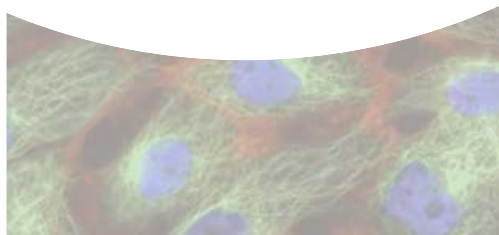




WINTER 2021
VIRTUAL MEETING
Jan. 28 - 30, 2021

Program Book

#NRG2021



NRG Oncology Winter 2021 Virtual Meeting

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FACULTY DISCLOSURE INFORMATION

NRG Oncology Winter 2021 Virtual Meeting – January 28-30, 2021

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>
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Bauman, Julie, MD	X	
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Brown, Jubilee, MD	X	
Cooley, Mary, PhD, RN	X	
Covens, Allan, MD	X	
Dicker, Adam, MD, PhD		Stock: Self Care Catalysts Advisory/Consulting/Stock: Oncohost Advisory/Consulting: European Commission; Rochel Janssen; Self Care Catalysts; Oncohost; Albert Einstein Medical College; Alcedim; Oranomed Consulting: Intellectual Property (Wilson Soncini)
DiSilvestro, Paul, MD	X	
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Edelman, Martin, MD		DSMB Member/Honorarium: AstraZeneca; Takeda; Seattle Genetics Consultant/Consulting Fees: Kanaph; Flame Biosciences Scientific Advisory Board/Consulting Fees: Windmill

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		Scientific Advisory Board/Lectures/Consulting Fees: Sanofi/Regeneron
Ellis, Matthew, MB, BCHIR, PhD		Advice on commercialization of Prosigna/Royalties: Veracyte/Prosigna Consulting/Fee: Novartis; Lilly; G1 Therapeutics; Sermonix
Efstathiou, Jason, MD		Consulting Fee: Blue Earth Biagnostics; Boston Scientific; AstraZeneca Honorarium: Roivant Pharma; Myovant Science; Progenics; Merck
Feng, Felix, MD		Scientific Advisory/Consulting Fee/Stock: SerImmune Co-Founder/Ownership/Personal Fees/Stocks: PFS Genomics Consultant/Fees: Bayer; Celgene; Blue Earth Diagnostics; Astellas; Janssen Oncology; Roivant Science; Myovant Science
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Ganz, Patricia, MD	X	
Geyer, Charles, MD		Consultant/Consulting Fee: Athenex Ad Board/Honorarium: Exact Sciences
Gore, Elizabeth, MD	X	
Hensley, Martee, MD		Spouse is employee/Salary: Sanofi Advisory/Honorarium: GSK
Hudson, Matthew, PhD, MPH	X	
Kachnic, Lisa, MD		Editor/Royalties: UpToDate
Klopp, Ann, MD	X	
Konstantinopoulos, Panagiotis, MD, PhD		Advisory Board/Consulting Fee: AstraZeneca; Alekermes; GSK
Lankes, Heather, PhD, MPH	X	
Leath, Charles, MD, III		Scientific Advisory Board Member/Honorarium: Abbvie; Clovis; Eisai; GSK; Seattle Genetics Contracted Research/Support: AstraZeneca; Celsion; GSK; Roche; Genentech; Abbvie; Agenus; Immunogen; Seattle Genetics Speaker/Honorarium: PeerView CME
Levine, Douglas, MD	X	
Licavoli, Cynthia, RN, BSN, MA	X	
Liu, Joyce, MD		Advisory Board/Consulting Fee: AstraZeneca; GSK; Genentech; Regeneron Pharmaceuticals
Mamounas, Eleftherios, MD		Advisory Board/Speakers Bureau; Honorarium: Exact Sciences; Genentech Advisory Board/Honorarium: Daiichi Sankyo Biotherapeutics; Merck Consulting/Honorarium: Merck
Mayadev, Jyoti, MD		Consulting/Honorarium: AstraZeneca Co-Chair Cervix Comm/Grant Fees: NRG Oncology
Moore, Katheen, MD		Advisory Com/Honorarium: AstraZeneca; GSK/Tesaro; Genentech/Roche Advisory Com/Honorarium: Aravive; Eisai; Immunogen; Merck; Mersana; VBL Therapeutics; Sorento; Elevar; Myriad
Morgan, Todd, MD	X	
Movsas, Benjamin, MD		Consulting Fee/Research Support: Varian, Inc.; ViewRay, Inc.; Philips, Inc.
O'Cearbhaill, Roisin, MD		Advisory Board/Honorarium: Regeneron; Genmab Therapeutics
Powell, Matthew, MD		Consulting/Fee: Roche Genentech; AstraZeneca; GSK/Tesaro; Johnson & Johnson; Clovis; Eisai; GOG Partners
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Sandler, Howard, MD		Member Clinical Trial Advisory Committee? Consulting Fee: Janssen Stock: Radiogel Member Editorial Advisory Board/Honorarium: Caribou Publishing
Sartor, Oliver, MD		Consultant/Consulting Fee/Honorarium: Advanced Accelerator Applications; Astellas; AstraZeneca; Bayer; Blue Earth Diagnostics Inc.; Bavarian Nordic; BMS; Clarity Pharmaceuticals; Clovis; Constellation; Dendreon; EMD Serono; Fusion; Isotpen Technologies Meunchen; Janssen; Myovant; Myriad; Noria Therapeutics, Inc.' Novartis; Noxopharm; Progenics; POINT Biopharma; Pfizer; Sanofi; Tenebio; Telix; Theragnostics Research Support/Grant: Advanced Accelerator Applications, AstraZeneca; Bayer; Constellation; Dendreon; Endocyte; Invitae; Janssen; Merck; Progenics; Sanofi; SOTIO
Schilder, Russell, MD		Independent/Consulting Fee: Incyte; Flatiron; Nextcure Ad hoc Ad Board/Consulting Fee: Clovis Lecture/Honorarium: Pfizer Chair/DSMB/Consulting Fee: Celsion
Secord, Angeles, MD	X	

FACULTY DISCLOSURE LIST

Swisher, Elizabeth, MD	X	
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Wenzel, Lari, MD	X	
White, Julia, MD		Speaking/Teaching/Honorarium: GHI
Zamarin, Dmitriy, MD, PhD		Consultant/Fee: Agenus; Targovax; Roche; Xencor; Synlogic Investigator on Clinical Trial/Payment to Institution: AstraZeneca; Genentech; Plexikon
Speaker Disclosures		
Abate, Lisa	X	
Antonelli, Mary Jo	X	
Alvarez, Ronald, MD		Ad Board/Honorarium: Genentech
Auth, Kim, RN, BSN	X	
Backes, Floor, MD		Advisory Board/Consulting Fee: Eisai; Agenus; Merck; GSK Teaching/Honorarium: CEC Oncology
Badders, Ashley	X	
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Bai, Jingbing, PhD	X	
Barry, Lisa, MAEd, BS	X	
Barton, Debra, PhD	X	
Bauman, Julie, MD	X	
Basen-Engquist, Karen, PhD	X	
Bauza, Joe, RT	X	
Beaverson, Lisa, BA, CCRP	X	
Bergantz, Wendy, RN	X	
Berlin, Alejandro, MD, PhD	X	
Bialy, Sally, MA	X	
Birrer, Michael, MD, PhD		Advisory Board: Clovis; AstraZeneca; GSK
Blessing, John, PhD	X	
Boparai, Karen	X	
Borges, Virginia, MD		Consultant/Chair: Consulting Fee: SeaGen
Boron, Matthew, RPh	X	
Boss, Michael, PhD	X	
Bovi, Joe, MD	X	
Brundage, Michael, MD, MSc		Researcher/Unrestricted Research Grant: Genentech; Pfizer
Bui, Thanh Cong, MD	X	
Camden, Sarah, RN	X	
Carter, Sherell, AAS	X	
Celender, Nick	X	
Chakravarti, Arnab, MD		Research Grant Funding: Varian Medical Systems, Inc. Advisory Board/Salary: NCI Advisory Board
Chase, Dana, MD	X	
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Cooley, Mary, PhD, RN	X	
Creasman, William, MD	X	
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FACULTY DISCLOSURE LIST

		Consulting: Intellectual Property (Wilson Soncini)
DiGati, Rebecca	X	
Duska, Linda, MD		Paid for DSMC: Inovio Editorial Board: UpToDate; British J OB/GYN Payment of service: ASCO; NCI Funding Research: Merck; GSK
Ellis, Matthew, MB, BCHIR, PhD		Advice on commercialization of Prosigna/Royalties: Veracyte/Prosigna Consulting/Fee: Novartis; Lilly; G1 Therapeutics; Sermonix
Ellis, Rodney, MD	X	
Efstathiou, Jason, MD		Consulting Fee: Blue Earth Biagnostics; Boston Scientific; AstraZeneca Honorarium: Roivant Pharma; Myovant Science; Progenics; Merck
Elsea, Tiffany, BA, CCRP	X	
Engel, Kristen	X	
Eskander, Ramez, MD		Advisory Board/Consulting Fee: AstraZeneca; Merck; Clovis; GSK Advisory Board/Speaking/Consulting Fee: Myriad
Finnigan, Meanie, BS	X	
Frak, Izabela, MPhil	X	
Gagh, Sheena	X	
Ganz, Patricia, MD	X	
Gay, Hiram, MD	X	
Geyer, Charles, MD		Consultant/Consulting Fee: Athenex Ad Board/Honorarium: Exact Sciences
Gogoi, Radhika, MD	X	
Gondi, Vinai, MD	X	
Goranova, Nadia	X	
Green, Renee	X	
Harper, Elaina	X	
Hayes, Yuliya	X	
Higgins, Kristin, MD		Consulting/Advisory Board/Consulting Fee: AstraZeneca Speaker/Honorarium: Precis CA
Holeva, Karen, MS	X	
Horowitz, Neil, MD		Author/Royalty: UpToDate
Hudson, Matthew, PhD, MPH	X	
Hughes-Halbert, Chanita, PhD	X	
Hunter, Joanne, BS, RT (R)(T)	X	
Hurwitz, Mark, MD		Consultant/Consulting Fee: Neotherma
Iyengar, Puneeth, MD	X	
Jacobson, Whitney, RN, CCRP, OCN	X	
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Jegadeesh, Naresh, MD	X	
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Kerwin, Mackenzie	X	
Kennish, Margaret, AS, CCRC	X	
Kim-Suh, HeeSun, RN, BSN, OCN	X	
Kirshner, Dolly, MPH, BS, BA	X	
Kocherginsky, Masha, PhD		Patent Royalty Payments: US Patent Grant Reviewer/Honorarium: LUNgevity Foundation
Kohn, Elise, MD	X	
Konstantinopoulos, Panagiotis, MD, PhD		Advisory Board/Consulting Fee: AstraZeneca; Alekermes; GSK
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Kotsko, Kristen, RN, BSN	X	
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Levine, Douglas, MD	X	
Liao, Xing, MD	X	
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Lorson, Christine, RN, BSN	X	
Lowenstein, Jessica, MS, DABR	X	
Lukka, Himanshu, MD		Membership Ad Board/Honorarium: Tesaro; Abbvie; Bayer; Sanofi; Jansen; Astellas; Variety, Knights Pharma
Malik, Shakun, MD	X	
Mamounas, Eleftherios, MD		Advisory Board/Speakers Bureau; Honorarium: Exact Sciences; Genentech Advisory Board/Honorarium: Daiichi Sankyo Biotherapeutics; Merck Consulting/Honorarium: Merck
Manfredi, Denise, BS, RT (T)	X	
Matisko, Mary Pat, RN, BSN	X	
McCartney, Sara, MS, RN	X	
McNulty, Susan, CMD, BS (R)(T)	X	
Michaelson, Dror, MD, PhD	X	
Michalow, Wendy	X	
Miller, Brian, PharmD		Pharmacy Consultant/Consulting Fee: Spring Bank Pharmaceuticals; HiberCell, Inc.
Movsas, Benjamin, MD		Consulting Fee/Research Support: Varian, Inc.; ViewRay, Inc.; Philips, Inc.
Mroziak, Joseph	X	
Morgan, Todd, MD	X	
Morgans, Alicia, MD		Consultant/Research/Honorarium: Bayer; Sanofi; Dendreon; Myovant Consultant/Honorarium: Janssen; AstraZeneca; Astellas; Clovis; Blue Earth
Motyka-Welsh, Elaine, RN, MSN, CCRP	X	
Moxley, Katherine, MD	X	
Mutch, David, MD	X	
Nguyen, Paul, MD		Consulting/Fee: Boston Scientific Advisory Board/Consulting/Fee/Research Funding: Janssen; Bayer; Myovant
Nguyen, Quynh-Nhu, MD	X	
Niccolai, Amy	X	
Novak, Matthew, MS	X	
O'Cearbhaill, Roisin, MD		Advisory Board/Honorarium: Regeneron; Genmab Therapeutics
Ohri, Nitin, MD		Consulting/Consulting Fee: AstraZeneca; Merck
Palazzolo, Paulette, RN, CCRC		Spouse/Shares/Stocks: Abbot; AstraZeneca; Danaher Corp; Edwards Life Sciences; GSK; Intuitive Surgical, Inc.; Medtronic; Merck; Novartis; Novo Nordisk; Sanofi; Thermo Fisher; United Health Group
Passarello, Mimi, MBA	X	
Patel, Vanita, MS	X	
Presley, Jennifer, BS, RT	X	
Price, Cynthia	X	
Powell, Matthew, MD		Consulting/Fee: Roche Genentech; AstraZeneca; GSK/Tesaro; Johnson & Johnson; Clovis; Eisai; GOG Partners
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Rimel, Bobbie, MD		Advisory Board/Honorarium: GSK/Tesaro; Merck; AstraZeneca
Rimner, Andreas, MD		PI/Research Grant: Varian Medical Systems PI/Consulting/Research Grant/Consulting Fee: AstraZeneca; Merck; Boehringer Ingelheim PI/Consulting Fee: Cybrexa Speaker/Teaching/Honorarium: ResearchToPractice Consulting/Honorarium: MoreHealth Conference Attendee/Travel: Philips/Elekta
Ritter, Marcie	X	
Robinson, Cliff, MD		Consulting/Consulting Fee: AstraZeneca; EMD Serono; Varian Consulting/Consulting Fee/Stok Options: Raidialogic Consulting/Stock Options: QRS
Sartor, Oliver, MD		Consultant/Consulting Fee/Honorarium: Advanced Accelerator Applications; Astellas; AstraZeneca; Bayer; Blue Earth Diagnostics Inc.; Bavarian Nordic; BMS; Clarity Pharmaceuticals; Clovis; Constellation; Dendreon; EMD Serono; Fusion; Isotpen Technologien Meunchen; Janssen; Myovant; Myriad; Noria Therapeutics, Inc.' Novartis; Noxopharm; Progenics; POINT Biopharma; Pfizer; Sanofi; Tenebio; Telix; Theragnostics Research Support/Grant: Advanced Accelerator Applications, AstraZeneca; Bayer; Constellation; Dendreon; Endocyte; Invitae; Janssen; Merck; Progenics; Sanofi; SOTIO
Schmitz, Kathryn, PhD	X	
Serianni, Jeffrey, BS	X	
Shaitelman, Simona, MD	X	
Simone, Charles, MD		Speaker/Honorarium: Varian Medical Systems
Slomovitz, Brian, MD		Consultant/Consulting Fee: AstraZeneca; Merck; GOG Foundation; Clovis; Genentech; GSK; Myriad
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Solanki, Abhisek, MD, MS	X	
Soto, Nancy	X	
Sullaway, Catherine, BS	X	
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Tewari, Krishnansu, MD		Speakers Bureau/Advisory Board/Honorarium: Merck; GSK; AstraZeneca; Eisai; Clovis Advisory Board/Consulting Fee: Abbvie
Thomas, Terry, MS, CCRC		Founder/Consultant/Consulting Fee: GammaTile, Inc.
Tran, Phuoc, MD, PhD		Consulting/Research Grant: RefleXion Medical Advisory Board: Novopharm Medical Medical Advisory Board/Consultant: Janssen Medical Advisory Board: Myovant; AstraZeneca Research Grant: Bayer; Astellas
Trilk, Jennifer, PhD	X	
Valicenti, Richard, MD	X	
Walker, Joan, MD	X	
Wang, Xin Shelley, MD, MPH		Ownership/Interest: Symptom Assessment Systems, LLC
Waqar, Saiama, MD	X	
Washington, Deborah, RN, MSN	X	
Washington, Christina, MD	X	
Weiblen, Melina, BS	X	
Wenzel, Lari, MD	X	
Winslow, Chrisann, RN, MSN	X	
White, Julia, MD		Speaking/Teaching/Honorarium: GHI
Wise, James	X	
Wise, Liz, CCRC	X	
Wolmark, Norman, MD	X	
Yeager, Kate, PhD, RN	X	
Zumsteg, Zachary, MD		Wife is attorney/Compensation to firm: Johnson & Johnson; Allergan

Welcome to the NRG Oncology Virtual Winter Meeting 2021

As we host our second “pandemic edition” virtual meeting, the occasion marks over 10 months since we – and all our Members, have added social distancing and remote work to our everyday lives. Where once we gathered in conference rooms and ballrooms, we now navigate meetings from our cubical or home office, safely distanced from others. With many of us already having received at least our first dose of the vaccine, a light shines at the end of the tunnel as we look ahead toward gathering once again.

Eventually, the pandemic will become just a memory, but some of what we have learned - such as the use of technology to make some of our in-person meetings accessible to those who cannot travel - will remain. Certainly, there are other positive outcomes as well – the widespread adopting of telehealth and remote tools for interacting with patients among them. We appreciate the efforts of NRG Members to continue this important work, and our accomplishments of 2020 reflect this devotion.

In the meantime, we welcome you to the first NRG Oncology Group meeting of 2021! We hope you will join us for many sessions that capture your interests and take advantage of some of the virtual tools to connect with colleagues and friends. Don't be shy on social media, we'd love to hear how things are going! Use our hashtag #NRG2021 to follow our meeting as it progresses.

Our General Session is a forum to learn more about our Group's activities, and especially to honor our friend Wally Curran, Jr., MD as he has stepped down as NRG Oncology Group Chair. The Thursday Plenary offers some thoughts about leveraging funding opportunities in addition to highlighting the work of a few of our committees – we hope you will enjoy this session as well.

As always, we appreciate all you do on NRG Oncology's behalf and wish a safe and healthy 2021. Please enjoy the meeting.



M Machtay

Mitchell Machtay, MD
Presiding Group Chair (*Interim*)



Robert S. Mannel, MD

Robert S. Mannel, MD
NRG Group Chair
& Board Chairman



N Wolmark

Norman Wolmark, MD
NRG Group Chair
& Contact PI

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



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

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

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.

Instructions for Claiming CME Credits NEW!

To receive CME credit hours or an Attendance Certificate for the NRG Oncology meeting, or CE (Nursing) credit hours for selected sessions, registered attendees are required to submit a CME/CE Evaluation. AFTER you have attended ALL sessions intended, please select button labeled CME/CE to complete Evaluation Forms on the virtual attendee hub.

Please allow 4 weeks to receive your certificate. Certificates will be sent to the email you used to register.

For questions please email: cmeinfo@gog.org.



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

Final Listing of Approved CME Credits

The following sessions/workshops have been approved to receive credits accredited by the GOG Foundation for the virtual meeting January 27-30, 2021				
WORKSHOP AGENDAS	Wednesday	Thursday	Friday	Saturday
Symposium "Survivorship – Surviving and Thriving in the Shadow of Cancer"		2		
Breast Cancer Committee			2	
Cancer Prevention and Control Committee		2		
Cancer Care Delivery Research Committee			2	
Cervix Cancer Committee			2	
Genitourinary Cancer Workshop			2	
Gynecologic Cancer Committee				2
GYN Developmental Therapeutics Committee			2	
Lung Cancer Committee				2
New Investigators " LOL/Concept Development Nuts and Bolts"		1.5		
Patient Centered Outcomes Research (PCOR)		2		
Rare Tumor Workshop Subcommittee			1	
Ovarian Cancer Subcommittee			2	
Translational Science Committee			1.5	
Uterine Corpus Committee			2	
<i>PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD's</i>				
PSC-Clinical Trial Nurse/Clinical Research Assoc. Ed Session		2		
PSC CTN/CRA – Breakout Sessions		2		
PSC-Clinical Trial Nurse/Clinical Research Assoc. Introduction to Clinical Trials	2			



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Mohamed E. Salem, MD
@SalemGIOncDoc



Chirag Shah, MD
@CShahMD



Nicole L. Stout, DPT, FAPTA
@NicoleStoutPT



Samilia Obeng-Gyasi, MD, MPH
@GyasiSamilia

#NRG2021



WINTER 2021
VIRTUAL MEETING
Jan. 28 - 30, 2021

Follow our Winter Meeting

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#NRG2021



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The NRG Oncology Winter 2021 Virtual Meeting

WEDNESDAY, JANUARY 27, 2021

- 1:00** Protocol Support Committee Presents - "Introduction to Clinical Trials: Principals of NRG Oncology Clinical Trials Management for Nurses and Clinical Research Associates"
- 3:00** NRG FORTE Study Update

THURSDAY, JANUARY 28, 2021

- 10:00** Health Disparities Committee
- 10:00** Protocol Support Committee Presents - "Clinical Trial Nurse/Clinical Research Associate Workshop" - Continuing Education Session
- 10:30** New Investigator Committee Presents - "LOI/Concept Development Nuts and Bolts"
- 12:30** New Investigators Networking Luncheon BYOL
- 1:00** Protocol Support Committee Presents - "Clinical Trial Nurse/Clinical Research Breakout Sessions"
- 1:00** Cancer Prevention & Control Committee
- 3:00** Plenary Keynote
- 4:00** Winter Symposium - "Survivorship: Surviving & Thriving in the Shadow of Cancer"
- 4:00** Patient Centered Outcomes Research Committee

FRIDAY, JANUARY 29, 2021

- | | |
|--|---|
| 8:00 Developmental Therapeutics Committee | 1:30 Cancer Care Delivery Research Committee |
| 8:00 Rare Tumor Subcommittee | 1:30 Head and Neck Cancer Committee |
| 8:00 Radiation Oncology Committee | 1:30 Genitourinary Cancer Committee |
| 10:00 NCORP Townhall | 1:30 Uterine Corpus Cancer Subcommittee |
| 10:00 Brain Tumor Committee | 3:30 Translational Science Committee |
| 10:00 Breast Cancer Committee | 3:30 Patient Advocate Committee |
| 10:00 Cervix/Vulvar Cancer Subcommittee | 3:30 Ovarian Cancer Subcommittee |
| 12:15 General Session | |

SATURDAY, JANUARY 30, 2021

- 9:00** Gastrointestinal Colorectal Cancer Committee
- 9:00** Lung Cancer Committee
- 9:00** Gynecologic Cancer Committee
- 10:45** Gastrointestinal Non-Colorectal Cancer Committee





Special Events/Sessions/Workshops





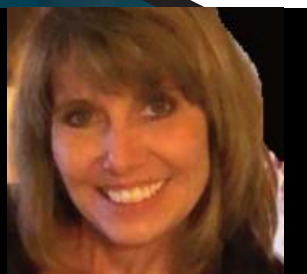
WINTER 2021
VIRTUAL MEETING
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The NRG Oncology Protocol Support
Committee presents:

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Cynthia Licavoli,
RN, BSN, MA



Karen Holeva, BS,
CCRP

Welcome

Introduction to Clinical Trials: Principals of NRG Oncology Clinical Trial Management for Nurses and CRAs

**Wednesday, January 27, 2021
1:00 pm - 3:30 pm EST**



Karan Boparai

NRG Membership



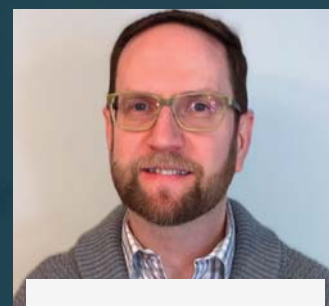
Judy Langer

Regulatory Affairs



Brian Miller, PharmD

**Investigational Drug
Management**



Joseph Mroziak

Medidata Rave



Mimi Passarello, MBA

Quality Assurance Audits



Shannon Puhalla, MD

RECIST Criteria



Nancy Fusco, RN, BSN

Mentorship Program



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The NRG Oncology Protocol Support
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#NRG2021



**Karen Holeva, BS,
CCRP**

Welcome

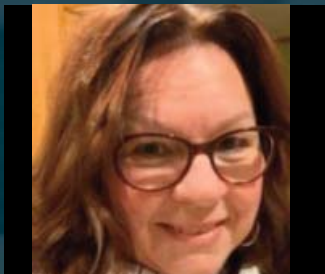
Clinical Trials Nurse / Clinical Research Associate Workshop - Educational Session

Thursday, January 28, 2021
10:00 am - 12:00 pm EST



**Sara McCartney,
MS, RN**

**Serious Adverse
Event Reporting**



Cyndi Price

IROC



Sandy DeVries

Biospecimen Collections



Marcie Ritter

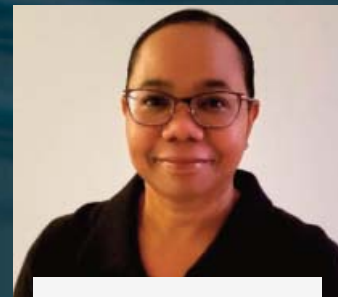
**Patient Reported
Outcomes/Patient
Cloud**



James Wise



Nadia Goranova



Renee Green

CIRB

Clinical Trial Nurse / Clinical Research Associate Workshop Breakout Sessions

Thursday, January 28, 2021
1:00 pm - 3:00 pm EST



The NRG Oncology Protocol Support
Committee presents:
#NRG2021

Brain Protocols

Liz Wise CCRC; Sherell Carter, AAS; Denise Manfredi, BS, RT (T); George Ballinger, RT(R)(T)

Breast (NRG-BR002) & GI-Non-Colorectal

Debora Washington RN, MSN; Susan McNulty, CMD, BS (R)(T); Wendy Bergantz, RN

Breast Topics (NRG-BR004/BR003)

Mary Pat Matisko, RN, BSN; Kim Auth, RN, BSN; Lisa Barry, MAEd, BS

GI FORTE (NRG-CC005)

Christine Lorson, RN, BSN; Kristen Kotsko, RN, BSN; Sarah Camden, RN

GU Protocols

Elaine Motyka-Welsh, RN, MSN, CCRP; Margaret Kennish, AS, CCRC; Joanne Hunter, BS, RT (R)(T)

GYN Protocols

Izabela Frak, MPhil; Dolores Kirschner, MPH, BS, BA; Ashley Badders; Nick Celnder

Head & Neck Protocols & Sarcoma

Vanita Patel, MS; Lisa Abate; Marsha Raddeb BS, RT, (R)(T)

Lung Protocols

Jeffrey Serrianni BS; Matthew Novak, MS; Jennifer Presley, BS, RT (R)(M)(T); Joe Bauza, RT

NCORP – NRG CC002

Kristen Engel

Neurocognitive Testing

Catherine Sullaway, BS

NRG Oncology Audit

Mary Jo Antonelli, MBA, BSChem; Jerry Koss, RN, BSN

NRG Oncology Audit

John Blessing, PhD; Sally Bialy, MA

NRG Oncology Consents

Judy Langer

NRG Oncology Membership/Payments

Karan Bopari; Julie Kardell; Yuliya Hayes; Wendy Michalow; Amy Niccolai

NRG Oncology Biospecimen Bank

Sandy DeVries, MA; Melanie Finnigan, BS; Lisa Beaverson, BA, CCRP; Heather Lankes, PhD, MPH

AE/SAE Reporting:

Sara McCartney, MS, RN

e-PRO – Patient Cloud

Elaina Harper; Marcie Ritter

IROC Radiation Therapy

Jessica Lowenstein, MS, DABR; Nancy Linnemann, BS, RT (R)(T)

IROC Diagnostic Imaging

Michael Boss; Cynthia Price; Lisa Cimino; Rebecca DiGati; Joseph Bauza

Pharmaceutical Management Branch

Tali Johnson, Pharm D, BCOP; Matthew Boron, RPh

Vision Tree

Sheena Gagh, Client Services, Manager; Mackenzie Kerwin, Account Manager

Best Practice: COVID 19 Workflow

Chrisann Winslow, RN, MSN

Best Practice: Top 20 Random Thoughts

Cynthia Licavoli, RN, BSN, MA, Tiffany Elsea, BA, CCRP

Best Practice: Study Start Up, Implementation & Management

Terry Thomas, MS, CCRC, Whitney Jacobson, RN, CCRP, OCN

Best Practice: Site Administrator:

Paulette Palazzolo

Best Practice: On Boarding New Coordinators (Nurse/CRAs)

HeeSun Kim-Suh, RN, BSN, OCN; Karen Holeva, BS, CCRP

FORTE Protocol Workshop

Wednesday, January 27, 2021

3:00 pm - 4:00 pm EST



WINTER 2021
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Lisa Kachnic, MD

Dr. Lisa Kachnic is the chief of Radiation Oncology Service at the New York-Presbyterian/Columbia University Irving Medical Center and Chair of the Department of Radiation Oncology at Columbia University. She currently serves as the Associate Chair for NRG NCORP and Co-Chair of NRG's Cancer Prevention and Control Committee.

Dr. Kachnic is one of the nation's leading radiation oncologists and her combined focus on clinical excellence, technological innovation and patient centered research continues to advance the field of radiation oncology.



**Robert E. Schoen,
MD, MPH**

Dr. Schoen is a Professor of Medicine and Epidemiology and Chief of Gastroenterology, Hepatology and Nutrition at the at the University of Pittsburgh and UPMC.

Dr. Schoen is the Principal Investigator of the FORTE trial and an international expert in early detection and prevention of colorectal cancer.



Jeffrey Dueker, MD

Dr. Dueker is an Assistant Professor of Medicine in the Division of Gastroenterology at the University of Pittsburgh Medical Center (UPMC) and the protocol co-chair for the FORTE trial. His research interests are in quality improvement and healthcare delivery models.



Sarah Camden, MS

Sarah Camden is an Assistant Project Manager at the Statistics and Data Management Center of NRG Oncology – Pittsburgh. Her specialty is using Medidata Rave to capture data elements for breast, colorectal, and gynecologic cancer trials. She will be serving as the Study Builder and Data Manager for the FORTE trial.



**Christine Lorson,
BSN, RN**

Christine Lorson is an Education and Communication Specialist with FORTE trial. Christine is a graduate of the University of Pittsburgh with thirty years of professional nursing experience. Christine will be contributing to the success of FORTE through site engagement, communications, and education.



FORTE Protocol Workshop Agenda

Date: January 27, 2021

Time: 3:00 p.m. – 4:00 p.m. EST

Location: Remote at NRG Winter Meeting

3:00 p.m.-3:05 p.m.	Welcome	TBD/ Lisa Kachnic, MD, NRG NCORP Associate Chair
3:05 p.m.-3:35 p.m.	Part I: FORTE Introduction 1. Introduction and importance of FORTE 2. Trial overview and eligibility 3. Retrospective Enrollment/ Patient selection Questions and Answers	Robert Schoen, MD, MPH, Principal Investigator/ Study Chair Jeffrey Dueker, MD, Protocol Co-chair Joshua E. Melson, MD
3:35 p.m.-3:45 p.m.	Part II: FORTE Site Resources 4. Forms/ VisionTree Overview 5. Social Media/ Clinical Coordinating Department, Will show video showcasing Dr. Schoen promoting FORTE Questions and Answers	Sarah Camden, MS, Assistant Project Manager Christine Lorson, RN, BSN, FORTE Education and Communication Specialist
3:45 p.m.-4:00 p.m.	Part III: FORTE Study is user friendly 6. Funding / User Friendly Study 7. Call to Action Questions and Answers	Robert Schoen, MD, MPH, Principal Investigator/ Study Chair





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The NRG Oncology New Investigator
Committee presents:

#NRG2021



Elise C. Kohn, MD
NCI CTEP

Welcome Remarks;
Distinguishing LOI/Concept;
Science Rationale;
How to Develop Your Idea;
Communications;
Biomarker Definitions

LOI/Concept Development Nuts & Bolts

Thursday, January 28, 2021
10:30 am - 12:30 pm EST



Charles Kunos, MD, PhD
NCI CTEP

Reviewing
Identification of
Potential Agents -
CTEP & Beyond;
Preclinical Prerequisites



Masha Kocherginsky, PhD
Northwestern, University

Statistical Considerations
for Clinical Trial Design



Nancy Soto
NRG Oncology

NRG Oncology
-specific Processes
for LOI/Concept
Development



Vinai Gondi, MD
Northwestern University

Pathway to Trial
Development:
Lessons Learned

**Session to be followed by breakout group networking sessions from
12:30 pm - 1:15 pm EST - Listed on the Meeting agenda as
“New Investigators Networking Luncheon BYOL”**



NRG ONCOLOGY WINTER PLENARY KEYNOTE

THURSDAY, JANUARY 28, 2021 – 3:00PM – 4:00PM ET

Welcome

Mitch Machtay, MD
Presiding Group Chair (Interim)

Federal Funding Landscape

Deborah Watkins Bruner, RN, PhD
NRG NCORP Contact PI

NRG Oncology Portfolio Updates

NRG Developmental Therapeutics Portfolio

Roisin E. O'Cearbhail, MD
NRG Developmental Therapeutics Committee Chair

NRG Genitourinary Cancer Portfolio

Felix Feng, MD
NRG Genitourinary Cancer Committee Chair

NRG Breast Cancer Portfolio

Elftherios Mamounas, MD, MPH
NRG Breast Cancer Committee Chair



WINTER 2021
VIRTUAL MEETING
Jan. 28 - 30, 2021

AGENDA
NCORP TOWN HALL
Friday, January 29, 2021
10:00 – 11:30am EST

10:00 – 10:15am	Welcome NRG NCORP Updates	Deb Bruner, PhD, RN, NRG NCORP PI
10:15 – 10:30am	Mentorship opportunities	Joan Walker, MD, NCORP PI
10:30 – 10:40am	Q&A – Open Discussion	
10:40 – 10:45am	Introduction of NCI speakers	Deb Bruner, PhD, RN, NRG NCORP PI
10:45 – 10:55am	NCI NCORP Update	Sandra Russo, MD, Community Oncology and Prevention Trials Research Group, DCP
10:55 – 11:05am	NCI CCDR Update	Kathleen Castro, RN, MS, Nurse Consultant, Office of the Associate Director of the Healthcare Delivery Research Program
11:05 – 11:25am	Q&A – Open Discussion – chat moderators	
11:25 – 11:30am	Closing Remarks	Deb Bruner/Joan Walker

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WINTER 2021
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Norman Wolmark, MD

**NRG Group Chair
& Contact PI**



Robert Mannel, MD

**NRG Group Chair
& Board Chairman**



**Mitchell Machtay,
MD**

**Presiding Group
Chair (Interim)**

Sponsored by: Seagen, Inc



Walter Curran, Jr., MD

Honored Speaker

NRG Oncology General Session

Friday, January 29, 2021
12:15 pm - 1:15 pm EST



David Miller, MD

**Deputy Group Chair for
Membership**



Deborah Watkins Bruner, RN, PhD

**NCORP Research Base
Contact PI**



James Dignam, PhD

Group Statistician



Harry Bear, MD

**Deputy Group Chair,
Communications & Publications**



Richard Jordan, DDS, PhD

Biospecimen Bank Grant Co-PI

NRG Oncology General Session

**Friday, January 29
12:15-1:15pm ET**

Opening

Mitchell Machtay, MD
NRG Oncology Presiding Group Chair (Interim)

NRG Research Center Update

Mitchell Machtay, M.D.
Deputy Group Chair, Research

NRG Membership Update

David Miller, M.D.
Deputy Group Chair for Membership

NRG NCORP Research Base Update

Deborah Watkins Bruner, RN, Ph.D.
NCORP Research Base Contact PI

**NRG Communications &
Publications**

Harry Bear, M.D.
Deputy Group Chair, Communications &
Publications

NRG Biospecimen Bank Update

Richard Jordan, DDS, Ph.D.
Biospecimen Bank Grant Co-PI

**NRG Statistical and Data Management
Center Update**

James Dignam, Ph.D.
Group Statistician

Closing Remarks

Mitchell Machtay, MD
NRG Oncology Presiding Group Chair (Interim)



Workshop Agendas (CME/Non-CME)



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NRG Scientific Committees

Breast Cancer Workshop Agenda (Virtual by Zoom)

Date: Friday, January 29, 2021
Start and End Time: 10:00 am – 12:00 pm
Chair: Eleftherios Mamounas, MD
Co-Chairs: Julia White, MD; Charles Geyer, MD; Matthew Ellis, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

10:00 – 10:15	Report from the Breast Working Group Meeting	Eleftherios Mamounas, MD Julia White, MD
	SABCS UPDATE	
10:15 – 10:45	ONCOTYPE/RxSPONDER Trial	Norman Wolmark, MD
10:45 – 11:00	MonarchE/PENELOPE-B Trials	Priya Rastogi, MD
11:00 – 11:15	ALTERNATE/ADAPT Trials	Matthew Ellis, MD
11:15 – 11:30	NRG BR-007: A Phase III Clinical Trial Evaluating De-Escalation of Breast Radiation for Conservative Treatment of Stage I, Hormone Sensitive, HER2-Negative, Breast Cancer with a Low Oncotype Recurrence Score	Julia White, MD
11:30 – 11:45	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	
11:45 – 12:00	NRG BR-004 A Randomized Phase III Trial of Taxane/ Trastuzumab/Pertuzumab/Placebo Compared to Taxane/ Trastuzumab/Pertuzumab/Atezolizumab in First Line HER2-Positive Metastatic Breast Cancer	Charles Geyer, Jr., MD
	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	

Cancer Prevention and Control Workshop

Date: Thursday, January 28, 2021
Start and End Time: 1:00pm – 2:45pm
Chairs: Lisa Kachnic, MD; Douglas Levine, MD
Vice Chairs: Debra Barton, PhD; Julie Bauman, MD

Thursday, January 28, 2021, 1:00 – 2:45pm

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss proposed and ongoing NRG clinical trials on cancer prevention and control in each of the primary disease sites
 2. Discuss proposed and ongoing NRG clinical trials on prevention and control in each of the four disciplines (disparities, chemoprevention, survivorship and biomarkers and early detection)
 3. Discuss multi-disciplinary aspects of ongoing and proposed clinical trials in each of the primary disease sites
 4. Discuss promising translational research objectives and priorities for future clinical trials
 5. Identify and prioritize areas of unmet need in cancer prevention research in each of the primary disease sites
 6. Apply standards and procedures required to design, submit, and conduct a research protocol for support by the NRG
-
- A. CPC overview – Lisa Kachnic, MD; Douglas Levine, MD
 - i. Pilot project awards
 - ii. Review of Open and Developing studies
 - B. Preoperative RT to Improve Cosmetic Outcomes in Breast Cancer Patients – Simona Shaitelman, MD
 - C. NRG-CC001 imaging report – Joe Bovi, MD
 - D. RTOG 0938, *A Randomized Phase II Trial Of Hypofractionated Radiotherapy For Favorable Risk Prostate Cancer-RTOG CCOP Study*” - 5 year update – Himu Lukka, MD
 - E. 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]”* – Douglas Levine, MD
 - F. NRG-CC009 *“Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for 10 or Fewer Brain Metastases from Small Cell Lung Cancer”* – Vinai Gondi, MD
 - G. Questions – 15 min
 - H. Breakout groups (30-40min)
 - i. Surgical prevention and evaluation of screening test results – Dr. Levine
 - ii. Chemoprevention and secondary cancer prevention – Dr. Bauman
 - iii. Control of long-term adverse events and fatigue – Neurocognition and lymphedema – Dr. Barton
 - iv. Mitigation of cancer related symptoms – Dr. Kachnic

Cancer Care Delivery Research (CCDR) Meeting

Date: Friday, January 29, 2021

Start and End Time: 1:30pm – 2:45pmEST

Co-Chair: Mary Cooley, PhD, RN

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

Learning Objectives

Following this activity, participants will be better able to:

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

SPEAKERS		
1:00 – 1:10pm	Welcome and Committee Updates <ul style="list-style-type: none"> Symposium – March 15, 2021, 12pm – 1:45pmEST Pilot project(s) awarded 	Mary Cooley, PhD, RN, CCDR Chair; Matthew Hudson, PhD, CCDR Vice-Chair
1:10 – 1:20pm	CCDR Concept in Early Development <i>Identification and Intervention Implementation Science</i>	Christina Washington/Joan Walker, MD
1:20 – 1:25pm	<i>Protocol for Food Insecurity Social Determinant of Health</i> Next steps/response	Karen Basen-Engquist
1:25 – 1:35pm	CCDR Concept in Early Development <i>Relational Agents in Cervical Cancer Education (RACE)</i>	Radhika Gogoi, MD
1:35 – 1:40pm	Next steps/response	Joan Walker, MD; Thanh Cong Bui, MD
1:40 – 1:50pm	CCDR Concept in Early Development <i>Leveraging Telehealth Technology</i> Next steps/response	Bridget Koontz, MD Matthew Hudson, PhD/Kate Yeager, PhD, RN
1:50 – 2:00pm	Completed CCDR pilot project <i>Rurality, neighborhood socioeconomic and environmental deprivation and patient-reported outcomes for men with prostate cancer in RTOG 0415</i>	Jingbing Bai, PhD
2:00 – 2:05pm	Next steps/response	Chanita Hughes-Halbert, PhD
2:05 – 2:15pm	CCDR Concept in Development <i>Exercise is Medicine in Medical Oncology</i>	Kathryn Schmitz, PhD and Jennifer Trilk
2:15 – 2:35pm	Open studies <ul style="list-style-type: none"> NRG-CC007CD NRGF-001 	Ronald Chen, MD Nitin Ohri, MD
2:35 – 2:45pm	QUESTIONS / DISCUSSION	Chat inbox facilitated by Matt Hudson

Developmental Therapeutics Committee Agenda

Date: Friday, January 29, 2021
Start and End Time: 8:00 am – 10:00 am
Chairs: Roisin O’Cearbhaill, MD (Dev. Therapeutics)
Michael Birrer, MD, PhD (Translational Science)
Translational Research Chair: Panagiotis Konstantinopoulos, MD, PhD (Dev. Therapeutics)
Co-Chairs: Floor Backes, MD (Phase II),
Russell Schilder, MD (Phase I)
Stephanie Gaillard, MD, PhD (Phase I)

Learning Objectives:

Following this activity, participants will be better able to:

1. Participants will become familiar with current status of translational research projects involving phase I and II studies that are under development or activated for accrual.
2. New concepts will be reviewed for approval or disapproval, including a discussion of 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.

8:00 AM – 8:05 AM Introduction, Dr. O’Cearbhaill. Welcome. Review of opportunities for new investigators.

8:05 AM – 8:30 AM Update on concepts from last meetings:

PI1915 Dr. Moxley, **PI1966** Simpkins, **PI2014** Fuh, **DT2013** Doll, **DT2059** Henson, **PI2058** Richardson

PTMA (originally ETCTN)

- **PI2054** Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Onstad/Westin)
- **UC2055** (Fuh/Moore) Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer

8:30 AM - 9:50 AM Review of new concepts

- **DT2104:** Anti-PD1 Therapy in Combination with Novel Immune Checkpoint Inhibitors in Recurrent and Progressive Endometrial Cancer. (Growdon)
- **DT2106:** A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent *ARID1A* mutated clear cell and endometrioid ovarian carcinomas. (Simpkins)

9:50 AM – 9:55 AM **ComboMatch** update (O’Cearbhaill, NRG representative for the ComboMATCH study)

9:55 AM – 9:59 AM Phase I site update. Other agenda items

List of Studies

No longer under development:

- **PI2029** *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 (Girda)*

Under development:

- **PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent recurrent squamous or non-squamous carcinoma of the cervix (Moxley) RSC Oct 2020
- **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) on hold
- **DT2013** CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer. (Corinne Doll) Data pending
- **PI2014** Phase IB of AVB500 in combination with carboplatin and paclitaxel or carboplatin and pegylated liposomal doxorubicin (Katherine Fuh)
- **DT2059**: Phase 1/2 M3814 plus hypo fractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (Henson/Moore)
- **PI2058**: A phase IA/IB study of ipatasertib in combination with carboplatin/paclitaxel or carboplatin/paclitaxel/atezolizumab in patients with advanced recurrent endometrial cancer (Richardson)
- **PI2054** Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Fuh/Moore)
- **UC2055** Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Onstad/Westin)

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

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

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

Ovarian Cancer and Endometrial cancer studies:

- **NRG-GY014** A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid/clear cell carcinoma of the ovary, and recurrent endometrioid endometrial adenocarcinoma (R Eskander) CTEP CRDL LOI. First stage completed accrual August 2019
- **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-GY009 (PTMA/CRDL)** A randomized, phase II/III study of pegylated liposomal doxorubicin and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab in platinum resistant ovarian cancer (O’Cearbhaill) **Phase II** completed accrual May 2019
- **NRG-GY012**, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Mackay) Prior DT safety review

Closed DT/Phase I studies:

Cervical Cancer

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

Endometrial Cancer Studies:

- **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 (Duska)

Ovarian Cancer Studies

- **NRG-GY007** A phase I/II study of ruxolitinib with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Landen) **Completed accrual**

QUESTIONS/DISCUSSION/EVALUATION

GI Non-Colorectal Cancer SubCommittee Agenda

Date: Saturday, January 30, 2021
Start Time: 10:45 am- 12:15 PM EST
Non-Colorectal Chair: Ted Hong, MD
Non-Colorectal Co-Chair: David 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

Meeting AGENDA

Discussion/Study Information	Speaker
Introduction and Opening Remarks	Ted Hong, MD David Ilson, MD, PhD

Review of New Concepts, Upcoming and Active Trials

LIVER STUDIES

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
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
NRG GI2022	Ablative RT +/- checkpoint inhibition in IHCC	Eugene Koay, MD

ESOPHAGOGASTRIC STUDIES

NRG GI006	Phase III RCT of Protons vs. Photons for Esophageal Carcinoma	Steven Lin, MD
NRG GI007	Phase I Trial with Expansion Cohort of OBP-301 (Telomelysin) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal And Gastroesophageal Adenocarcinoma Who are Not Candidates for Surgery	Geoff Ku, MD
EA2183	Rand phase II evaluating consolidative radiation + immunotherapy during first-line systemic therapy in patients with oligometastatic esophagogastric cancer	Kimberly Mak, MD
S2009	Phase II/III Randomized trial of pembrolizumab with or without cabozantinib for third line treatment of patients with advanced PD-L1+ gastric and GE junction cancer	Sam Klempner, MD
EA2174	A phase II study of peri-operative nivolumab and ipilimumab in patients with locoregional esophageal and gastroesophageal junctional adenocarcinoma	Evan Wuthrick

ANAL CANCER STUDIES

EA2165	Nivolumab after Combined Modality Therapy in Treating Patients with High Risk Stage II-IIIB Anal Cancer	Paul Romesser, MD
EA2182	A Randomized Phase II Study of De-intensified ChemoRadiation for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)	Prajnan Das, MD

GI Colorectal Cancer SubCommittee Agenda

Date: Saturday, January 30, 2021
Time: 9:00 – 10:30 am EST
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		Speaker
Introduction and Opening Remarks		Thomas George, MD Scott Kopetz, MD, PhD
Review of New Concepts, Upcoming and Active Trials		
Neuroendocrine Tumors		
	NCTN Portfolio of NET Studies	Heloisa Soares, MD
Adjuvant Colon Studies		
NRG-GI005	cfDNA as a decision tool for stage II colon cancer treatment	Kyle Van Morris, MD
NRG-GI008 (CIRCULATE-US)	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
S0820 (PACES)	Eflornithine & Sulindac for polyp prevention after CRC	Jenny Dorth, MD
Metastatic CRC Studies		
NRG-CR2003 (ERASure)	Update on Oligometastatic CRC Total Ablative Therapy	Paul Romesser, MD Kate Hitchcock, MD, PhD Eric Miller, MD, PhD
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
Rectal Cancer Studies		
A022003/NRG-CR1861 (JANUS)	Non-operative rectal cancer study concept	William Hall, MD
NRG-GI002 (TNT) and CR2064	TNT Trial and national rectal cancer studies	Thomas George, MD
New Early Phase Rectal Cancer Concepts	ATR inhibition	Terry Williams, MD, PhD Eric Miller, MD, PhD
	IDO inhibition	Haeseong Park, MD, MPH Matthew Ciorba, MD

Genitourinary Cancer Workshop Agenda

Date: Friday, January 29, 2021
Start and End Time 1:30 pm – 3:30 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

1:30 – 1:35 **Opening Remarks and Update**

1:35 – 2:45 **Review of Active Trials**

NRG GU002	PhII-III Adjuvant RT Following Radical Prostatectomy ± Adjuvant Docetaxel (RADD trial)	Mark Hurwitz, MD
NRG GU005	Phase III IGRT & SBRT vs. IGRT & Hypofrax IMRT localized prostate cancer	Rod Ellis, MD
NRG GU007	Phase I/II of RT + ADT +/- the PARP inhibitor Niraparib for patients with high-risk prostate cancer	Dror Michaelson, MD, PhD Zach Zumsteg, MD
NRG GU008	Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial	Ronald Chen, MD, MPH
NRG GU009 (PREDICT-RT). – newly activated!	Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with High Genomic Risk (PREDICT-RT)	Paul Nguyen, MD; Oliver Sartor, MD
RTOG 3506	Randomized Phase II Trial of Salvage Radiotherapy With Std vs Enhanced ADT (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features (STEEL trial)	Hiram Gay, MD

SWOG/NRG 1806	Chemoradiation +/- Immune Checkpoint Blockade for Bladder Cancer	Jason Efstathiou, MD
ECOG/NRG EA8185	Phase 2 Study of Bladder-Sparing Chemoradiation with Durvalumab in Clinical Stage 3, node Positive Urothelial Carcinoma (INSPIRE)	Abhishek Solanki, MD MS Jason Efstathiou, MD
SWOG 1802	Local therapy for M1 prostate cancer, a SWOG study	Richard Valicenti, MD
EA8183	Phase III Double Blinded Study of Early Intervention After RADICAL Prostatectomy with Androgen Deprivation Therapy with Darolutamide vs. Placebo in Men at Highest Risk of Prostate Cancer Metastasis by Genomic Stratification (ERADICATE).	Alicia Morgans, MD
2:45 – 3:10	Review of Pending Studies	
NRG GU010 (GUIDANCE)	Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-intensification and Intensification Clinical Trial (GUIDANCE)	Neil Desai, MD; Ale Berlin, MD PhD
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
NRG GU011	Phase II trial of Prostate oligometastatic radiotherapy with or without Androgen deprivation therapy (NRG PROMETHEAN).	Bridget Koontz, MD
3:10 – 3:25	Other issues	
Translational Research Medical Oncology Update Urology Update New Business		Phuoc Tran, MD PhD Oliver Sartor, MD Todd Morgan, MD Group
3:25 – 3:30	Closing Remarks	

Cervix Workshop Agenda

Date: Friday, Jan 29, 2021
Start and End Time: 10:00am- 11:55am EST (via zoom)
Chair: Charles A. (Trey) Leath, III, MD, MSPH
Co-Chair: Jyoti Mayadev, MD
Translational Co-Chair: Dmitriy Zamarin, MD, PhD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

Scientific Developmental Focus

- A. Introduction / Announcements (10:00-10:30AM)
 - a. Welcome, committee membership and rotation plan and review of Jan 2020 minutes
 - b. Cervix updates from the task forces
 - i. Cervical Cancer Task Force – Dana Chase (2nd Term), Katherine Moxley (1st Term)
 - ii. Cervical Cancer Task Force (Junior Investigator) – Naresh Jegadeesh
- B. Scientific updates (10:30-10:50AM)
 - a. Non-CTEP Relevant Cervical Cancer Trials
 - i. GCIG (Dr. David Gaffney)
 - ii. GOG Partners (Dr. Leslie Randall)
- C. New Concepts (10:50-11:30AM)
 - i. RT2111 A Phase II Trial of the efficacy of nivolumab and low dose ipilimumab with and without Abemaciclib in high grade neuroendocrine carcinoma (small cell and large cell carcinomas) of cervix and other gynecologic origins (Mahdi)
- D. Previously Approved Concept Updates (11:30-11:45AM)
 - I. **GY0024** (Brian Slomovitz / Lillian Gien): GROINSS V3
 - II. **CV1964** (Scott Glaser / Oladapo Yeku): Incorporation of Immunotherapy into The Management of Locally Advanced Carcinoma of the Vulva
 - III. **UC1963** (Junzo Chino): A Randomized Phase II trial of ablative radiation therapy for women with oligometastatic gynecologic cancers
 - IV. **PI1915** (Katherine Moxley): A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor

(AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix **CTEP IND**

- V. **DT2013** (Corrine Doll): CB-839 before and concurrent with chemoradiotherapy in patients with locally advanced, node positive cervical cancer
- VI. **CV2040, Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARTACUS) II** (Eric Leung)
- VII. **CV2061**: A Phase I/II Study of Atezolizumab and tiragolumab with chemoradiotherapy vs. chemoradiotherapy standard of care for Locally Advanced Cervical Cancer (Jyoti Mayadev)
- VIII. **DT2059**: Phase 1/2 M3814 plus hypofractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (Kathleen Moore)

Operational management on-going NRG trials (11:45-11:55AM)

E. Closed Studies

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

F. Active / Recently Completed Trials

- a. **GOG-0724/RTOG0724**: Phase III trial randomized study of concurrent chemotherapy and pelvic RT with or without adjuvant chemotherapy in high-risk patients with early stage cervical carcinoma following radical hysterectomy. (Heidi Gray, Anuja Jhingran)
 - i. Opened April 2009
 - ii. Accrual 222/285 (77.9%)
- 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 331/360 (91.9%)
- 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)
 - v. Presented at Virtual SGO 2020
- d. **GOG-0274**: A phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: GOG collaboration with the OUTBACK trial (ANZGOG 0902/GOG 0274 / RTOG 1174). (Kathleen Moore)
 - i. Opened January 2012; NRG target accrual 500
 - ii. Expanded target accrual to 900 patients
 - iii. Accrual completed May 2017
 - iv. Study closed 6/1/2017 – 924/900 accrued – NRG accrual 627

- e. **GOG-0278:** Evaluation of physical function and quality of life (QOL) before and after non-radical surgical therapy for stage IA1-IB1 (≤ 2 cm) cervical cancer. (Al Covens)
 - i. Opened October 1, 2012
 - ii. PET imaging amendment approved July 2015
 - iii. Accrual 214/220 (97.3%)
- 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 309/450 (68.7%)
- 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. Suspended to accrual – Amendment to increase sample size disapproved

Reports from Other Committees and Groups

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

Next Semi-Annual Meeting

QUESTIONS / DISCUSSION

GYNECOLOGIC CANCER COMMITTEE AGENDA

Date: Saturday, January 30, 2021
Start and End Time: 9:00 am – 11:00 am
Chair: Carol Aghajanian, MD
Co-Chairs: Paul DiSilvestro, MD & David Gaffney, MD, PhD
Translational Science Co-Chair: Heather Lankes, PhD, MPH

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

I. General Business

- A. Call to order
- B. Approval of minutes from January 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 II/III, Phase III

Ovarian Cancer Subcommittee

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

Rare Tumor Subcommittee

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

Uterine Corpus Cancer Subcommittee

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

GYN Developmental Therapeutics Committee

- Early phase trials (Phase I, Phase I/II, Phase II), Window of opportunity trials

- Cervical cancer
- Endometrial cancer
- Ovarian cancer
- Uterine sarcoma

GYN Phase I Subcommittee

- Safety lead-ins
- Phase I

Other NCTN Group Trials & Study Champions

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

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

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

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

III. Cervix/Vulvar Cancer Subcommittee

New Concepts

- a. **RT2111**, Phase II Trial of the efficacy of nivolumab, and low dose ipilimumab with and without Abemaciclib in high grade neuroendocrine carcinoma (small cell and large cell carcinomas) of cervix and other gynecologic origins (Haider Mahdi)

Studies Under Development

- a. **GY024**, GROINSS-V III, Groningen International Study on Sentinel Nodes in Vulvar Cancer – III, A Prospective Phase II Treatment Trial
- b. **GY025**, PARP inhibitor or PD1 inhibitor with bevacizumab versus bevacizumab alone as maintenance therapy following chemotherapy in women with advanced, persistent, or recurrent cervical cancer (Ritu Salani)
- c. **CV1964**, Incorporation of Immunotherapy Into The Management of Locally Advanced Carcinoma of the Vulva (Scott Glaser/Oladapo Yeku)
- d. **CV2061**, A Phase I/II Study of Atezolizumab and tiragolumab with chemoradiotherapy vs. chemoradiotherapy standard of care for Locally Advanced Cervical Cancer (Jyoti Mayadev/Dmitriy Zamarin)

Active Studies:

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

GYN Developmental Therapeutics Committee - Cervical Cancer

Studies Under Development

- a. PI1915**, A phase I study of the combination of poly-ADP ribose polymerase inhibitor, olaparib and DNA damaging ATR kinase inhibitor (AZD6738) in the treatment of persistent or recurrent squamous or non-squamous carcinoma of the cervix (Katherine Moxley)
- b. DT2013**, CB-839 Before and Concurrent with Chemoradiotherapy in Patients with Locally Advanced, Node Positive Cervical Cancer (Corinne Doll)
- c. DT2059**, Phase 1/2 M3814 plus hypo-fractionated radiation followed by M3814 plus avelumab in recurrent cervical cancer (CrDL: Christina Henson/Kathleen Moore)

Closed Studies, primary manuscript NOT published (Cervix): GOG-0279

Closed Studies, primary manuscript NOT published (DT): GY017

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

Terminations:

IV. Ovarian Cancer Subcommittee

New Concepts

- a. OV2109**, Combination ATR and PARP Inhibitor following PARP inhibition in recurrent ovarian cancer: a comparison of ATRi monotherapy (AZD6738), PARPi and ATRi combination (olaparib and AZD6738) and standard of care platinum doublet. (F Simpkins/ S Wethington)
- b. OV2112**, Efficacy of carboplatin/gemcitabine with or without ATR inhibition, M6620 in patients with platinum-sensitive, PARPi resistant recurrent ovarian cancer with pathogenic *BRCA* 1/2 or *ATM* mutations: Randomized Phase II trial (Haider Mahdi)

Studies Under Development

- a. 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)
- b. OV2008**, A Randomized Phase 2 trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu)
- 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. OV2056**, A Randomized Phase III Study of the ATR inhibitor Berzosertib in Combination with Gemcitabine versus Gemcitabine alone in Platinum Resistant/Refractory High Grade Serous Ovarian Cancer (HGSOC) (Panagiotis Konstantinopoulos)

Active Studies:

- a. 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)
- b. NRG-GY021**, A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Sarah Adams) – [Temporarily closed to accrual](#)

Rare Tumor Subcommittee

New Concepts

a.

Studies Under Development

a.

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. DT2106**, A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent *ARID1A* mutated clear cell and endometrioid ovarian carcinomas (Fiona Simpkins)

Studies Under Development

- b. PI1966**, A phase I study of combination WEE1 kinase (AZD1775) and ATR kinase inhibition (AZD6738) for the treatment of recurrent CCNE1 amplified ovarian and endometrial carcinomas (Fiona Simpkins)
- c. PI2054** (PTMA #100805), Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (K Fuh/K Moore)

Active Studies:

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

Closed Studies, primary manuscript NOT published (Ovarian): 212 (SGO 2017), GY004 (ASCO 2020), GY005, GY007

Closed Studies, primary manuscript NOT published (Rare Tumor): 264 (IGCS 2020), 268 (ASCO 2016), 281 (ESMO 2019), 283

Closed Studies (primary manuscript published): 213, 262, GY003

Terminations:

V. Uterine Corpus Cancer Subcommittee

New Concepts

- a. UC2105**, Medroxyprogesterone and Entinostat in PR+ endometrioid endometrial cancer (EC): a randomized phase II study (Jerzak)
- b. UC2107**, A Phase II Study of Tumor Biology-Based Adjuvant Systemic Therapy After Salvage Radiation Therapy for Pelvic or Nodal Recurrences of Endometrial Cancer (Taunk)
- c. UC2108**, Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Women with Advanced or Recurrent AR Positive ER Low Endometrial Cancer (Kurnit)
- d. UC2110**, Randomized Phase II Trial of Volume-Directed Salvage Therapy with or without Pembrolizumab for Limited Abdominal-pelvic recurrences of endometrial cancer (Harkenrider)

Studies Under Development

- a. UC1963**, A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino)
- b. GY026 (UC1972)**, A randomized phase II/III trial of paclitaxel/carboplatin alone or combined with either trastuzumab or trastuzumab/pertuzumab in HER2 Positive Stage I-IV uterine serous carcinoma and carcinosarcoma after primary surgery (Erikson, Fader, Santin)
- c. 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)
- d. UC2043**, A Pilot Study of Dactinomycin plus Avelumab as First line Treatment for Selected Patients with Gestational Trophoblastic Neoplasia (Lua Eiriksson)
- e. UC2055 (PTMA#100828)**, Phase IB and Randomized Phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer. (Weston/Onstad)

Active Studies:

- a. NRG-GY012**, A Randomized Phase II Study Comparing Single Agent Olaparib, Single Agent Cediranib, and the Combination of Cediranib/Olaparib in Women with Recurrent, Persistent or Metastatic Endometrial Cancer. (Helen Mackay)
- b. NRG-GY018**, A randomized phase III Placebo-Controlled Study of Pembrolizumab in addition to Paclitaxel and Carboplatin for Measurable Stage III Or IVA, Stage IVB or Recurrent Endometrial Cancer. (Ramez Eskander)
- c. NRG-GY020**, Randomized phase III trial of radiation +/- pembrolizumab for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer. (Floor Backes)

Rare Tumor Subcommittee

New Concepts

- a.**

GYN Developmental Therapeutics Committee – Uterine Corpus Cancer

New Concepts

- a. DT2104**, Anti-PD1 Therapy in Combination with Novel Immune Checkpoint Inhibitors in Recurrent and Progressive Endometrial Cancer (Growdon)

Studies Under Development

- a. PI2058**, A phase Ia/Ib study of Ipatasertib in Combination with Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Atezolizumab in Patients with Advanced Recurrent Endometrial Cancer (Debra Richardson/Victoria Bae Jump)

Active Studies:

- a.**

Closed Studies, primary manuscript NOT published (Corpus): 238, 261 (ASCO 2019)

Closed Studies, primary manuscript NOT published (DT): 286B (SGO 2020), GY011

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

**patient on active treatment*

Terminations:

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

Studies Under Development

a. MATCH COMBO

Active Studies:

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

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

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

IX. Translational Science Committee Report (Birrer, Lankes)

X. Cancer Prevention and Control Committee Report (Walker)

Active Studies:

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

QUESTIONS / DISCUSSION

Ovarian Workshop Agenda

Date: Friday, January 29, 2021
Start and End Time: 3:30 pm – 5:30 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:

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

WORKSHOP AGENDA

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

A. Introduction

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

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

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). NEJM 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 (Zamarin) J Clin Oncology Jun 2020
- GOG0281 RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson). Presented at IGCS 2019

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

- GOG0264 RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Jubilee Brown)
 - Activated 08FEB2010
 - Futility limits met, Study closed to accrual 6/12/2020
 - Presented at IGCS 2020
- NRG-GY004 Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Joyce Liu and Ursula Matulonis). Expanded overall accrual to 550 patients, closed to accrual 10-NOV-2017
 - Presented ASCO 2020-
- NRG-GY005: A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Jung-Min Lee and Angeles Alvarez Secord)
 - Closed 10/2/2020 – total accrual 562
- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer. (Chip Landen)
 - Closed to accrual
- NRG-GY009 A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab vs Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Roisin O’Cearbhaill, Carol Aghajanian).
 - Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
 - Second-stage safety lead-in (all three arms) opened 14NOV2017
 - Group-wide activation 6/18/2018
 - Suspended at the end of phase 2 (May 2019) –
 - Reopened 8/25/2020

- 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)
 - Activated 4/2019
 - Suspended 8/2019
- NRG-GY016 - phase 2 pembrolizumab + epacadostat (IDO inhibitor) in recurrent clear cell of the ovary (L Gien)
 - Activated Oct 2018/suspended for first phase accrual completion 4/2019
 - Amendment to reopen submitted 12/11/2020
- NRG-GY019 (RT1753) A Phase III Randomized Three Arm trial of paclitaxel/carboplatin compared to paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV primary low-grade serous carcinoma of the ovary or peritoneum. (Amanda Nickles-Fader).
 - Activated 8/26/19
 - 51/450
- NRG-GY021 Randomized Phase II Trial of olaparib + tremelimumab vs olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams)
 - Activated Oct, 12 2019
 - Safety calls coordinated through DT committee
 - Temporarily closed to accrual 10/19/2020 – awaiting DLT review
- NRG-GY022 (DT1833): Assessment of carboplatin clearance predictors: PK protocol to allow for extra sample collection and collection of demographic data, laboratory values, and outcome data. (Liz Villaruz/Jan Beumer) GYN Cancer Committee: 7/14/18
 - Activated 11/2019
 - 75/250
- 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
 - 9/22262
- AGCT1531 (RT1205) Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, AI Covens NRG)
 - Activated group-wide 30MAY2017
 - 254/1680

Ovarian Cancer Subcommittee

E. Review of Approved Concepts under Development

- OV1838 PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib vs Standard Chemotherapy in Patients with Recurrent, Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos) LOI submitted 10/2018
 - Submitted to OTF 11/20 for Dec review
 - Approved by GCSC 6/2/2020
 - Drug supply refused – concept to be redesigned

- NRG GY023: A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) vs doublet therapy (durvalumab and cediranib) vs physician choice chemotherapy in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung Min Lee)
 - Approved by GCSC 9/19; drug supply confirmed
 - Drop dead date extended to 1/4/2021
- OV1960 A phase III randomized trial of heated intraperitoneal chemotherapy (HIPEC) with cisplatin at the time of interval cytoreductive surgery versus intravenous chemotherapy only followed by niraparib maintenance in patients with newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer. (Crispens)
 - Submitted to OTF 11/20 for 12/2019 meeting
 - OTF second review 12/2020 – comments being addressed for planned GCSC submission
- OV2008: A Randomized Phase II trial of PARP-inhibitor combinations in PARP inhibitor Resistant Ovarian Cancer (PaROC) (Joyce Liu/Angela Secord)
 - Submitting to GCSC 1/21/2021 meeting
- P11966: Wee1 + ATRi in CCNE1 amplified ovarian and endometrial (Simpkins)
 - For RSC 10/29/19
 - Phase I UD
- PI2014: A Phase IB Trial of AVB500 in combination with carboplatin and paclitaxel or carbo and pegylated liposomal doxorubicin. (Katherine Fuh)
- PI2054: A Phase IB Trial of Ipatasertib plus paclitaxel and carboplatin in women undergoing neoadjuvant chemotherapy for treatment naïve, epithelial ovarian cancer (Katherine Fuh/Kathleen Moore)

F. Review of New Concepts and Future Request for Proposals

- OV2056 A Randomized Phase III Study of the ATR inhibitor Berzosertib in Combination with Gemcitabine versus Gemcitabine alone in Platinum Resistant/Refractory High Grade Serous Ovarian Cancer (HGSOC) (Panagiotis A. Konstantinopoulos MD, PhD)
- OV2109 Combination ATR and PARP Inhibitor following PARP inhibition in recurrent ovarian cancer: a comparison of ATRi monotherapy (AZD6738), PARPi and ATRi combination (olaparib and AZD6738) and standard of care platinum doublet (Simpkins)
- OV2112 Efficacy of carboplatin/gemcitabine with or without ATR inhibition, M6620 in patients with platinum-sensitive, PARPi resistant recurrent ovarian cancer with pathogenic BRCA 1/2 or ATM mutations: Randomized Phase II trial (Mahdi)

QUESTIONS / DISCUSSION

Rare Tumor Workshop

Date: Friday, January 29, 2021
Start and End Time 8:00am – 10:00am
Chair: Allan Covens
Co-Chair: Jubilee Brown

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss past, ongoing, and emerging NRG clinical trials in rare gynecologic cancers
2. Discuss priorities and promising preclinical and translational objectives for future clinical trials
3. Discuss strategies to increase the portfolio of clinical trials in rare gynecologic cancers, including strategies to increase knowledge and access to preclinical data.
4. Discuss new amendments to AGCT 1531 and strategies to disseminate and increase accrual

A. Active Studies

- **AGCT1531:** A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors (Covens) (406/6/1680)
- **GOG-3026:** Phase II trial of letrozole + Ribociclib for women with recurrent low-grade serous carcinoma. (Slomovitz) **GOG Partners**
- **GOG-3051:** A Phase II, Open Label, Multicenter, Platform Study Evaluating the Efficacy and Safety of Biomarker-Driven Therapies in Patients with Persistent or Recurrent Rare Epithelial Ovarian Tumours **GOG Partners**
- **NRG-GY016:** A Phase II Study of MK-3475 (Pembrolizumab) (NSC #776864) + Epcadostat (NSC #766086) in Recurrent Clear Cell Carcinoma of the Ovary (Gien) 2nd stage to be open soon (n=14)
- **NRG-GY019:** A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum (Fader). (39/450)

B. Proposed Studies/in development

- **RT1841:** A phase II evaluation of bevacizumab and ixazomib for recurrent sex-cord stromal ovarian tumors (Gien). 2nd priority behind RT1849- withdrawn after IDB mtg.
- **DT1822:** A Randomized Phase II Trial Of Adjuvant Nivolumab With Or Without Cabozantinib In Patients With Mucosal Melanoma. (Vicus) Alliance will lead. Rejected by CTEP. Response pending.

C. New concepts

- **RT2111:** Phase II Trial of the efficacy of nivolumab, and low dose ipilimumab with and without Abemaciclib in high grade neuroendocrine carcinoma (small cell and large cell carcinomas) of cervix and other gynecologic origins (Mahdi)
- **DT2106:** A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent *ARID1A* mutated clear cell and endometrioid ovarian carcinomas (Simkins)

D. Discussion Topics:

- a) Strategies to improve concept development for rare tumours
- b) Amendments to AGCT1531- Dr. Shaikh (COG)

Uterine Corpus Workshop

Date: Friday January 29, 2021
Start and End time: 1:30 PM- 3:30 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. **GOG0188:** Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [[Gynecol Oncol 120\(2\): 185-8, 2011](#)]:
2. **GOG0210:** A Molecular Staging study of Endometrial Carcinoma (William T Creasman): **Mutch in separate report**
3. **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)**
4. **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)**
5. **GOG0286B** A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer **(Bae-Jump to discuss)**
6. **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**)

7. **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**)

C. Review of Active Studies

1. Endometrial Protocols:

- a. **S1609**, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors (**Horowitz to discuss**)
- b. **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**)
- c. **GY018** (UC1710) Prospective randomized phase 3 trial of carboplatin and paclitaxel with or without pembrolizumab in the treatment of primary advanced stage (3 or 4) or recurrent endometrial cancer (**Eskander to discuss**)
- d. **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):
2. **UC1963**, A Randomized Phase II trial of Ablative Radiation therapy for Women with Oligometastatic Gynecologic Cancers (Junzo Chino) **TBR UTF 1/15/21**
 3. **GY026 (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) (**GCSC Approved. CTEP AOH pending pharma**)
 4. **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) **GCSC gave Pending decision**

5. **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 (**GCSC disapproved 12/31/2020 Backes to update**)
6. **CV2040,** Stereotactic Pelvic Adjuvant Radiation Therapy in Cancers of the Cervix and Uterus (SPARTACUS) II (Eric Leung)
7. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health- Related Quality of Life in Endometrial Cancer (**Tanner to Update**)
8. (**CCRD study**) Molecular classification-directed care in endometrial carcinoma: a prospective cohort study (Temkin to Update)

E. Proposed studies New Concepts:

- a. **UC2105:** (formerly UC1731) Medroxyprogesterone and Entinostat in PR+ endometrioid endometrial cancer (EC): a randomized phase II study (Jerzak)
- b. **UC2107:** A Phase II Study of Tumor Biology-Based Adjuvant Systemic Therapy After Salvage Radiation Therapy for Pelvic or Nodal Recurrences of Endometrial Cancer. (Taunk)
- c. **UC2108:** Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Women with Advanced or Recurrent AR Positive ER Low Endometrial Cancer. (Kurnit)
- d. **UC2110:** Randomized Phase II Trial of Volume-Directed Salvage Therapy with or without Pembrolizumab for Limited Abdominal-pelvic recurrences of endometrial cancer (Harkenrider)

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

- a. **DT2104:** Anti-PD1 Therapy in Combination with Novel Immune Checkpoint Inhibitors in Recurrent and Progressive Endometrial Cancer. (Growdon)
- b. **DT2106:** A Phase IB study of combination BET protein inhibition (I-BET-762) and ATR kinase (AZD6738) for the treatment of recurrent *ARID1A* mutated clear cell and endometrioid ovarian carcinomas. (Simpkins)

G. New Business

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

Head and Neck Workshop

Date: Friday, January 29, 2021
Start and End Time: 1:30 – 3:30 PM ET
Chair: Quynh-Thu Le, MD, FACP, FASTRO
Co-Chair: Erich Sturgis, MD, MPH; Stuart Wong, MD

Learning Objectives:

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

A. Head and Neck portfolio overview

Quynh-Thu Le, MD

B. Actively developing studies

- **HN009 trial (formerly 1937 concept)** Phase II-III HD vs. Weekly cisplatin in high risk LA HNSCC (HPV- and HPV+ cohorts) Paul Harari, MD
- **HN2004 concept:** Phase II of T-DM1 +/- Atezo in recurrent/metastatic HER2 positive SDC and SGC Alan Ho, MD
- **HN2115 LOI (formerly 1936):** Single-arm phase II trial of chemo-immunoselection for salvage surgery (SS) with life-long morbidity in recurrent/persistent PD-L1 enriched SCCHN Nabil Saba, MD
- **HN2001 concept:** Phase II-III of placebo vs. adjuvant IO in LA NPC with persistently detectable EBV DNA Nancy Lee, MD
- **Proposed trial:** HypoPORT: A randomized phase II-III trial of hypofractionated PORT for HNC Shlomo Koyfman, MD
Matthew Ward, MD

C. Review on active studies

Actively accruing trials

RTOG 1216	RT+cisplatin vs. RT+docetaxel+cetuximab vs. RT+cisplatin+atezolizumab for “high risk” resected HNSCC (Phase IIIR)	Julie Bauman Paul Harari David Rosenthal
NRG-HN006	Phase II-III SLN Biopsy vs. END in T1-2N0 oral cavity cancer	Stephen Lai
NRG-HN007	Phase III Gem/Cis vs. Gem/Cis/Nivo in 1 st line rec/met NPC	Brigitte Ma
NRG-HN008	Phase I RT + DNA-PK inhibitor in High risk LA HNSCC	Maura Gillison Michael Samuels

RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong
RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR)	Cristina Rodriguez
NRG-HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III)	Nancy Lee
NRG-HN004	Phase II-IIIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC	Loren Mell
NRG-HN005	Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer	Sue Yom

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. New Investigator

Shlomo Koyfman, MD

F. EA3191 trial: Phase II adjuvant reirradiation vs pembro for recurrent/second primary HNSC

Zain Husain, MD

QUESTIONS / DISCUSSION

NRG ONCOLOGY LUNG CANCER WORKSHOP AGENDA

Held during scheduled NRG Virtual Meeting on Saturday January 30

9:00 am to 10:45 am (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.)	RTOG 1308: Protons vs photons for St III NSCLC	Xing Liao
b.)	NRG CC003: Hippocampal avoidance brain	Vinai Gondi
c.)	LU002: Phase III chemo +/- SBRT for Stage IV	Puneeth Iyengar
e.)	NRG LU004 Phase I/II anti-PD1 concurrent with RT	Steven Lin
f.)	NRG/Alliance LU005 Limited-stage SCLC	Kristin Higgins
g.)	NRG LU006 Phase III; Dose-painting IMRT for mesothelioma	Andreas Rimner
h.)	RTOG 3515 SBRT +/- durva for medically-inoperable Stage I	Cliff Robinson
i.)	SWOG S1914/NRG LU – SBRT +/- neoadjuvant atezo for Stage I	Charles Simone
j.)	NRG LU007 Phase II/III ES-SCLC; chemo + atezo +/- RT	Quynh-Nhu Nguyen
k.)	NRG CC1974: SLCL Brain mets; SRS vs HA-WBI	Vinai Gondi
l.)	Lung-MAP SWOG S-1400	Saiana Waqar
m.)	ALCHEMIST Trial	Saiana Waqar
n.)	NRG-LU003: NCI NRG ALK Master Protocol	Shakun Malik

QUESTIONS / DISCUSSION

Patient Centered Outcomes Research (PCOR) Workshop Agenda

Date: Thursday, January 28, 2021
Start and End Time: 4:00 pm – 6:00 pm
Co-Chairs: Benjamin Movsas, MD; Patricia Ganz, MD; Lari Wenzel, PhD

Learning Objectives:

Following this activity, participants will be better able to:

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

Educational Needs: Identified through current PRO topics of interest and PCOR Committee meeting evaluations from prior meetings.

WORKSHOP AGENDA

4:00 – 4:05	Session Introduction and Welcome	
4:05 – 4:45	PROTEUS "Patient-Reported Outcomes Tools: Engaging Users & Stakeholders" Presentation Q&A	Michael Brundage, MD, MSc and Claire Snyder, PhD
4:45 – 5:05	PRO Data Delinquency Update RTOG-1308 QOL Compliance	Ron Chen, MD Xin Shelley Wang, MD, MPH
5:05 – 5:45	Developing Concepts/Protocols	Disease Site Liaisons
5:45 – 6:00	Closing Remarks	PCOR Co-Chairs

Translational Science Workshop Agenda

Date Friday, January 29, 2021
Start and End Time: 3:30PM - 5:00PM
Chair: Michael Birrer, MD, PhD
Co-Chairs: Adam Dicker, MD, PhD
Matthew Ellis, MB, BCHIR, PhD

Learning Objectives: To better understand the translational research efforts of NRG Oncology.

Following this activity, participants will be better able to:

1. To understand ongoing proteomic research efforts in NRG Oncology.
2. To understand NRG Oncology translational science efforts in GU cancers.
3. To understand NRG Oncology translational science in Brain cancer.
4. To understand important biomarkers for patients receiving new agents in developmental therapeutics.

WORKSHOP AGENDA

3:30 – 3:35	Opening Remarks and Introduction	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD
3:35 – 3:55	CPTAC Updates	Matthew Ellis, BCM Michael Birrer MD PhD
3:55 – 4:15	Translational science in GU Cancers	Phuoc Tran, MD, PhD
4:15 – 4:35	What's new in translational research in Brain cancers	Arnab Chakravarti, MD
4:35 – 4:55	Important Biomarkers in Developmental Therapeutics	Panos Konstantinopoulos, MD, PhD
4:55 – 5:00	Closing Remarks and Discussion	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD

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Scientific Core Committees

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NRG Oncology Health Disparities Committee
Thursday, January 28 (Virtual Meeting)
10am – 12pm ET
Agenda

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

- | | |
|---------------------|---|
| 10:00 - 10:10 am | Welcome/Announcements - Kate Yeager / Chanita Hughes Halbert |
| 10:10 – 10:30 am | Committee Leadership Updates: Introduction of the new Chair
Jennifer Wenzel, PhD, RN, CCM, FAAN |
| 10:30 – 10:45 am | Rural capacity and CCDR accrual barriers - Shellie Ellis |
| 10:45 – 11:00 am | HDC Rural Survey of NRG Members summary and Rural Research SIG updates - Kate Yeager/
Na Tosha Gatson |
| 11:00 – 11:30 am | HDC Research Concept Development SIG update - Chanita Hughes Halbert |
| 11:30 – 11:45 am | Research Implementation (Education/Training/Mentorship) SIG update - Kathie-Ann Joseph,
William Robinson |
| |
Clinical Trial Enrollment Updates - <i>Statistics/Metrics</i> - <i>SDMC Reports</i> -William
Robinson; Reena Cecchini |
| |
Education/Training- Kathie-Ann Joseph |
| 11:45 – 11:55 am | Older Adult Research SIG update – William Tew |
| 11:55 am – 12:00 pm | Closing remarks/Summary/Adjournment |

JANUARY 2021 VIRTUAL PSC MEETING AGENDA
Protocol Support Committee
Introduction to Clinical Trials: Principles of NRG Oncology Clinical Trial Management for Nurses and CRAs

Date: Wednesday, January 27, 2021
Start and End Time: 1:00 pm ET–3:30 pm ET
PSC Chair: Terry Thomas MS, CCRC
PSC Vice-Chairs: Nancy Fusco RN, BSN & Cynthia Licavoli RN, BSN, MA
Facilitator: Karen Holeva, BS, CCRP & Cynthia Licavoli, RN, BSN, MA

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss NRG Oncology membership requirements
2. Identify and describe relevant regulations for federally funded clinical research involving human subjects
3. Describe the standard drug accountability procedures for NCTN trials
4. Navigate in the RAVE system
5. Utilize basic commands to key data into the RAVE system
6. Discuss the nature of and preparation for NCI-mandated Quality Assurance Audits
7. Describe the basic methodology of RECIST 1.1 and other response criteria used in NRG Oncology trials
8. Discuss NRG Oncology Mentorship Program

AGENDA

<u>Time*</u>	<u>Topic</u>	<u>Speakers</u>
1:00 pm- 1:10 pm	Welcome	Cynthia Licavoli, RN, BSN, MA & Karen Holeva, MS
1:10 pm-1:25 pm	NRG Membership	Karan Boparai, BS, RT(R)(M)
1:25 pm- 1:45 pm	Regulatory Affairs	Judy Langer, BS
1:45 pm- 2:05 pm	Investigational Drug Management	Brian Miller, PharmD
2:05 pm- 2:30 pm	Medidata Rave	Joseph Mroziak
2:30 pm-2:55 pm	Quality Assurance Audits	Mimi Passarello, MBA
2:55 pm- 3:20 pm	RECIST Criteria	Shannon Puhalla, MD
3:20 pm- 3:30 pm	Mentorship Program	Nancy Fusco, RN, BSN

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

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

Date: Thursday, January 28, 2021
Start and End Time: 10:00 am ET – 12:00 pm ET
PSC Chair: Terry Thomas MS, CCRC
PSC Vice-Chairs: Nancy Fusco RN, BSN & Cynthia Licavoli RN, BSN, MA
Lead Facilitator: Karen Holeva, BS, CCRP
Co - Facilitators: Melinda Weiblen, BS, Chrisann Winslow RN, MSN

Learning Objectives

Following this activity, participants will be better able to:

1. Describe the key components of serious adverse event assessment including term selection, grading and attribution
2. Discuss the basics of pathology and translational research specimen requirements and submissions during COVID-19
3. Discuss Best Practices for Submission, Collection, and Quality Control of images and Radiation Therapy Plans
4. Discuss Protocol Deviation Form and Delegation of Tasks Log
5. Discuss Patient Reported Outcomes and use of Patient Cloud
6. Discuss acceptable ways for sites to provide consent and reconsent to study participants and how to report any protocol deviations during COVID-19

AGENDA

<u>Time*</u>	<u>Topic</u>	<u>Speakers</u>
10:00 am -10:05 am	Welcome	Karen Holeva, BS, CCRP
10:05 am-10:25 am	Serious Adverse Event Reporting	Sara McCartney, MS, RN
10:25 am-10:45 am	IROC	Cynthia Price, AS RT (R)(MR)(ARRT)
10:45 am-11:05 am	Biospecimen Collections	Sandy DeVries, MA, Lisa Beaverson, BA, CCRP, Melanie Finnigan, BS
11:05 am-11:25 am	Patient Reported Outcomes- Patient Cloud	Marcie Ritter, PhD
11:25 am-11:45 am	CTSU	James Wise & Nadia Goranova, MS
11:45 am-12:00 pm	CIRB	Renee Green, BA, RN

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

Protocol Support Committee Workshop

Clinical Trial Nurse/Clinical Research Associate Workshop- Breakout Sessions

Date: Thursday, January 28, 2021
Start and End Time: 1:00 pm ET – 3:00 pm ET
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. Describe how the information obtained during the breakout discussions will impact the work process at your institution
2. Identify how the best practices from the experts will improve quality of protocol reporting
3. Explain how utilizing resources from the experts at NRG Oncology will improve conducting clinical trials

Each breakout session is scheduled for approximately 18 minutes in length. At the conclusion of each breakout session, participants will have two minutes to join a new breakout session topic. This setup allows for each breakout session to be offered six times during the workshop 1:00 pm ET- 3:00 pm ET (1:00-1:20 pm ET, 1:20-1:40 pm ET, 1:40-2:00 pm ET, 2:00-2:20 pm ET, 2:20-2:40 pm ET and 2:40-3:00 pm ET)

AGENDA

<u>Topic</u>	<u>Speakers</u>
• Breakout Sessions HELP DESK	Nancy Fusco, RN, BSN, Melinda Weiblen, BS
• Brain Protocols	Liz Wise CCRC, Sherell Carter, AAS, Denise Manfredi, BS, RT (T); George Ballinger, RT (R) (T)
• Breast (BR002) & GI- Non-Colorectal	Deborah Washington RN, MSN, Susan McNulty, CMD, BS (R)(T), Wendy Bergantz, RN
• Breast Topics (BR004/BR003)	Mary Pat Matisko, RN, BSN, Kim Auth, RN, BSN, Lisa Barry, MAEd, BS
• GI FORTE (CC005)	Christine Lorson, RN, BSN, Kristen Kotsko, RN, BSN, Sarah Camden, RN
• GU Protocols	Elaine Motyka-Welsh, RN, MSN, CCRP, Margaret Kennish, AS, CCRC, Joanne Hunter, BS, RT (R)(T)
• GYN Protocols	Izabela Frak, MPhil, Dolly Kirshner, MPH, BS, BA, Ashley Badders, Nick Celnder
• Head & Neck Protocols & Sarcoma	Vanita Patel, MS, Lisa Abate, Marsha Raddeb BS, RT, (R)(T)
• Lung Protocols	Jeffrey Serrianni BS, Matthew Novak, MS, Jennifer Presley, BS, RT (R)(M)(T), Joe Bauza, RT
• Neurocognitive Testing	Catherine Sullaway, BS
• NRG Oncology Audit	Mary Jo Antonelli, M.B.A., BSChem, Jerry Koss, RN, BSN
• NRG Oncology Audit	John Blessing, PhD, Sally Bialy, MA
• NRG Oncology Consents	Judy Langer, BS
• NRG Oncology Membership/Payments	Karan Boparai BS, RT(R)(M), Julie Kardell, Yuliya Hayes, Wendy Michalow, Amy Niccolai
• NRG Oncology Biospecimen Bank	Sandy DeVries, MA, Melanie Finnigan, BS, Lisa Beaverson, BA, CCRP Heather Lankes, PhD, MPH
• AE/SAE Reporting	Sara McCartney, MS, RN
• e-PRO – Patient Cloud	Elaina Harper, Marcie Ritter, PhD
• IROC Radiation Therapy	Jessica Lowenstein, MS, DABR, Nancy Linnemann, BS, RT (R)(T)
• IROC Diagnostic Imaging	Michael Boss, Cynthia Price AS RT (R)(MR)(ARRT), Lisa Cimino, Rebecca DiGati, Joseph Bauza

- Pharmaceutical Management Branch Tali Johnson, Pharm D, BCOPI, Matthew Boron, RPh
- Vision Tree Sheena Gagh, Client Services, Manager, Mackenzie Kerwin, Account Manager
- Best Practice: COVID 19 Workflow Chrisann Winslow, RN, MSN
- Best Practice: Top 20 Random Thoughts Cynthia Licavoli, RN, BSN, MA, Tiffany Elsea, BA, CCRP
- Best Practice: Study Start Up, Implementation & Management Terry Thomas, MS, CCRC, Whitney Jacobson, RN, CCRP, OCN
- Best Practice: Site Administrator Paulette Palazzolo, RN, CCRC, Alison Ivey, RN, MS, MBA, OCN, CCRP
- Best practice: On Boarding New Coordinators (Nurse/CRAs) HeeSun Kim-Suh, RN, BSN, OCN, Karen Holeva, BS

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

Date: Friday, January 29, 2021
Start and End Time: 8:00 am – 10:00 am
Chair: Jeff Michalski, MD
Co-Chairs: Ivy Petersen, MD and Evan Wuthrick, MD
Participation Link: TBA

VIRTUAL MEETING AGENDA

- 8:00 – 8:05** **Welcome / Introduction** Jeff Michalski, MD
- 8:05 – 8:35** **3rd Annual RO Symposium Theme “Radiopharmaceutical Therapy (RPT)” hosted by Evan Wuthrick, MD, NRG Radiation Oncology Committee**
- **Amir Iravani, MD** – Asst. Professor/ Division of Nuclear Medicine Mallinckrodt Institute of Radiology at Washington Unvi. School of Medicine, St. Louis
Title: Overview of opportunities of RPT in the NCTN
 - Radiation dosimetry in RPT trials
 - **Charles Kunos, MD, PhD** – Medical Officer, Investigational Drug Branch Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute, National Institutes of Health
Title: NIH Commitment – ETCTN
 - Vision - how these RPT trials will be done
 - Development in clinical trials
 - **Hiram Gay, MD– Department of Radiation Oncology, Washington University of Saint Louis**
Title: PI Update on NCI Protocol #10301
 - A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC)
 - **Jyoti Malhotra, MD, MPH – Rutgers Cancer Institute of New Jersey**
Title: PI Update on NCI Protocol #10302
 - Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer
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8:35 – 8:40	NRG Oncology Updates	Jeff Michalski, MD/Evan Wuthrick, MD/Ivy Petersen, MD
	<ul style="list-style-type: none"> a. NRG Oncology Meeting agenda: NRG Meeting Agenda b. NCI COVID-19 in Cancer Patients Study (N-CCaPS): A Longitudinal Natural History Study (Create a bank of clinical data, research blood specimens & radiological images for future research.) <ul style="list-style-type: none"> • Activated on 5/21/2020 – Targeting 2,000 patient enrollment • Capitation by Credited Group (NCTN, NCORP or ETCTN) 	
8:40– 8:50	<u>Update on NCTN Cooperative Cores</u>	
	a. Imaging and Radiation Oncology Core (IROC) RT Update For NRG Trials	Stephen Kry ,MD Denise Manfredi,BS
	b. Imaging and Radiation Oncology Core (IROC) Imaging Update for NRG Trials	Michael Boss, PhD Mark Rosen, MD
8:50– 8:55	Overview of Medical Physics	
	a. Overview of Medical Physics	Ying Xiao,PhD Stan Benedict, PhD
	b. NCTN Physics Committee	Ceferino Obcema, PhD
9:00 – 9:05	Proton Sites Credentialing	Paige Taylor, MS
	MR Guided Linac	Jeff Michalski, MD Evan Wuthrick, MD
9:05 – 9:57	<u>Disease Site Liaisons Reports</u>	
	a. H&N (8 min.)	Sue Yom, MD / Min Yao, MD
	b. Brain (8min.)	Christina Tsien, MD / Tong Wang, MD
	c. Breast (8 min.)	Steven Chmura, MD / Simona Shaitelman, MD
	d. Gyn (8 min.)	Sushil Beriwal, MD / Mark Bernard, MD
	e. GI (8 min.)	Evan Wuthrick, MD / Emma Holliday, MD
	f. GU (8 min.)	Dan Krauss, MD / Hiram Gay, MD
	g. Lung (8 min.)	Charles Simone, MD / Pending
	h. Sarcoma (4 min.)	Philip Wong, MD / Dian Wang, MD
9:57 – 10:00	Other Business / Q & A Discussion	



Administrative Committees

The NRG Oncology New Investigators' Committee Presents LOI/Concept Development Nuts and Bolts Agenda

Date: Thursday, January 28, 2021

Start and End Time: 10:30 am-12:30 pm ET

Chairs: Elizabeth Gore, MD; Priya Rastogi, MD; Angeles Secord, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Provide a comprehensive overview regarding important elements of NRG LOI and Concept submissions
2. Enhance understanding of NRG processes for LOI/Concept Development
3. Define different types of biomarkers and review biomarker clinical trials designs
4. Review examples of LOI and Concept submissions

WORKSHOP AGENDA

A. 10:30am-10:50am

Introduction remarks; Distinguishing LOI/Concept; Science Rational; How to Develop your Idea; Communications; Biomarker Definitions

Elise C. Kohn, MD – National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)

B. 10:50-11:05am

Reviewing Identification or Potential Agents – CTEP and Beyond; Preclinical Prerequisites

Charles Kunos, MD, PhD – National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)

C. 11:05-11:15am: QUESTION AND ANSWER SEGMENT

D. 11:15-11:35am

Major Statistical Designs for Hierarchical Analysis or Biomarker Driven vs. Selected vs. Stratified

Masha Kocherginsky, PhD – Northwestern Medicine Robert H. Lurie Comprehensive Cancer Center

E. 11:35-11:45am: QUESTION AND ANSWER SEGMENT

F. 11:45am-12:00pm

NRG Oncology-specific Processes for LOI/Concept Development

Nancy Soto – NRG Oncology

G. 12:00pm-12:20pm

NRG Oncology LOI/Concept Development Experience

Vinai Gondy, MD – Northwestern Medicine Cancer Center, Warrenville and the Northwestern Medicine Chicago Proton Center

H. 12:20-12:30pm: QUESTION AND ANSWER SEGMENT



Institutional Accrual

Accrual For Agenda Book from 1/1/2020 to 12/31/2020 Run Date: 1/13/2021				
NRG Main Member (Network)	CTEP ID	Accrued to NRG Studies and Credited to NRG	Accrued to Non-NRG NCTN Studies and Credited to NRG	Total
21st Century Oncology MHP - Farmington	MI310	19	7	26
Allan Blair Cancer Centre	11076	10	0	10
Allegheny General Hospital	PA009	15	45	60
AMITA Health Alexian Brothers Medical Center	IL280	4	5	9
Arizona Center for Cancer Care-Peoria	AZ127	3	10	13
Aurora NCI Community Oncology Research Program	AURORA	16	15	31
Avera Cancer Institute	SD021	5	13	18
Banner University Medical Center - Tucson	AZ017	24	9	33
Baptist Health Cancer Research Network	BHCRN	3	18	21
Bay Area Tumor Institute NCORP	BATI	0	0	0
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	TX041	0	10	10
Baystate Medical Center	MA004	0	6	6
Berkshire Medical Center - Cancer Center	MA125	0	4	4
Boston Medical Center	MA043	4	391	395
Cancer Research Consortium of West Michigan NCORP	CRCWM	11	3	14
Cancer Research for the Ozarks NCORP	OZARKS	18	12	30
Cancer Research of Wisconsin and Northern Michigan Consortium	CROWN	27	10	37
Cancer Trials Ireland	ICORG	5	0	5
Carle Cancer Center NCI Community Oncology Research Program	CARLE	4	0	4
Carolinas Medical Center/Levine Cancer Institute	NC042	5	1	6
Catholic Health Initiatives NCORP	CORA	15	4	19
Cedars-Sinai Medical Center	CA016	3	5	8
Centre Hospitalier Universitaire de Sherbrooke-Fleurimont	11065	2	0	2
Chinese University of Hong Kong-Prince of Wales Hospital	34003	7	0	7
CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)	11073	6	0	6
CHUM - Centre Hospitalier de l'Universite de Montreal	11062	9	0	9
City of Hope Comprehensive Cancer Center	CA043	7	0	7
CIUSSSEMTL-Hopital Maisonneuve-Rosemont	11060	4	0	4
Columbia University Minority Underserved NCORP	COLUMBIA	1	11	12
Columbus NCI Community Oncology Research Program	COLUMBUS	13	3	16
Community Cancer Center North	IN006	2	9	11
Cooper Hospital University Medical Center	NJ036	3	24	27
Covenant Medical Center-Lakeside	TX054	0	1	1
Cross Cancer Institute	11132	10	0	10
CWRU Case Comprehensive Cancer Center LAPS	LAPS-OH029	83	28	111
Dana-Farber / Partners CancerCare LAPS	LAPS-MA036	16	4	20
Danbury Hospital	CT030	4	4	8
Dartmouth College - Norris Cotton Cancer Center LAPS	LAPS-NH012	10	10	20
Dayton NCI Community Oncology Research Program	DAYTON	1	4	5

Delaware/Christiana Care NCI Community Oncology Research Progra	CHRISTIANA	34	4	38
Dell Seton Medical Center at The University of Texas	TX063	0	0	0
Duke University - Duke Cancer Institute LAPS	LAPS-NC010	3	0	3
Edward Hospital/Cancer Center	IL104	8	14	22
Einstein Medical Center Philadelphia	PA094	0	0	0
Emory University - Winship Cancer Institute LAPS	LAPS-GA005	23	13	36
Essentia Health NCI Community Oncology Research Program	ESSENTIA	1	0	1
Fox Chase Cancer Center	PA086	8	12	20
Fred Hutchinson Cancer Research Center LAPS	LAPS-WA008	11	0	11
Froedtert and the Medical College of Wisconsin LAPS	LAPS-WI013	23	7	30
Geisinger Cancer Institute NCI Community Oncology Research Progra	GEISINGER	13	9	22
Georgia Cares Minority Underserved NCORP	GACARES	21	3	24
Georgia NCI Community Oncology Research Program	GEORGIA	20	35	55
Greater Baltimore Medical Center	MD018	4	19	23
Gulf South Minority Underserved NCORP	GULFSOUTH	16	3	19
Hackensack University Medical Center	NJ022	2	1	3
Hartford Hospital	CT009	4	5	9
Hawaii Minority Underserved NCORP	HAWAII	4	77	81
Heartland Cancer Research NCORP	HEARTLAND	37	6	43
Henry Ford Hospital	MI026	10	116	126
Houston Methodist Hospital	TX036	5	9	14
Indiana University/Melvin and Bren Simon Cancer Center	IN007	8	27	35
Iowa-Wide Oncology Research Coalition NCORP	IWORC	5	28	33
James A. Haley Veterans Affairs Hospital	FL064	0	0	0
Jewish General Hospital	11116	5	0	5
JHU Sidney Kimmel Comprehensive Cancer Center LAPS	LAPS-MD017	2	13	15
Juravinski Cancer Centre at Hamilton Health Sciences	11183	4	0	4
Kaiser Permanente NCI Community Oncology Research Program	KAISER	35	52	87
Kaiser Permanente-Gaithersburg Medical Center	MD198	0	16	16
Kantonsspital Aarau	67029	1	0	1
Lahey Hospital and Medical Center	MA017	3	6	9
Lankenau Medical Center	PA125	8	1	9
Legacy Good Samaritan Hospital and Medical Center	OR013	6	0	6
Loyola University Medical Center	IL017	8	0	8
MaineHealth Cancer Care Network	MAINE	18	26	44
Mayo Clinic LAPS	LAPS-MN026	14	4	18
Medical University of South Carolina Minority Underserved NCORP	MUSC	16	7	23
MedStar Franklin Square Medical Center/Weinberg Cancer Institute	MD029	9	15	24
Memorial Sloan-Kettering Cancer Center LAPS	LAPS-NY016	38	18	56
Mercy Cancer Center - Sacramento	CA729	2	3	5
Metro Minnesota Community Oncology Research Consortium	METROMIN	30	22	52
Miami Cancer Institute	FL078	28	1	29
Michigan Cancer Research Consortium NCORP	MCRC	26	0	26
Michigan State University Clinical Center	MI038	0	1	1
Midwestern Regional Medical Center	IL120	6	11	17
Moffitt Cancer Center	FL065	14	37	51
Montana Cancer Consortium NCORP	MONTANA	12	1	13
Montefiore Minority Underserved NCORP	MONTEFIORE	12	3	15
Mount Sinai Hospital	NY021	5	7	12

National Cancer Centre Singapore	47005	1	0	1
National Institutes of Health Clinical Center	MD004	0	0	0
NCORP of the Carolinas (Greenville Health System NCORP)	GREENVILLE	20	20	40
Nevada Cancer Research Foundation NCORP	NCRF	0	0	0
New Mexico Minority Underserved NCORP	NEWMEXICO	22	28	50
New York-Presbyterian/Brooklyn Methodist Hospital	NY075	5	0	5
NorthShore University HealthSystem-Evanston Hospital	IL018	7	5	12
Northwell Health NCORP	NORTHWELL	0	14	14
Northwestern Medicine Cancer Center Warrenville	IL387	12	35	47
Northwestern University LAPS	LAPS-IL036	13	24	37
Norton Hospital Pavilion and Medical Campus	KY049	8	3	11
Odette Cancer Centre- Sunnybrook Health Sciences Centre	11118	9	0	9
Ohio State University Comprehensive Cancer Center LAPS	LAPS-OH007	23	6	29
Orlando Health Cancer Institute	FL020	4	7	11
Ottawa Hospital and Cancer Center-General Campus	11025	2	0	2
Pacific Cancer Research Consortium NCORP	PCRC	16	3	19
Parkview Regional Medical Center	IN181	4	23	27
Peter MacCallum Cancer Centre	3003	1	0	1
Piedmont Hospital	GA027	2	7	9
ProMedica Flower Hospital	OH012	5	3	8
Puerto Rico Minority Underserved NCORP	PUERTORICO	9	0	9
Rabin Medical Center	40021	0	0	0
Reading Hospital	PA107	5	6	11
Rhode Island Hospital	RI005	7	0	7
Roswell Park Cancer Institute LAPS	LAPS-NY158	15	3	18
Rush University Medical Center	IL043	2	8	10
Rutgers Cancer Institute of New Jersey	NJ066	16	21	37
Saint Joseph Hospital - Orange	CA087	2	9	11
Saint Joseph's Hospital and Medical Center	AZ009	3	11	14
Saitama Medical University International Medical Center	42061	12	0	12
Sanford NCI Community Oncology Research Program of the North Ce	SANFORD	11	13	24
Saskatoon Cancer Centre	11120	8	0	8
Seoul National University Hospital	43002	16	0	16
Southeast Clinical Oncology Research Consortium NCORP	SCOR	42	12	54
Stanford Cancer Institute Palo Alto	CA141	16	0	16
Staten Island University Hospital	NY035	0	0	0
Stony Brook University Medical Center	NY184	6	20	26
Stroger Hospital of Cook County Minority Underserved NCORP	STROGER	17	0	17
Summa Health System - Akron Campus	OH055	2	8	10
Sun Yat-sen University Cancer Center	60021	19	0	19
Sutter Cancer Research Consortium	SUTTER	12	45	57
Tel Aviv Sourasky Medical Center	40019	0	0	0
The Community Hospital	IN044	0	12	12
The James Graham Brown Cancer Center at University of Louisville	KY002	8	10	18
The Research Institute of the McGill University Health Centre (MUHC)	11318	10	0	10
Thomas Jefferson University Hospital LAPS	LAPS-PA121	22	22	44
Thompson Cancer Survival Center	TN038	1	2	3
Tibor Rubin VA Medical Center	CA041	0	0	0
Tom Baker Cancer Centre	11134	8	0	8

Trinity Cancer Care Center	ND026	0	14	14
Tulane University Health Sciences Center	LA001	1	3	4
UC Davis Comprehensive Cancer Center LAPS	LAPS-CA189	4	0	4
UC Irvine Health/Chao Family Comprehensive Cancer Center	CA088	7	24	31
UC San Diego Moores Cancer Center	CA249	18	3	21
UCLA / Jonsson Comprehensive Cancer Center	CA006	2	4	6
UCSF Medical Center-Mount Zion	CA136	12	123	135
UMass Memorial Medical Center - Memorial Division	MA009	0	0	0
UNC Lineberger Comprehensive Cancer Center LAPS	LAPS-NC007	4	26	30
University Health Network-Princess Margaret Hospital	11030	19	0	19
University of Alabama at Birmingham / Deep South Research Consortium	LAPS-AL002	22	28	50
University of Arkansas for Medical Sciences	AR006	9	7	16
University of Chicago Comprehensive Cancer Center LAPS	LAPS-IL057	18	29	47
University of Cincinnati/Barrett Cancer Center	OH070	27	120	147
University of Colorado Cancer Center LAPS	LAPS-CO070	18	69	87
University of Connecticut	CT002	0	0	0
University of Florida Health Science Center - Gainesville	FL015	1	77	78
University of Illinois	IL040	3	14	17
University of Iowa/Holden Comprehensive Cancer Center	IA018	18	16	34
University of Kansas Cancer Center - MCA Rural MU NCORP	KANSAS	31	0	31
University of Kentucky/Markey Cancer Center	KY010	7	15	22
University of Maryland/Greenebaum Cancer Center	MD015	22	13	35
University of Miami Miller School of Medicine-Sylvester Cancer Center	FL028	8	17	25
University of Michigan Comprehensive Cancer Center LAPS	LAPS-MI014	7	12	19
University of Minnesota/Masonic Cancer Center	MN022	5	0	5
University of Mississippi Medical Center	MS005	0	4	4
University of Nebraska Medical Center	NE003	5	2	7
University of Oklahoma Health Sciences Center LAPS	LAPS-OK003	96	81	177
University of Pennsylvania/Abramson Cancer Center	PA075	8	6	14
University of Pittsburgh Cancer Institute LAPS	LAPS-PA015	23	13	36
University of Rochester LAPS	LAPS-NY167	29	7	36
University of South Alabama Mitchell Cancer Institute	AL068	2	10	12
University of Tennessee - Knoxville	TN021	0	8	8
University of Tennessee Health Science Center	TN030	0	0	0
University of Texas Health Science Center at San Antonio	TX059	6	13	19
University of Texas MD Anderson Cancer Center LAPS	LAPS-TX035	50	15	65
University of Texas Medical Branch	TX045	0	24	24
University of Texas Southwestern Medical Center LAPS	LAPS-TX011	27	4	31
University of Utah - Huntsman Cancer Institute LAPS	LAPS-UT003	11	3	14
University of Vermont and State Agricultural College	VT004	9	1	10
University of Virginia Cancer Center	VA009	7	8	15
University of Wisconsin Carbone Cancer Center LAPS	LAPS-WI020	14	11	25
Upstate Carolina Consortium Community Oncology Research Program	UPSTATE	35	4	39
USC Norris Comprehensive Cancer Center LAPS	LAPS-CA011	3	60	63
Vanderbilt University - Ingram Cancer Center LAPS	LAPS-TN008	4	3	7
VCU Massey Cancer Center Minority Underserved NCORP	VCU	3	39	42
Veterans Administration Hospital	FL051	0	0	0
Wake Forest University Health Sciences	NC002	12	1	13
Walter Reed National Military Medical Center	MD001	3	0	3

Washington University - Siteman Cancer Center LAPS	LAPS-MO011	43	14	57
Wayne State University - Karmanos Cancer Institute LAPS	LAPS-MI020	26	35	61
WellSpan Health-York Hospital	PA047	3	16	19
West Virginia University Charleston Division	WV004	7	8	15
West Virginia University Healthcare	WV025	7	17	24
Western States Cancer Research NCORP	WESTERN	12	27	39
William Beaumont Hospital-Royal Oak	MI005	13	61	74
Wisconsin NCI Community Oncology Research Program	WINCORP	8	17	25
Women and Infants Hospital	RI012	31	10	41
Women's Cancer Center of Nevada	NV049	32	0	32
Yale University - Yale Cancer Center LAPS	LAPS-CT018	9	5	14
Yonsei University Health System-Severance Hospital	43027	0	0	0



WINTER 2021
VIRTUAL MEETING
Jan. 28 - 30, 2021

NRG Oncology wishes to acknowledge the following sponsors and exhibitors:

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Exhibitors

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Exhibit Dates/Hours:

Thursday, Jan 28, 2021 and Friday, Jan 29, 2021

9 am - 5 pm EST

Please take the time to visit the virtual exhibit booths on the Virtual Attendee Hub

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Seagen, Inc.

Seagen Inc. is a global biotechnology company that discovers, develops, and commercializes medicines for cancer. The company has a pipeline of therapies at various stages of preclinical testing, clinical testing, and development. We are leveraging our expertise in antibodies to build a portfolio of proprietary antibody-drug conjugates and immuno-oncology agents in clinical trials for hematologic malignancies and solid tumors. For more information, visit www.seagen.com.

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NRG Oncology Winter 2021 Virtual Meeting - January 28-30, 2021

NRG Oncology would like to recognize and thank its commercial supporters for Independent Medical Educational Support associated with the NRG Oncology Winter 2021 Virtual Meeting.

NRG Oncology Commercial Supporters

A photograph of an audience seated in a conference hall, viewed from behind. The audience members are seated in rows of chairs, and the focus is on the back of a person in the foreground with blonde hair tied in a ponytail, wearing a light-colored turtleneck sweater. The background is slightly blurred, showing other attendees and the interior of the meeting space.

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