 2020 (Virtual Meeting)

Start and End Time: 4:30 pm - 6:00 pm

Co-Chairs: Benjamin Movsas, MD; Patricia Ganz, MD; Lari Wenzel, PhD

4:30 - 4:35	Welcome	Ben Movsas, MD
4:35 – 4:45	PCOR Compliance Update Comments/Audience Q & A	Ron Chen, MD
4:45 – 4:55	Digital Health Update	Adam Dicker, MD
4:55 - 5:40	Concepts in Development NRG-BN2028: A Randomized Phase III Trial of Pre-Operative Compared to Post-Operative Stereotactic Radiosurgery (SRS) in Patients with Resected Brain Metastases NRG-EORTC 1634: Personalized Risk-Adapted Therapy in Post- Pubertal Patients with Newly-Diagnosed Medulloblastoma (PersoMed-I) NRG-HN1937: Randomized Phase II/III Trial of Radiation Combined with High Dose Cisplatin (100 mg/m2) Every Three Weeks vs. Low Dose Weekly Cisplatin (40 mg/m2) for Patients with Locoregionally Advanced SCCHN NRG-UC1972: Phase III Study of Carboplatin/Paclitaxel Alone or Combined with Either Trastuzumab or Trastuzumab/Pertuzumab in HER2 Positive, Stage I-IV Uterine Serous Carcinoma and Carcinosarcoma after Primary Surgery	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD Vinai Gondi, MD Laura Havrilesky, MD Farzan Siddiqui, MD
5:40 -5:55	NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD Laura Havrilesky, MD Jason Efstathiou, MD
5:55 -6:00	Other Business	Ben Movsas, MD Patricia Ganz, MD Lari Wenzel, PhD



NRG Oncology Health Disparities Committee Thursday, July 16, 2020 (Virtual Meeting) 1 -2:30 pm ET Agenda

Chairs: Chanita Hughes Halbert, PhD

Kate Yeager, PhD, RN, MS

- 1:00 1:10 pm Welcome/Announcements Kate Yeager
- 1:10 1:30 pm Member Spot Light Life Cycle of a Health Disparities Researcher Jennifer Griggs
- 1:30 1:45 pm Clinical Trial Enrollment Updates Reena Cecchini, William Robinson
 - > Statistics/Metrics SDMC Reports
- 1:45 2:15 pm HDC Special Interest Groups (SIG)
 - > Research Implementation (Education/Training/Mentorship) Kathie-Ann Joseph, Rusty Robinson

Education/Training- Kathie-Ann Joseph

- HDC Workshop January 2021 (Community Outreach/Engagement) Kathie-Ann Joseph, Chanita Hughes Halbert
- Future Webinars/Member Spotlights- Kathie-Ann Joseph

NRG Oncology HDC Mentor Program- Kathie-Ann Joseph, William Robinson

- > Older Adult Research William Tew
- > Rural Research Kate Yeager
- ➤ HDC Research Concept Development Chanita Hughes Halbert
- 2:15 2:25 pm A Clinicians Perceptions on SGM Patients Survey Edith Mitchell
- 2:25 2:30 pm **Summary**
- 2:30 pm **Adjournment**

JULY 2020 VIRTUAL PSC MEETING AGENDA

Protocol Support Committee Workshop Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session (A)

Date: Thursday, July 16, 2020
Start and End Time: 10:00am -12:00pm EDT
PSC Chair: Terry Thomas MS, CCRC

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

Lead Facilitator Karen Holeva, MS

Co - Facilitator: Melinda Weiblen, BS, Chrisann Winslow RN, MSN

Learning Objectives:

Following this activity, participants will be better able to:

- 1. Discuss the nature and preparation for NCI-mandated Quality Assurance Audits
- 2. Identify current procedures and approval with CTSU, protocol development and CIRB
- 3. Identify and discuss best practices for remote trial coordination and program management to integrate into practice.

Time	Topic	Speakers
10:00am – 10:10am	Welcome	Karen Holeva, BS
10:10am – 10:30am	Headquarters/SDMC Quality Assurance	Mimi Passarello, MBA
10:35am – 10:55am	CTSU	Megan Rossman Blackburn
11:00am - 11:20am	CIRB	Amanda P. Sly, MS, CIP
11:25am – 12:00pm	Best Practices for Remote Trial Coordination & Program Management	Jennifer Dill, BS, CCRP

Protocol Support Committee Workshop Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session (B)

Date: Thursday, July 16, 2020
Start and End Time: 1:00pm - 2:30pm EDT
PSC Chair: Terry Thomas MS, CCRC

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

Lead Facilitator: Karen Holeva, MS

Co - Facilitators: Melinda Weiblen, BS, Chrisann Winslow RN, MSN

Learning Objectives

Following this activity, participants will be better able to:

1. Identify and discuss dietary changes to alleviate stress and tension

- 2. Identify and discuss the concept of mindfulness.
- 3. Describe and apply a short, guided meditation exercise.
- 4. Describe and discuss breath techniques to address stress and tension.

Time	Topic	Speakers
1:00pm – 1:05pm	Welcome	Karen Holeva, BS
1:05pm – 1:45pm	Diet and Nutrition	Cherita N. Ogunsanya MBA, RD, LD
1:45pm – 2:30pm	Mindfulness for the Provider Movement, Meditation and Mindfulness	Sadie Grossman, MS Yoga Therapy, C-IAYT

FORTE Protocol Workshop

Date: Thursday, July 16, 2020 Time: 11:30 am-1:00 pm EDT

Location: Zoom (link TBD)

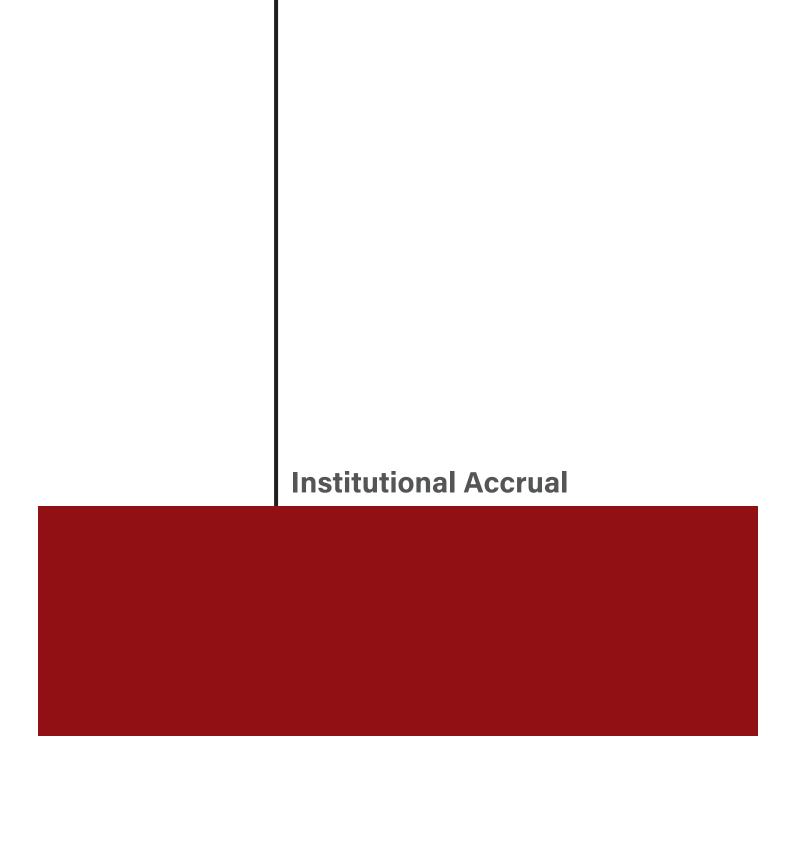
Learning Objectives/Following this activity, participants will be better able to:

- 1. Discuss the study design and eligibility for the FORTE study.
- 2. Discuss enrollment and models of recruitment.

3. Identify resources available to assist sites enrolling participants in the FORTE study.

Educational need for the presentation is based on the discussion at the FORTE May 2020 meeting.

Educational need for the presentation is based on the discussion at the FORTE May 2020 meeting.			
11:30 am-11:35 am 11:35 am-12:00 am	Welcome Part I: FORTE Introduction	Lisa Kachnic, MD, NRG NCORP Associate Chair	
	1. Introduction and importance of FORTE	Robert Schoen, MD, MPH, Principal Investigator/ Study Chair	
	2. Trial overview and eligibility	Jeffrey Dueker, MD, Protocol Co-chair	
	3. Statistical overview/Non-Inferiority Trial	Hanna Bandos, PhD, Study Statistician	
	4. Questions and Answers		
12:00 am-12:30 pm	Part II: Enrollment and Models of Delivery		
	University of Pittsburgh FORTE initialization and participant accrual process	Robert Schoen, MD, MPH, Principal Investigator/ Study Chair	
	Kaiser Permanente FORTE initialization and participant accrual process	Doug Corley, MD, PhD, Chief Scientific Officer	
	 North Shore University Health System FORTE initialization and participant accrual process 	Jay Goldstein, MD	
	4. Questions/Answers/ Comments		
12:30 am 12:55 pm	Part III: FORTE Site Resources		
	Protocol support materials/Social Media/ Clinical Coordinating Department	Christine Lorson, RN, FORTE Education and Communication Specialist	
	2. Forms / VisionTree	Sarah Camden, MS, Assistant Project Manager	
	3. Funding	Robert Schoen, MD, MPH, Principal Investigator/	
	4. Questions/Answers/Comments	Study Chair	
	5. Final Remarks/ Closing	Doug Levine, MD; Chair, NRG Cancer Prevention	



Accrual For Agenda Book from 6/1/2019 to 6/30/2020 Run Date: 7/6/2020				
NRG Main Member (Network)	CTEP ID	Accrued to NRG Studies and Credited to NRG	Accrued to Non- NRG NCTN Studies and	Total
21st Century Oncology MHP - Farmington	MI310	12	1	13
Allan Blair Cancer Centre	11076	15	0	15
Allegheny General Hospital	PA009	10	35	45
AMITA Health Alexian Brothers Medical Center	IL280	4	4	8
Arizona Center for Cancer Care-Peoria	AZ127	7	13	20
Aurora NCI Community Oncology Research Program	AURORA	9	10	19
Avera Cancer Institute	SD021	2	14	16
Banner University Medical Center - Tucson	AZ017	19	5	24
Baptist Health Cancer Research Network	BHCRN	4	21	25
Bay Area Tumor Institute NCORP	BATI	0	0	0
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer C	TX041	0	6	6
Baystate Medical Center	MA004	7	6	13
Berkshire Medical Center - Cancer Center	MA125	0	3	3
Boston Medical Center	MA043	2	599	601
Cancer Research Consortium of West Michigan NCORP	CRCWM	15	4	19
Cancer Research for the Ozarks NCORP	OZARKS	20	1	21
Cancer Research of Wisconsin and Northern Michigan Consortium	CROWN	16	14	30
Cancer Trials Ireland	ICORG	11	0	11
Carle Cancer Center NCI Community Oncology Research Program	CARLE	15	1	16
Carolinas Medical Center/Levine Cancer Institute	NC042	10	2	12
Catholic Health Initiatives NCORP	CORA	18	6	24
Cedars-Sinai Medical Center	CA016	3	1	-
Centre Hospitalier Universitaire de Sherbrooke-Fleurimont	11065	14	0	14
Chinese University of Hong Kong-Prince of Wales Hospital	34003	11	0	11
CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)	11073	25		-
CHUM - Centre Hospitalier de l'Universite de Montreal	11062	16		
City of Hope Comprehensive Cancer Center	CA043	6	1	8
CIUSSSEMTL-Hopital Maisonneuve-Rosemont	11060	7		.
Columbia University Minority Underserved NCORP	COLUMBIA	3		
Columbus NCI Community Oncology Research Program	COLUMBUS	12		
Community Cancer Center North	IN006	3	1	-
Cooper Hospital University Medical Center	NJ036	1		
Covenant Medical Center-Lakeside	TX054	0		1
Cross Cancer Institute	11132	10		
CWRU Case Comprehensive Cancer Center LAPS	LAPS-OH029	82	+	
Dana-Farber / Partners CancerCare LAPS	LAPS-MA036	24	+	-
Danbury Hospital	CT030	6		-
Dartmouth College - Norris Cotton Cancer Center LAPS	LAPS-NH012	7		22
Dayton NCI Community Oncology Research Program	DAYTON	2		-

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Delaware/Christiana Care NCI Community Oncology Research Progr		44	0	44
Dell Seton Medical Center at The University of Texas	TX063	0	4	4
Duke University - Duke Cancer Institute LAPS	LAPS-NC010	8	3	11
Edward Hospital/Cancer Center	IL104	4	17	21
Einstein Medical Center Philadelphia	PA094	0	0	0
Emory University - Winship Cancer Institute LAPS	LAPS-GA005	30	11	41
Essentia Health NCI Community Oncology Research Program	ESSENTIA	0	0	0
Fox Chase Cancer Center	PA086	11	7	18
Fred Hutchinson Cancer Research Center LAPS	LAPS-WA008	16	0	16
Froedtert and the Medical College of Wisconsin LAPS	LAPS-WI013	21	1	22
Geisinger Cancer Institute NCI Community Oncology Research Progr	GEISINGER	9	34	43
Georgia Cares Minority Underserved NCORP	GACARES	31	2	33
Georgia NCI Community Oncology Research Program	GEORGIA	24	32	56
Greater Baltimore Medical Center	MD018	5	17	22
Gulf South Minority Underserved NCORP	GULFSOUTH	22	2	24
Hackensack University Medical Center	NJ022	5	4	9
Hartford Hospital	CT009	3	3	6
Hawaii Minority Underserved NCORP	HAWAII	6	112	118
Heartland Cancer Research NCORP	HEARTLAND	41	7	48
Henry Ford Hospital	MI026	10	62	72
Houston Methodist Hospital	TX036	8	6	14
·		12	8	20
Indiana University/Melvin and Bren Simon Cancer Center	IN007			
Iowa-Wide Oncology Research Coalition NCORP	IWORC	8	18	26
James A. Haley Veterans Affairs Hospital	FL064	0	0	0
Jewish General Hospital	11116	7	1	8
JHU Sidney Kimmel Comprehensive Cancer Center LAPS	LAPS-MD017	8	13	21
Juravinski Cancer Centre at Hamilton Health Sciences	11183	6	0	6
Kaiser Permanente NCI Community Oncology Research Program	KAISER	34	53	87
Kaiser Permanente-Gaithersburg Medical Center	MD198	0	14	14
Kantonsspital Aarau	67029	2	0	2
Lahey Hospital and Medical Center	MA017	5	10	15
Lankenau Medical Center	PA125	12	1	13
Legacy Good Samaritan Hospital and Medical Center	OR013	10	1	11
Loyola University Medical Center	IL017	7	0	7
MaineHealth Cancer Care Network	MAINE	12	27	39
Mayo Clinic LAPS	LAPS-MN026	17	0	17
Medical University of South Carolina Minority Underserved NCORP	MUSC	9	6	15
MedStar Franklin Square Medical Center/Weinberg Cancer Institute	MD029	9	16	25
Memorial Sloan-Kettering Cancer Center LAPS	LAPS-NY016	50	19	69
Mercy Cancer Center - Sacramento	CA729	2	1	3
Metro Minnesota Community Oncology Research Consortium	METROMIN	35	16	51
Miami Cancer Institute	FL078	11	1	12
Michigan Cancer Research Consortium NCORP	MCRC	25	0	25
Michigan State University Clinical Center	MI038	0	2	2
Midwestern Regional Medical Center	IL120	7	13	20
Moffitt Cancer Center	FL065	17	40	57
Montana Cancer Consortium NCORP	MONTANA	13	0	13
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Mount Sinai Hospital	Montefiore Minority Underserved NCORP	MONTEFIORE	11	3	14
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	Thomas Jefferson University Hospital LAPS	LAPS-PA121	31	-	44

Thompson Cancer Survival Center	TN038	1	0	1
Tibor Rubin VA Medical Center	CA041	0	0	0
Tom Baker Cancer Centre	11134	11	0	11
Trinity Cancer Center	ND026	0	8	8
Tulane University Health Sciences Center	LA001	1	3	4
	LAPS-CA189	15		15
UC Davis Comprehensive Cancer Center LAPS	CA088	7	0 11	18
UC Irvine Health/Chao Family Comprehensive Cancer Center	CA088	23	14	37
UC San Diego Moores Cancer Center	CA249 CA006	1	0	1
UCLA / Jonsson Comprehensive Cancer Center UCSF Medical Center-Mount Zion	CA136	12	115	127
			115	14
UF Cancer Center at Orlando Health	FL020	7	7	
UMass Memorial Medical Center - Memorial Division	MA009	0 7	170	105
UNC Lineberger Comprehensive Cancer Center LAPS	LAPS-NC007		178	185
,	11030	48	0	48
University of Alabama at Birmingham / Deep South Research Conso		21	0	21
University of Arkansas for Medical Sciences	AR006	6	0	6
University of Chicago Comprehensive Cancer Center LAPS	LAPS-IL057	9	14	23
University of Cincinnati/Barrett Cancer Center	OH070	31	188	219
University of Colorado Cancer Center LAPS	LAPS-CO070	12	82	94
University of Connecticut	CT002	0	0	0
University of Florida Health Science Center - Gainesville	FL015	3	77	80
University of Illinois	IL040	3	14	17
University of Iowa/Holden Comprehensive Cancer Center	IA018	22	16	38
University of Kansas Cancer Center - MCA Rural MU NCORP	KANSAS	23	0	23
University of Kentucky/Markey Cancer Center	KY010	12	12	24
University of Maryland/Greenebaum Cancer Center	MD015	30	5	35
University of Miami Miller School of Medicine-Sylvester Cancer Cen		5	13	18
University of Michigan Comprehensive Cancer Center LAPS	LAPS-MI014	25	2	27
, ,	MN022	2	0	2
University of Mississippi Medical Center	MS005	0	4	4
,	NE003	7	4	11
University of Oklahoma Health Sciences Center LAPS	LAPS-OK003	116	98	214
University of Pennsylvania/Abramson Cancer Center	PA075	14	1	15
University of Pittsburgh Cancer Institute LAPS	LAPS-PA015	13	10	23
University of Rochester LAPS	LAPS-NY167	23	11	34
University of South Alabama Mitchell Cancer Institute	AL068	1	14	15
University of Tennessee - Knoxville	TN021	0	6	6
University of Tennessee Health Science Center	TN030	5	0	5
University of Texas Health Science Center at San Antonio	TX059	5	12	17
University of Texas MD Anderson Cancer Center LAPS	LAPS-TX035	54	22	76
University of Texas Medical Branch	TX045	2	25	27
University of Texas Southwestern Medical Center LAPS	LAPS-TX011	35	1	36
University of Utah - Huntsman Cancer Institute LAPS	LAPS-UT003	16	12	28
University of Vermont and State Agricultural College	VT004	5	14	19
University of Virginia Cancer Center	VA009	5	1	6
University of Wisconsin Carbone Cancer Center LAPS	LAPS-WI020	17	6	23
Upstate Carolina Consortium Community Oncology Research Progra	UPSTATE	12	19	31

LAPS-CA011	7	127	134
LAPS-TN008	10	8	18
NY131	0	1	1
VCU	2	32	34
NC002	9	4	13
MD001	0	0	0
LAPS-MO011	57	7	64
LAPS-MI020	35	30	65
PA047	7	13	20
WV004	9	5	14
WV025	7	11	18
WESTERN	22	43	65
MI005	9	40	49
WINCORP	6	5	11
RI012	34	9	43
NV049	27	0	27
LAPS-CT018	7	0	7
43027	4	0	4
	LAPS-TN008 NY131 VCU NC002 MD001 LAPS-M0011 LAPS-MI020 PA047 WV004 WV025 WESTERN MI005 WINCORP RI012 NV049 LAPS-CT018	LAPS-TN008 10 NY131 0 VCU 2 NC002 9 MD001 0 LAPS-M0011 57 LAPS-MI020 35 PA047 7 WV004 9 WV025 7 WESTERN 22 MI005 9 WINCORP 6 RI012 34 NV049 27 LAPS-CT018 7	LAPS-TN008 10 8 NY131 0 1 VCU 2 32 NC002 9 4 MD001 0 0 LAPS-M0011 57 7 LAPS-MI020 35 30 PA047 7 13 WV004 9 5 WV025 7 11 WESTERN 22 43 MI005 9 40 WINCORP 6 5 RI012 34 9 NV049 27 0 LAPS-CT018 7 0

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