FINAL PROGRAM

NRG Oncology Semiannual Meeting

July 12 - 14, 2018

Philadelphia Downtown Marriott, Philadelphia, PA

NRG ONCOLOGY

Advancing Research. Improving Lives.

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CME Education Program

FACULTY DISCLOSURE INFORMATION

NRG Oncology Semiannual Meeting
Philadelphia, PA July 12-14, 2018

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>
Planning Disclosures		
Aghajanian, Carol, MD		Steering Committee Meeting/Honorarium: Mateon Therapeutics Ad Board/Honorarium: Clovis
Alvarez, Ronald, MD	X	
Armstrong, Deborah, MD	X	
Arthur, Doug, MD	X	
Backes, Floor, MD		Advisory Board/Consulting Fee: Tesaro Author/Honorarium: UpToDate
Bahary, Jean-Paul, MD	X	
Birrer, Michael, MD, PhD		Ad board/Honorarium: Tesaro; Clovis
Bodis, Stephan, MD	X	
Brown, Jubilee, MD		Speaker/Honorarium: Clovis; Ligo Advisory Board/Honorarium:Genmab
Bruner, Deborah, PhD	X	
Burger, Robert, MD		Consultant/Consulting Income: Amgen; Clovis; Tesaro; Regeneron; Merck; Janssen Education of Employees/Honorarium: AstraZeneca
Corn, Ben, MD	X	
Covens, Allan, MD		Speaker/Honorarium: AstraZeneca
Crane, Christopher, MD	X	
Dicker, Adam, MD, PhD		Consultant/Honorarium: EMD Serono
DiSilvestro, Paul, MD		Consultant/Consulting Fee: AstraZeneca; Tesaro
Ellis, Matthew, PhD		Royalty Income/Royalty/Ownership/Patent: Nanostrins; Prosigna; Bioclassifier Ad hoc Consultant/Consult fee: AstraZeneca; Pfizer; Novartis
Farley, John, MD	X	
Ganz, Patricia, MD	X	
Gaillard, Stephanie, MD, PhD	X	
George, Thomas, MD, FACP		Consulting/Advisory Role: Merck; Bayer Research Funding: Bristol Myers Squibb; Merck; AstraZeneca/MedImmune; Eli Lilly; Bayer; Incyte; Tesaro
Gore, Elizabeth, MD	X	
Horowitz, Neil, MD	X	
Hudson, Matthew, PhD, MPH	X	
Ilson, David, MD		Ad Board/Consultant/Honorarium: Pfizer; Merck; AstraZeneca; Roche; Bristol

FACULTY DISCLOSURE LIST

		Myers Squibb; Bayer; Eli Lilly
Joseph, Kathie-Ann, MD, MPH	X	
Julian, Thomas, MD	X	
Knudsen, Nancy, RN, BSN	X	
Konstantinopoulos, Panagiotis, MD, PhD		Advisory Board Member/Consulting Fee: Pfizer
Kopetz, Scott, MD, PhD		Consultant/Honorarium: Amgen; Bayer; Genentech; Molecular Match; Taiho
Langer, Corey, MD		Institutional Grant/Research Support: Bristol Myers Squibb; ImClone; Pfizer; Eli Lilly; Genentech; OSI Pharmaceuticals; GlaxoSmithKline; Clovis; Merck; Nektar; Atvantagene; Inovio; Ariad Scientific Advisory: Bristol Myers Squibb; ImClone; Pfizer; Eli Lilly; AstraZeneca; Novartis Pharmaceuticals; Genentech; Bayer HealthCare/ Onyx Pharmaceuticals; Abraxis Oncology (Celegene); Abbott; Biodesix; Claiant; CarisDx; ARIAD; Boehringer Ingelheim; Syntha; Clovis DSMC Member: Amgen; Synta; Peregrine; SWOG; Incyte CME: PIK; PER; NOCR; CCO; RTP
Lankes, Heather, PhD, MPH	X	
Le, Quynh, MD	X	
Leath, Charles, MD, MSPH		Advisory Board – Ovarian Chair/Honorarium: Celsion
Levine, Douglas, MD	X	
Lin, Steven, MD, PhD		Grant Research: Hitachi Chemical Diagnostic, Inc.; Protea Biosciences; Peregrine Pharmaceuticals AstraZeneca: Advisory Board
Lu, Bo, MD, PhD	X	
Machey, Denise	X	
Markham, Merry-Jennifer, MD	X	
Mayadev, Jyoti, MD		Speaker/Honorarium: Samsung Advisory Board/Honorarium: GOG Foundation; Regeneron Consulting/Honorarium: Varian
Movsas, Benjamin, MD		Investigator/Research Support Dept.: Varian, Inc.; Philips Inc. Speaker/Honorarium: ViewRay
Nolte, Susan, PhD, CRNP	X	
O'Cearbhaill, Rosin, MD		Advisory Board/Honorarium: Tesaro
Powell, Matthew, MD		Speaker/Consultant: Merck; AstraZeneca; Clovis; Tesaro
Raben, David, MD		Ad Board/Speaker/Honorarium, Consulting fee: AstraZeneca Ad Board/Honorarium: Genentech; Merck; Nanobiotix
Reese, Jill	X	
Ridge, Drew, MD	X	
Ritzwoller, Debra, PhD	X	
Robidoux, Andre, MD	X	
Sharp, Mary	X	
Shumaker, Lauren	X	
Schilder, Russell, MD		Speaker/Honorarium: Pfizer
Simko, Jeff, MD, PhD		Consultant/Honorarium: Bristol Myers Squibb Scientific Advisor/Ownership Interest: 3D Biopsy Inc.; 3D Scan Inc.
Small, Michelle, BSHA	X	
Small, William, MD		Speaker/Honorarium: Zeiss
Smith, Judith, PharmD	X	
Spirtos, Nick, MD	X	
Stehman, Frederick, MD	X	
Sturgis, Erich, MD, MPH	X	
Tew, William, MD	X	
Tewari, Krishnansu, MD	X	
Thomas, Alexandra, MD, FACP	X	
Thomas, Terry, MS, CCRC	X	
Trotti, Andy, MD	X	
Wenzel, Lari, PhD	X	
Wong, Stuart, MD	X	
Zamarin, Dmitriy MD, PhD		Consultant/Consulting Fee: Merck
Speaker Disclosures		
Abrams, Ross, MD	X	
Adams, Sarah, MD	X	
Aghajanian, Carol, MD		Steering Committee Meeting/Honorarium: Mateon Therapeutics

FACULTY DISCLOSURE LIST

		Ad Board/Honorarium: Clovis
Ahmed, Amina, MD		Speaker/Consulting Fee: Tesaro
Arend, Rebecca, MD	X	
Armstrong, Deborah, MD	X	
Arthur, Doug, MD	X	
Backes, Floor, MD		Advisory Board/Consulting Fee: Tesaro Author/Honorarium: UpToDate
Bahary, Jean-Paul, MD	X	
Ballinger, George, RT	X	
Barror, Nick	X	
Barry, Lisa, MAEd, BS	X	
Bauman, Julie, MD, MPH		Consultant/Honorarium: Merck/EMD Serono (Europe); AstraZeneca
Beaverson, Lisa, BA, CCRP	X	
Bergantz, Wendy, RN	X	
Birrer, Michael, MD, PhD		Ad board/Honorarium: Tesaro; Clovis
Bodis, Stephan, MD	X	
Bonanni, Roseann, CTR, CCRP	X	
Bradley, Jeffrey, MD		Consultant/Honorarium: AstraZeneca Speaker/Travel reimbursement: Mevion Medical Systems
Bregar, Amy, MD	X	
Brown, Jubilee, MD		Speaker/Honorarium: Clovis; Ligo, Advisory Board/Honorarium: Genmab
Brown, Sally, RN, BSN, MGA	X	
Bruner, Deborah, PhD	X	
Buatti, John, MD		Editorial Board: UptoDate
Burger, Robert, MD		Consultant/Consulting Income: Amgen; Clovis; Tesaro; Regeneron; Merck; Janssen Education of Employees/Honorarium: AstraZeneca
Cesscon, Terrence, MD	X	
Chan, Timothy, MD, PhD		Ownership Interest/Stock Options: Gritstone Oncology; Bristol Myers Squibb; AstraZeneca Speaker: Illumina
Chase, Dana, MD	X	
Chen, Ron MD		Consultant/Consulting Fee: Bayer
Chung, Christine, MD, PhD	X	
Coleman, Robert, MD		Consulting: AbbVie; Cerulean; Debiopharma; Genmab; ImmunoGen; Merrimack; Navigate Consulting; Perthera; Vaniam Group, LLC Speaker: BioAscend; Onc Live; Platform Q Health; Prime Oncology; Research to Practice; Roche; Targeted Oncology Scientific/Advisory Board: AstraZeneca; Bayer Healthcare, Inc.; Caris Life Science; Cerulean; Clovis; Eisai-Morphotek; Gamamabs; Janssen; Novocure; Precision Oncology; Roche; Tesaro Funded Research: Array Bio Pharmaceuticals; AstraZeneca; Clovis; EMD Serano; Gradalis; Janssen; Merck
Constatino, Joseph, DrPH	X	
Copeland, Larry, MD		Consulting/Honorarium: Tesaro; Imminogen
Corn, Ben, MD	X	
Covens, Allan, MD		Speaker/Honorarium: AstraZeneca
Cowher, Michael, MD	X	
Crane, Christopher, MD	X	
Crane, Tracy, PhD	X	
Daily, Karen, DO	X	
Davis, Charleen	X	
Davis, Christine	X	
De Los Santos, Jennifer, MD	X	
DeNero, Lisa	X	
DeVries, Sandy, MA	X	
Dhanarajan, Asha, MD	X	
Dicker, Adam, MD, PhD, FASTRO		Consultant/Honorarium: EMD Serono
DiSilvestro, Paul, MD		Consultant/Consulting Fee: AstraZeneca; Tesaro
Donington, Jessica, MD		Speaker/Ad Board/Honorarium: AstraZeneca
Donnelly, Carole	X	
Dorth, Jenny, MD	X	
Duncan, Marth, RN, MSN	X	

FACULTY DISCLOSURE LIST

Duska, Linda, MD		Research Funding: Merck; Novartis Advisory Committee: Merck;Mersana
Dymond, Rebecca	X	
Eaton, Sue, CCRP	X	
Fakih, Marwan, MD		Consultant/Speaker/Consulting Fee/Honorarium: Amgen; Taino
Ellis, Matthew, MB, MCHIR, PhD		Royalty Income/Royalty/Ownership/Patent: Nanostrins; Prosigna; Bioclassifier Ad hoc Consultant/Consult fee: AstraZeneca; Pfizer; Novartis
Elsea, Tiffany	X	
Field Erica	X	
Finnigan, Melanie, BS	X	
Frak, Izabela, Mphil	X	
Fusco, Nancy, RN, BSN	X	
Gaillard, Stephanie, MD, PhD	X	
Ganz, Patricia, MD	X	
George, Thomas, MD, FACP		Consulting/Advisory Role: Merck; Bayer Research Funding: Bristol Myers Squibb; Merck; AstraZeneca/MedImmune; Eli Lilly; Bayer; Incyte; Tesaro
Gilarski, Linda	X	
Gillison, Maura, MD, PhD		Consultant/Consulting Fee: Bristol Myers Squibb; Celgene
Gnjatic, Sacha, MD		PI/Co-PI of sponsored study/Research Support: Janssen R & D; Agenus; Immune Design; Genentech Advisory Committee Member/Consulting Fees: Merck
Gomella, Lenny, MD		Advisory/Consulting Fee: Astellas; Janssen; MDX; Merck; Bayer
Gore, Elizabeth, MD	X	
Grant, Deborah, RN, MSN	X	
Grisham, Rachel, MD	X	
Guha, Chandan, MD		Research Grant: Johnson&Johnson; Cellden
Hall, Laura	X	
Hayes, Neil, MD, MPH	X	
Hensley, Martee, MD		Spouse is employee/Salary: Sanofi Consulting/Consulting Fee: Eli Lilly
Hesse, Bradford, PhD	X	
Herzog, Thomas, MD		Advisory Committee; Consulting Fee: Johnson&Johnson; AstraZeneca; Roche; Caris; Clovis; Tesaro
Hillman, Tyler, MD	X	
Hong, Theodore, MD	X	
Horton, Janet, MD	X	
Hu, Chen, PhD	X	
Hudson, Matthew, PhD, MPH	X	
Hunter, Joanne, BS, RT	X	
Hutcheson, Katherine, PhD	X	
Ilson, David, MD		Ad Board/Consultant/Honorarium: Pfizer; Merck; AstraZeneca; Roche; Bristol Myers Squibb; Bayer; Eli Lilly
Iqbal, Atif, MD	X	
Ivy, S. Percy, MD	X	
Jabbour, Salma, MD		Research Funding: Merck; Nestle
Jim, Heather, PhD		Consultant/Consulting Fee: Redhill Biopharma
Johnson, Tali	X	
Joseph, Kathie-Ann, MD, MPH	X	
Julian, Thomas, MD	X	
Kahn, Atif, MD	X	
Kardell, Julie	X	
Kennish, Margaret, AS, CCRC	X	
Kim-Suh, Hee Sun, RN, BSN	X	
Kirschner, Dolly, MPH, BS, BA, CCRP	X	
Klopp, Ann, MD	X	
Kluetz, Paul, MD	X	
Knudsen, Nancy, RN, BSN	X	
Konstantinopoulos, Panagiotis, MD, PhD		Advisory Board Member/Consulting Fee: Pfizer

FACULTY DISCLOSURE LIST

Kopetz, Scott, MD, PhD		Consultant/Honorarium: Amgen; Bayer; Genentech; Molecular Match; Taiho
Kotsko, Kristen, RN, BSN	X	
Kishon, Amir	X	
Koss, Jerry	X	
Krystkiewicz, Amy, RN	X	
Ku, Geoffrey, MD		Research/Research Funding: AstraZeneca; Arog; Aduro Consulting/Consulting Fee: Bristol Myers Squibb; Merck
Kunos, Charles, MD, PhD	X	
Lacouture, Mario, MD	X	
Lacy, Michele, RN, BSN	X	
Lai, Stephen, MD, PhD		Consultant/Research/Grant: Navidea
Langer, Corey, MD		Institutional Grant/Research Support: Bristol Myers Squibb; ImClone; Pfizer; Eli Lilly; Genentech; OSI Pharmaceuticals; GlaxoSmithKline; Clovis; Merck; Nektar; Atvantagene; Inovio; Ariad Scientific Advisory: Bristol Myers Squibb; ImClone; Pfizer; Eli Lilly; AstraZeneca; Novartis Pharmaceuticals; Genentech; Bayer HealthCare/ Onyx Pharmaceuticals; Abraxis Oncology (Celegene); Abbott; Biodesix; Claiant; CarisDx; ARIAD; Boehringer Ingelheim; Syntha; Clovis DSMC Member: Amgen; Synta; Peregrine; SWOG; Incyte CME: PIK; PER; NOCR; CCO; RTP
Lankes, Heather, PhD, MPH	X	
Leath, Charles, MD, MSPH		Advisory Board – Ovarian Chair/Honorarium: Celsion
Le, Quynh, MD	X	
Lee, James, MD, PhD		Advisory Board/Honorarium: Incyte; LOXO
Lee, Nancy, MD	X	
Leitao, Mario, MD	X	
Leong, Stephen, MD		Institutional PI/Research Funding: Deaphera; Bristol Myers Squibb; Karyopharm Stocks: ATRS; Spectrum
Levine, Douglas, MD	X	
Licavoli, Cindy, RN, BSN, MA	X	
Lin, Diana, RN, MPH	X	
Lin, Steven, MD, PhD		Grant Research: Hitachi Chemical Diagnostic, Inc.; Protea Biosciences; Peregrine Pharmaceuticals Advisory Board: AstraZeneca
Lowenstein, Jessica, MS, DABR	X	
Lu, Bo, MD, PhD	X	
Machtay, Mitchell, MD	X	
Malik, Shakun, MD	X	
Mamon, Harvey, MD, PhD		Author/Honorarium: UpToDate
Manfredi, Denise, BS, RT (T)	X	
Markham, Merry-Jennifer, MD	X	
Matisko, Mary Pat, RN, BSN	X	
Matuszek, Mallory	X	
Mayadev, Jyoti, MD		Speaker/Honorarium: Samsung Advisory Board/Honorarium: GOG Foundation; Regeneron Consulting/Honorarium: Varian
McCartney, Sara, RN, MS	X	
McLaughlin, Tamara, MHA, MPH	X	
McNulty, Susan, CMD, BS, (R) (T)	X	
Medina, Patrick, PharmD, BCOP	X	
Mehta, Minesh, MD		Consultant/Honorarium: IBA; Oncoceutics; AstraZeneca; Celgene; Tocagen; Abbvie Medical Advisory Board/Honorarium: Colby; Stemina; Provectus Board of Directors/Honorarium: Monteris; Oncoceutics
Mell, Loren, MD		Speaker/Honorarium: Varian Medical Systems Advisory Board/Honorarium: Pfizer Advisory Board/Travel/Honorarium: Merck Panel/Consultant/Travel/Honorarium: Bristol Myers Squibb
Michalski, Jeffrey, MD		Speaker/Consultant/Honorarium: Augmenix
Miller, Sheralee, BS	X	
Moore, Kathleen, MD		Advisor/Honorarium: Clovis; Tesaro; Immunogen; Genentech; VBL Therapeutics; Janssen
Morris, Van Karlyle, MD	X	

FACULTY DISCLOSURE LIST

Motyka-Welsh, Elaine, RN, MSN, CCRP	X	
Movsas, Benjamin, MD		Investigator/Research Support Dept.: Varian, Inc.; Philips Inc. Speaker/Honorarium: ViewRay
Mutch, David, MD	X	
Neading, Joyce	X	
Nichols, Elizabeth, MD	X	
Nickles-Fader, Amanda, MD		Ad Board/Honorarium: Ethican Endosurgery
Nolte, Susan, PhD, CRNP	X	
O'Cearbhaill, Rosin, MD		Advisory Board/Honorarium: Tesaro
O'Regan, Ruth, MD		Grant Research: Novartis; Pfizer Advisor: Eli Lilly; Novartis; Pfizer
Passarello, Mimi, MBA	X	
Patel, Vanita, MS	X	
Pellinat, Martin	X	
Powell, Matthew, MD		Speaker/Consultant: Merck; AstraZeneca; Clovis; Tesaro
Prendergast, George, PhD		Board Membership/Ownership Interest: Meditope Biosciences, Inc.
Presley, Jennifer, RT (R) (M) (T)	X	
Raben, David, MD		Ad Board/Speaker/Honorarium/ Consulting fee: AstraZeneca Ad Board/Honorarium: Genentech; Merck; Nanobiotix
Rastogi, Priya, MD	X	
Ridge, Drew, MD	X	
Riley, Ginger	X	
Ritzwoller, Debra, PhD	X	
Robidoux, Andre, MD	X	
Robinson, Clifford, MD		Chief Medical Officer/Phantom equity: Radialogica Investigator/Consultant/Teaching/Grant Funding to Institution/Consulting Fee: Varian Investigator/Grant Funding to Institution: Elekta Speaking & Teaching/Honorarium: ViewRay
Robinson, Janelle, BA, CCRP	X	
Rodriguez, Cristina, MD		Institutional PI/Institutional Funding: Merck; Merck; Bristol Myers Squibb; AstraZeneca; Ignyta
Rosenthal, David, MD		Ad Board/Honorarium: Merck
Saba, Nabil, MD	X	
Samules, Michael, MD	X	
Schilder, Russell, MD		Speaker/Honorarium: Pfizer
Sears, Leslie	X	
Serrianni, Jeffrey, BS	X	
Shaitelman, Simona, MD	X	
Sherman, Eric, MD		Consultant/Honorarium: Novartis; Eisai
Shriner, Donna, RPH, PharmD, MPH	X	
Simko, Jeff, MD, PhD		Consultant/Honorarium: Bristol Myers Squibb Scientific Advisor/Ownership Interest: 3D Biopsy Inc.; 3D Scan Inc.
Solokov, Sylvia, MS, RN	X	
Small, William, MD		Speaker/Honorarium: Zeiss
Smigel-Croker, Kara	X	
Smith, Judith, PharmD	X	
Smith, Tiffany	X	
Spirtos, Nick, MD	X	
Stockman, Sharon, BA CCRP	X	
Stoermer, Kati, MSBA	X	
Sturgeon, Karen	X	
Sturgis, Erich, MD, MPH	X	
Swisher, Elizabeth, MD	X	
Suhayda, Lynne, RN, BSN, MSEd	X	
Sullaway, Catherine	X	
Tewari, Krishnansu, MD	X	
Thomas, Alexandra, MD, FACP	X	

FACULTY DISCLOSURE LIST

Thomson, Cynthia, PhD, RD, CSO		Consultant/Honorarium: Produce for Better Health Reviewer/Honorarium: AICR; NIH Speaker/Honorarium: Academy of Nutrition & Dietetics
Thomas, Terry, MS, CCRC	X	
Timmerman, Robert, MD		PI/Honorarium: Varian Medical Systems; Elekta Oncology; Accuray, Inc.
Trotti, Andy, MD	X	
Umphrey, Heidi, MD	X	
Vogelbaum, Michael, MD, PhD		Founder/Chief Medical Officer/Indirect Equity Interest/Royalties: Infuseon Therapeutics Direct stock ownership: Johnson&Johnson Advisory Board/Honorarium: Medicenna
Wapnir, Irene, MD		Advisory Board/Honorarium: Amgen; Genomic Health; Tolman
Webster, Jennifer		Employee/Salary: Foundation Medicine
Weiblen, Melinda, BS	X	
Weidhaas, Joanne, MD, PhD, MSM		Consultant/IP Licensed/Owner: MiraDx
Welliver, Meng, MD, PhD	X	
Wenzel, Lari, PhD	X	
Whitney, Charles, MD	X	
Williams, Sam, PhD	X	
Williams, Terence, MD		Principal Investigator/Research Grant: Varian Medical Systems Review Panel/Honorarium: National Institute of Health
Winslow, Chrisann, RN, MSN		Speaker/Honorarium: Clovis
Wise, Liz, CCRC	X	
Wong, Phil, MD		Advisor/ Research Fund: Bristol Myers Squibb; AstraZeneca
Wong, Stuart, MD	X	
Wright, Alexi, MD, MPH	X	
Xiao, Changchung, PhD	X	
Yom, Sue, MD		PI/Clinical Trial: Genentech; Merck; Bristol Myers Squibb Author/Royalty: Springer; UpToDate
Zafar,Yousuf, MD, MHS	X	
Zamarin, Dmitriy MD, PhD		Consultant/Consulting Fee: Merck
Zimmer, Alexandra, MD	X	

LAS – 06/19/18

Welcome to the July 2018 NRG Oncology Semiannual Meeting

It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Philadelphia, PA, July 12- 14, 2018.

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

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

Meeting highlights include:

- A day-long summer Symposium titled, "Implementation of Precision Medicine in Gynecologic Cancer Clinical Practice &Trial Design" with noted Oncologists and Scientists serving as speakers and moderators The speakers will focus their presentations on topics brought to light from recent FDA-approved biomarker-directed drug treatments and the expanding menu of precision medicine-based therapeutic options. The perceived need to develop a smarter use of targeted therapeutics requires in depth knowledge and understanding of molecular oncology, laboratory science and the regulatory environment to synergize the biologic basis of gynecologic malignancies with the practical applications of patient care and trial operations. These and other topics will be addressed in an attempt to engage the audience in a discussion of the best next steps for incorporating precision medicine into clinical practice and trial design.
- A Clinical Trial Nurse/Clinical Research Associate Workshop-Educational Session will take place on Thursday.
- A Digital Health and Personal Connected Health Mini-symposium will take place on Thursday. This session is aimed to help provide a conceptual framework for better mechanistic understanding of the pathways by which digital tools can impact cancer care.
- NRG Oncology research achievements will be featured during Friday's Scientific Session, "NRG Oncology Research Review," which will highlight the results of recently reported studies in breast, prostate, ovarian, lung, and pancreatic cancer as well as cancer presentation on the NCI Quantitative Imaging Network (QIN).
- A Social Media Workshop will take place on Friday. Social media is an increasingly important communication tool for health professionals. This session will help attendees identify potential risks and barriers to social media use in professional practice, and provide potential methods for utilizing social media as part of clinical trial outreach and awareness.
- At the NRG Oncology General Session on Friday, Group leadership will provide updates on topics of significance for our members and the research community.

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

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

Robert Mannel, MD
NRG Oncology Group Chair

Norman Wolmark, MD
NRG Oncology Group Chair

NRG Oncology

Mission Statement

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

For the Educational Objectives, we list the following:

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

Disclosure Information

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

CONTINUING MEDICAL EDUCATION CREDIT INFORMATION

Accreditation Statement

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

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

AMA PRA Category 1 Credits™

The GOG Foundation, Inc. designates this live activity for a maximum of 26 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

GOG FOUNDATION, INC.

Continuing Medical Education Program

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

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

NRG Oncology Semiannual Workshop CME Credits

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

Evaluations/CME/Attendance Certificates

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

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

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

How to submit your evaluation:

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

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

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

NO EVALUATIONS WILL BE ACCEPTED AFTER:
August 3, 2018.

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

FINAL LISTING OF APPROVED CME CREDITS
The following sessions/workshops have been approved to receive CME credits
Accredited by the GOG Foundation, Inc. in Philadephia, PA July 12-14, 2018
AMA PRA Category 1 credits™

	THURSDAY	FRIDAY	SATURDAY
Symposium –Implementation of Precision Medicine in Gynecologic Cancer Clinical Practice and Trial Design TICKETED	6		
WORKSHOP AGENDAS			
Breast Cancer Rare and Genetically Linked Subcommittee Workshop		2	
Canadian Members Workshop			1
Cancer Prevention and Control Workshop		3	2
Cervix		2	1
Digital Health and Personal Connected Health Mini Symposium TICKETED	2		
Gastrointestinal Cancer Workshop			2
Gynecologic Cancer Workshop			1.5
GYN Developmental Therapeutics Workshop/Phase I			2
GYN Dev. Therapeutics/Phase I/Translational Science	2		
Health Disparities Committee Workshop		2	
Head and Neck Cancer Workshop			2
International Members Workshop		1	
Medical Oncology			1
NRG – LU003		1.5	
Local Regional Breast Cancer Subcommitee		1	
NRG Protocol NRG-BR005 Workshop			1
NRG Protocol G1002 and Protocol G1004 Workshop		1.5	
NRG Protocol Workshop: NRG BR003 and BR004 and NSABP B-55		1	
NRG Scientific Session - NRG Oncology Research Review TICKETED		2	
Ovarian Workshop		2	1
Pathology Workshop		4	
Patient Centered Outcomes Research (PCOR)	2		
Pharmacy Subcommittee Workshop		1	
Radiation Development Therapeutics			2
Rare Tumor Workshop		2	
Social Media Workshop		1.5	
Surgical Oncology Workshop			1.5
Translational Science Workshop	1.5		
Translational Science GYN		1.5	
Translational Science Lung Cancer Workshop		2	
Uterine Corpus Workshop		2	1
PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD's			
PSC Clinical Trial Nurse/Clinical Research Assoc Workshop Ed Session TICKETED	3		
PSC- CTN/CRA Workshop Educational Luncheon TICKETED	1		
PSC Roundtable Sessions TICKETED	3		
PSC Education and Training Group (Closed)	1		
PSC Mentorship Working Group (Closed)	1		
PSC Protocol Review Working Group (Closed)	1		
PSC Quality Control Working Group (Closed)	1		
PSC Clinical Research Associate Subcommittee (Closed) open for 1st hour		2	
PSC Clinical Trial Nurse Subcommittee (Closed) open for 1st hour		2	

CONVERSE AND MEET

at the July 2018
NRG Oncology Semiannual Meeting

Stay up-to-date with updates and announcements from the NRG Oncology Semiannual Meeting 2018 on Twitter, Facebook and the Meeting App!

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LIKE US ON FACEBOOK!

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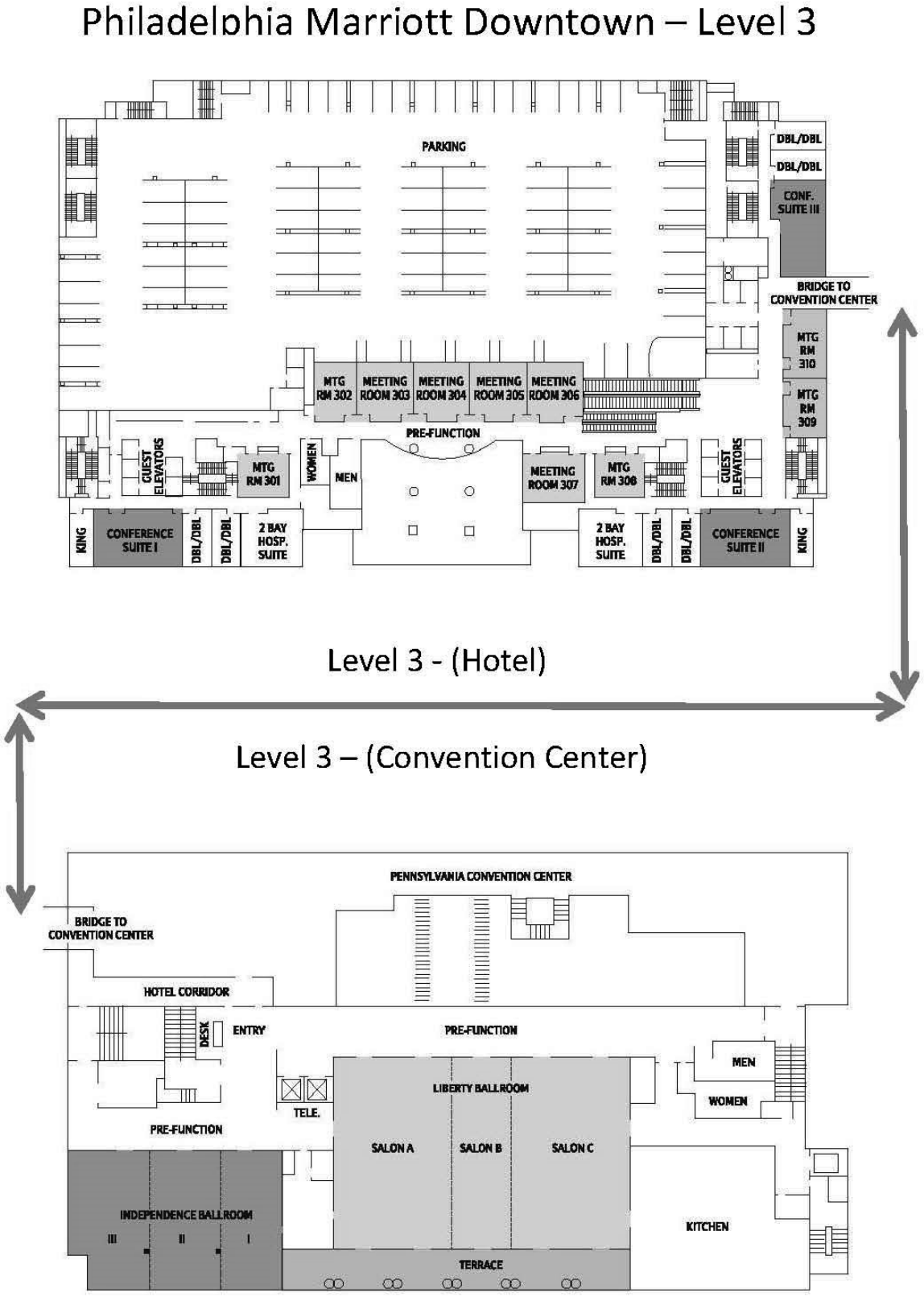
DOWNLOAD THE NRG ONCOLOGY MEETING APP EVENTSXD

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

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

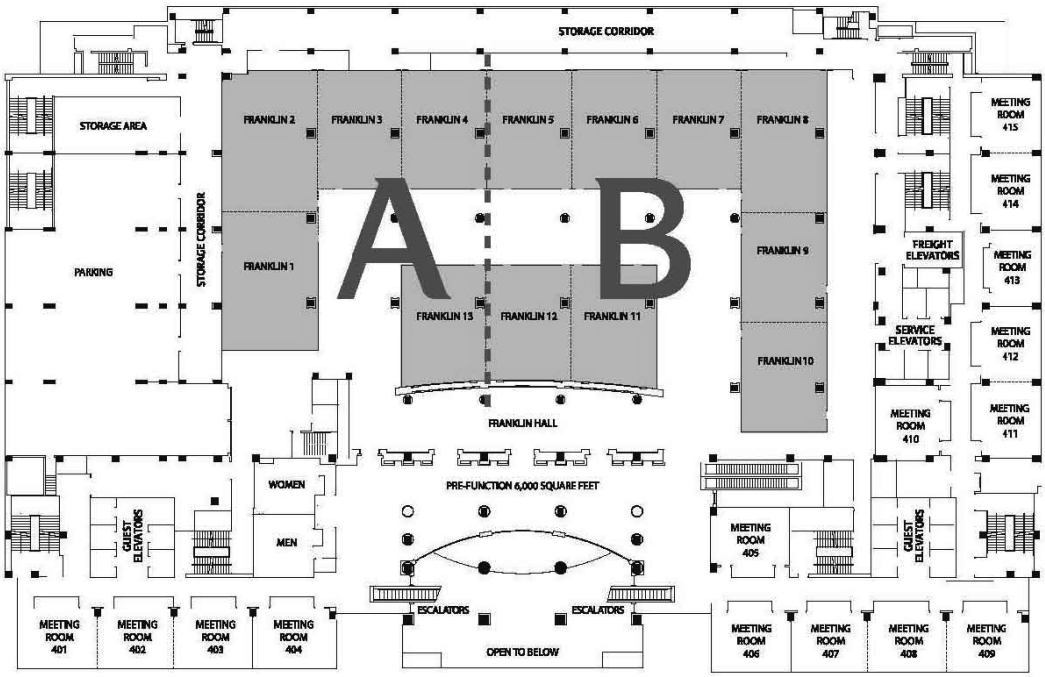
Network Login: nrgmeeting Passcode: n1r2g345

Philadelphia Marriott Downtown
Floor Plan



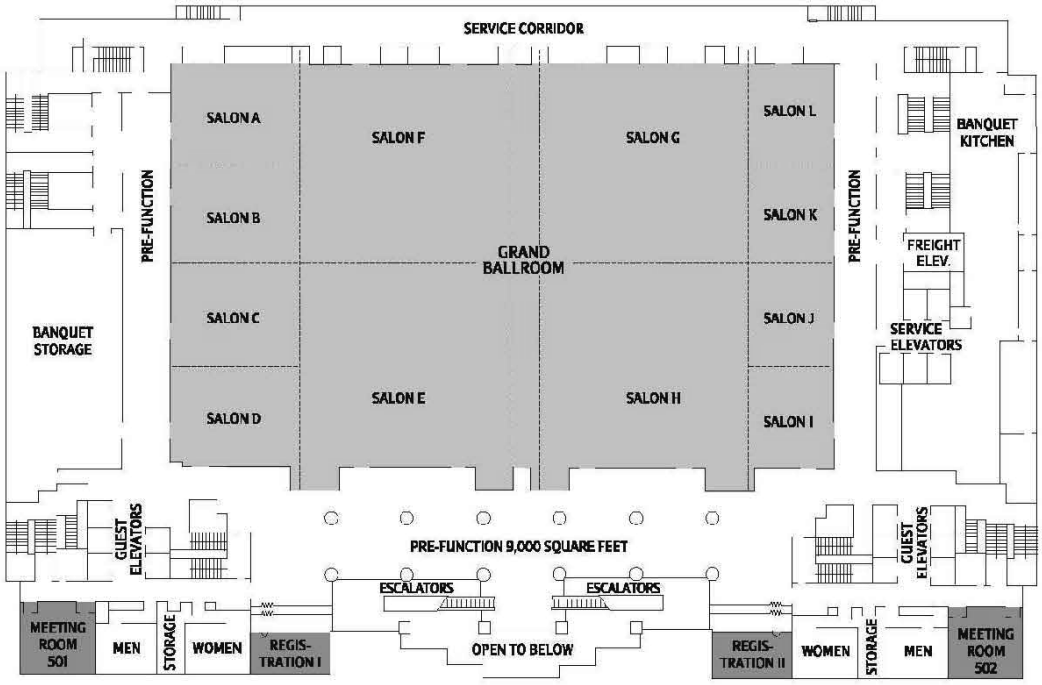
Philadelphia Marriott Downtown
Floor Plan

Philadelphia Marriott Downtown – Levels 4 & 5



Level 4 - (Hotel)

Level 5 - (Hotel)



NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 12 – 14, 2018

Thursday, July 12, 2018		
7:00 am – 8:00 am	PSC Clinical Trials Nurse/Clinical Research Associate Breakfast	Salon GKL/5th Fl.
7:00 am – 8:30 am	Symposium Breakfast	Salon AB/5th Fl.
7:00 am – 6:00 pm	Registration/CME/Information Desk	Grand Ballroom Foyer/5th Fl.
10:30 am – 10:45 am	Symposium Coffee Break	Salon AB/5th Fl.
12:35 pm – 1:30 pm	Symposium Lunch	Salon AB/5th Fl.
2:00 pm – 6:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Room 406/4th Fl.
4:00 pm – 6:00 pm	Exhibit Setup	Franklin Hall Foyer/4th Fl.
8:00 am – 12:00 pm	Imaging and Radiation Oncology Core (IROC) RT and Imaging Focused Staff Meeting for NRG Oncology Protocols *(held offsite at ACR Center for Research and Innovation)* *	Off-Site
8:00 am – 1:00 pm	PSC Clinical Trials Nurse/Clinical Research Associate Workshop and Educational Lunch	Salon GKL/5th Fl.
8:00 am – 3:00 pm	Summer Symposium - *"Implementation of Precision Medicine in Gynecologic Cancer Clinical Practice and Trial Design "*	Salon F/5th Fl.
9:00 am – 12:00 pm	NRG DMC Panel A *	Room 405/4th Fl.
9:00 am – 1:00 pm	SOCRA Certification Exam	Independence 1/3rd Fl.
12:00 pm – 6:00 pm	Research Advocate Training Workshop *	Room 410/4th Fl.
1:00 pm – 3:00 pm	Minisymposium: Digital & Personal Connected Health	Salon CD/5th Fl.
1:00 pm – 4:00 pm	NRG DMC Panel B *	Room 405/4th Fl.
1:30 pm – 4:30 pm	PSC Clinical Trial Nurse/Clinical Research Associate Workshop – Roundtable Educational Session	Salon HIJ/5th Fl.
2:00 pm – 4:00 pm	Immunotherapy and Immune Modulation Workshop	Salon E/5th Fl.
2:30 pm – 4:00 pm	Comparative Effectiveness Research (CER) Committee *	Room 403/4th Fl.
3:00 pm – 5:00 pm	Clinical Trials 101 – New Investigator Educational Session	Salon CD/5th Fl.
3:00 pm – 5:00 pm	NRG-Harvard-Ohio State-Case Western R01 Grant Meeting*	Room 401-402/4th Fl.
4:00 pm – 6:00 pm	GYN Developmental Therapeutics/Phase 1/Translational Science Workshops	Salon GKL/5th Fl.
4:00 pm – 6:00 pm	Patient Centered Outcomes Research (PCOR) Workshop	Salon E/5th Fl.
4:30 pm – 6:30 pm	PSC Education & Training Working Group *	Room 413/4th Fl.
4:30 pm – 6:30 pm	PSC Mentorship Working Group *	Room 403/4th Fl.
4:30 pm – 6:30 pm	PSC Protocol Review Working Group *	Independence 1/3rd Fl.
5:00 pm – 6:30 pm	NRG Oncology Japan Meeting	Room 401-402/4th Fl.
5:30 pm – 7:00 pm	PSC Quality Control Working Group *	Room 404/4th Fl.
6:00 pm – 7:00 pm	Early Phase Trial Oversight Committee *	Room 405/4th Fl.
6:00 pm – 8:00 pm	NCORP Concept Review *(Invitation Only)*	Room 408-409/4th Fl.

Revised 6/25/18

Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 12 – 14, 2018

Thursday, July 12, 2018		
6:30 pm – 8:00 pm	**Translational Science Workshop**	**Salon CD/5th Fl.**
8:00 pm – 10:00 pm	**Ancillary Projects Committee***	**Room 405/4th Fl.**
9:00 pm – 10:00 pm	**Communications Committee**	**Room 403/4th Fl.**

Revised 6/25/18

Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 12 – 14, 2018

Friday, July 13, 2018		
6:30 am – 8:30 am	Continental Breakfast	Franklin Hall Foyer/4th Fl.
7:00 am – 5:00 pm	Exhibits	Franklin Hall Foyer/4th Fl.
7:00 am – 5:30 pm	Registration/CME/Information Desk	Grand Ballroom Foyer/5th Fl.
7:00 am – 6:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Room 406/4th Fl.
9:00 am – 1:00 pm	CTN/CRA Information Table	Grand Ballroom Foyer/5th Fl.
10:00 am – 10:30 am	General Coffee Break	Franklin Hall Foyer/4th Fl.
2:00 pm – 3:30 pm	General Coffee Break	Franklin Hall Foyer/4th Fl.
6:45 am – 9:00 am	Patient Advocates Meeting *	Room 410/4th Fl.
7:00 am – 8:00 am	Digital Health Working Group	Franklin 3-4/4th Fl.
7:00 am – 8:00 am	IROC RT Contouring Workshop on NRG Oncology Head & Neck and Liver Trials	Room 411-412/4th Fl.
7:00 am – 8:00 am	GYN Cancer Committee Executive Session *	Room 304/3rd Fl.
7:00 am – 8:00 am	Local Regional Breast Cancer Subcommittee *	Independence 1/3rd Fl.
7:00 am – 9:00 am	Health Disparities Workshop – *Intervening on the Financial Toxicity of Cancer Care*	Salon H/5th Fl.
7:00 am – 9:00 am	PSC Clinical Trials Nurse Subcommittee * *(Open for first hour)*	Salon IJ/5th Fl.
7:00 am – 9:00 am	PSC Clinical Research Associate Subcommittee * *(Open for first hour)*	Franklin 10/4th Fl.
7:00 am – 12:00 pm	GYN/RT Case Review	Room 406/4th Fl.
8:00 am – 9:00 am	NRG SDMC Executive Committee *	Independence 1/3rd Fl.
8:00 am – 9:00 am	Protocol 210 Subcommittee	Room 401-402/4th Fl.
8:00 am – 9:30 am	Radiation Oncology GYN Working Group	Salon AB/5th Fl.
8:00 am – 10:00 am	Ovarian Cancer Workshop	Salon GKL/5th Fl.
8:00 am – 10:00 am	**Scientific Session** – *NRG Oncology Research Review*	Salon EF/5th Fl.
8:00 am – 10:30 am	Translational Science Brain Cancer Subcommittee/Low-Grade Glioma Working Group	Franklin 11-12/4th Fl.
8:00 am – 5:00 pm	Pathology Workshop & Review	Independence 2-3/3rd Fl.
9:00 am – 10:30 am	Cancer Prevention and Control Committee Meeting *(Invitation Only)*	Franklin 3-4/4th Fl.
10:00 am – 11:00 am	International Members Meeting	Salon IJ/5th Fl.
10:00 am – 11:00 am	NRG BR003/NSABP B-55 and NRG BR004 Workshops	Franklin 8/4th Fl.
10:00 am – 11:30 am	GYN GTN Subcommittee	Franklin 10/4th Fl.
10:00 am – 11:30 am	Social Media Workshop	Franklin 13/4th Fl.
10:00 am – 12:00 pm	Health Disparities Committee	Salon AB/5th Fl.
10:00 am – 12:00 pm	Cervix Cancer Workshop	Salon GKL/5th Fl.
10:00 am – 12:00 pm	Sarcoma Working Group	Room 411-412/4th Fl.
10:00 am – 12:00 pm	Imaging Committee	Room 408-409/4th Fl.

Revised 6/25/18

Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 12 – 14, 2018

Friday, July 13, 2018		
10:30 am – 12:00 pm	Translational Science GYN Workshop	Salon CD/5th Fl.
11:00 am – 12:00 pm	Protocol 225 Information Session	Room 405/4th Fl.
11:00 am – 12:00 pm	New Investigators Committee	Franklin 9/4th Fl.
11:00 am – 12:30 pm	Audit Training Workshop	Franklin 1-2/4th Fl.
11:00 am – 12:30 pm	Immunotherapy and Immune Modulation Workshop	Liberty BC/3rd Fl.
11:00 am – 1:00 pm	Neurosurgical Subcommittee	Franklin 11-12/4th Fl.
11:00 am – 1:00 pm	Older Adult Working Group	Salon IJ/5th Fl.
11:00 am – 1:00 pm	NRG Oncology Foundation Board of Directors *	Room 401-402/4th Fl.
11:30 am – 1:00 pm	Breast Cancer Rare & Genetically-Linked Subcommittee Workshop	Franklin 6-7/4th Fl.
11:30 am – 1:00 pm	NRG GI002 and NRG GI004 Workshops	Franklin 8/4th Fl.
11:30 am – 1:00 pm	NRG LU003 Kick-Off Meeting	Franklin 13/4th Fl.
11:30 am – 1:00 pm	Cancer Care Delivery Research Session Workshop	Salon H/5th Fl.
12:00 pm – 1:00 pm	NRG GU006 Training Session	Room 408-409/4th Fl.
12:00 pm – 1:00 pm	NRG Pharmacy Subcommittee	Independence 1/3rd Fl.
12:00 pm – 1:00 pm	Pathology Committee *	Independence 2-3/3rd Fl.
1:00 pm – 2:00 pm	NRG Oncology General Session	Salon EF/5th Fl.
2:00 pm – 3:00 pm	Translational Science Head & Neck Cancer Subcommittee	Franklin 11-12/4th Fl.
2:00 pm – 3:30 pm	Publications Committee *	Independence 1/3rd Fl.
2:00 pm – 3:30 pm	Translational Science Breast Cancer Subcommittee	Salon CD/5th Fl.
2:00 pm – 4:00 pm	Translational Science GU Cancer Subcommittee	Salon IJ/5th Fl.
2:00 pm – 4:00 pm	Rare Tumor Workshop	Liberty BC/3rd Fl.
2:00 pm – 4:00 pm	Radiation Oncology Workshop	Franklin 1-2/4th Fl.
2:00 pm – 5:00 pm	Brain Tumor Core Committee *	Salon H/5th Fl.
2:30 pm – 4:30 pm	Uterine Corpus Cancer Workshop	Salon GKL/5th Fl.
2:30 pm – 5:30 pm	Cancer Prevention and Control Workshop	Franklin 6-7/4th Fl.
3:00 pm – 6:00 pm	Head & Neck Cancer Core Committee *	Franklin 3-4/4th Fl.
3:30 pm – 6:30 pm	Breast Cancer Working Group *	Salon AB/5th Fl.
4:00 pm – 5:00 pm	NRG Oncology Human Research Committee *	Room 304/3rd Fl.
4:00 pm – 6:00 pm	Medical Physics Workshop	Franklin 9/4th Fl.
4:00 pm – 6:00 pm	Translational Science Lung Cancer Workshop	Franklin 11-12/4th Fl.
4:00 pm – 6:00 pm	Genitourinary Cancer Core Committee *	Salon IJ/5th Fl.
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group Meeting	Room 401-402/4th Fl.
5:00 pm – 7:00 pm	Brain Tumor Workshop	Salon H/5th Fl.
6:00 pm – 8:00 pm	NRG Oncology Welcome Reception	Salon EF/5th Fl.
7:00 pm – 9:00 pm	NRG CC001/CC003 Analysis Planning *	Independence 1/3rd Fl.

Revised 6/25/18

Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 12 – 14, 2018

Saturday, July 14, 2018		
6:30 am – 8:30 am	Continental Breakfast	Franklin Hall Foyer/4th Fl.
7:00 am – 1:00 pm	IT Resource Room/Internet Café/Speaker Ready Room	Room 406/4th Fl.
7:00 am – 2:00 pm	Exhibits	Franklin Hall Foyer/4th Fl.
7:00 am – 3:00 pm	Registration/CME/Information Desk	Grand Ballroom Foyer/5th Fl.
10:00 am – 11:00 am	General Coffee Break	Franklin Hall Foyer/4th Fl.
6:30 am – 8:00 am	Surgical Oncology Workshop	Franklin 6-7/4th Fl.
6:45 am – 8:30 am	Proton Working Group Workshop	Salon AB/5th Fl.
7:00 am – 8:00 am	Canadian Members Meeting	Room 304/3rd Fl.
7:00 am – 8:00 am	NRG SDMC Data Management Working Group *	Room 413/4th Fl.
7:00 am – 8:00 am	NRG SDMC IT Working Group *	Room 302/3rd Fl.
7:00 am – 8:00 am	NRG SDMC Statistical Working Group *	Franklin 8/4th Fl.
7:00 am – 8:00 am	Medical Oncology Workshop	Salon CD/5th Fl.
7:00 am – 9:00 am	Translational Science GI Cancer Subcommittee	Salon F/5th Fl.
7:00 am – 9:30 am	Protocol Support Committee Business Meeting *	Room 303/3rd Fl.
8:00 am – 9:00 am	NRG BR005 Workshop	Franklin 6-7/4th Fl.
8:00 am – 9:30 am	Safety Review Committee *	Franklin 8/4th Fl.
8:00 am – 10:00 am	NCORP PI & Administrators Meeting	Salon CD/5th Fl.
8:00 am – 10:00 am	GYN Developmental Therapeutics/Phase I Workshops	Salon GKL/5th Fl.
8:00 am – 10:00 am	Genitourinary Cancer Workshop	Franklin 11-12/4th Fl.
8:00 am – 10:00 am	Head & Neck Surgical Subcommittee	Salon IJ/5th Fl.
8:00 am – 10:00 am	Lung Cancer Core Committee *	Salon E/5th Fl.
9:00 am – 10:00 am	Quality Assurance Audit Meeting *	Room 302/3rd Fl.
9:00 am – 11:00 am	GI Colorectal Cancer Subcommittee *	Salon F/5th Fl.
9:00 am – 1:00 pm	Breast Cancer Workshop	Liberty ABC/3rd Fl.
10:00 am – 11:00 am	Ovarian Cancer Workshop	Salon GKL/5th Fl.
10:00 am – 11:00 am	Cervix Cancer Workshop	Salon IJ/5th Fl.
10:00 am - 11:00 am	Uterine Corpus Cancer Workshop	Salon E/5th Fl.
10:00 am – 11:30 am	Membership Committee *	Franklin 8/4th Fl.
10:00 am – 12:00 pm	Radiation-Developmental Therapeutics Workshop	Franklin 6-7/4th Fl.
10:00 am – 12:00 pm	Protocol 225 Workshop	Room 304/3rd Fl.
10:00 am – 12:00 pm	Head & Neck Cancer Workshop	Franklin 11-12/4th Fl.
11:00 am – 1:00 pm	GI Non-Colorectal Cancer Subcommittee *	Salon F/5th Fl.

Revised 6/25/18

Sessions for Committee Member

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Philadelphia Marriott Downtown
Philadelphia, Pennsylvania
July 12 – 14, 2018

Saturday July 14, 2018		
12:00 pm – 1:00 pm	Voting Members PI Meeting *	Franklin 9-10/4th Fl.
1:00 pm – 3:00 pm	Gastrointestinal Cancer Workshop	Salon CD/5th Fl.
1:00 pm – 3:00 pm	Lung Cancer Workshop	Franklin 11-12/4th Fl.
1:00 pm – 3:00 pm	Gynecologic Cancer Workshop	Salon E/5th Fl.
2:00 pm – 3:00 pm	VA/MTF Meeting	Salon F/5th Fl.
3:00 pm – 6:00 pm	Research Strategy Meeting *	Salon H/5th Fl.

Revised 6/25/18

Sessions for Committee Member

Information Technology Resource Center

NRG Semi-Annual Meeting

Philadelphia, PA

July 12-14, 2018

Philadelphia Marriott Downtown

Room 406

Fourth Floor

Open
Thur. Jul 12: 2PM -6PM
Fri. Jul 13: 7AM-6PM
Sat. Jul 14: 7AM-1PM

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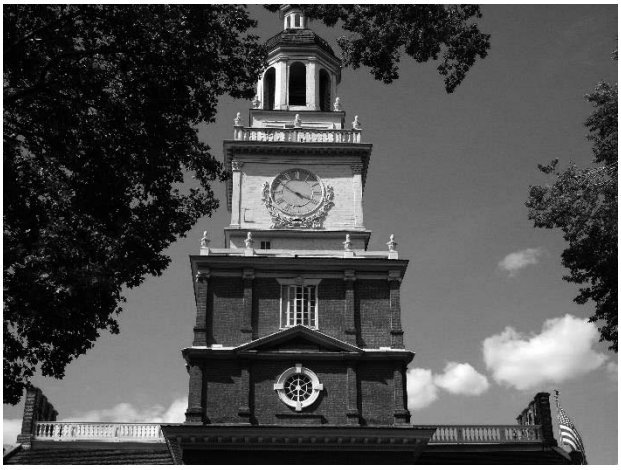

The Resource Center will feature:

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

- Medidata RAVE
- CTSU OPEN
- User Accounts

Available services include:

- Internet Access
- Email
- Printing

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

Special Sessions/Events

NRG Oncology Semiannual Meeting /July 2018

NRG Oncology's Digital Health and Personal Connected Health Minisymposium

NRG ONCOLOGY

Advancing Research. Improving Lives.™

Thursday, July 12, 2018

1-3 PM Eastern Time

NRG Oncology Semiannual Meeting

Philadelphia Marriott Downtown - Philadelphia, PA

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

Questions regarding the minisymposium can be directed to Dr. Dicker at adam.dicker@jefferson.edu

SPEAKERS

Paul G. Kluetz, MD
Food and Drug Administration
CDER
"FDA Oncology Center of Excellence: Core Patient Outcomes and Digital Health"

Heather S. Jim, PhD
Moffitt Cancer Center
"Emerging Trends in Cancer Research Using Patient-Generated Data"

Amir Kishon, PhD
RMDY Health Inc.
"Platforms for Patient Engagement and Research"

S. Percy Ivy, MD
National Cancer Institute
CTEP
"Technology APPlications for Digital Safety and Compliance in Drug Development"

Alexi Wright, MD MPH
Harvard Medical School
Dana-Farber Cancer Institute
"Harnessing Patient-Reported Outcomes and Digital Phenotyping to Improve Cancer Care"

Bradford W. Hesse, PhD
National Cancer Institute
HCIRB, BRP
"Improving Cancer Outcomes Through Connected Health"

PROGRAM CO-CHAIRS

Adam P. Dicker, MD, PhD, FASTRO
Thomas Jefferson University

Matthew F. Hudson, PhD, MPH
Greenville Health System

Debra Ritzwoller, PhD
Kaiser Permanente

Register for the NRG Oncology Semiannual Meeting to attend.

nrgoncology.org/About-Us/Meetings/July-2018-Semiannual-Meeting-Resources

Digital Health and Personal Connected Health Minisymposium Agenda

Date: Thursday, July 12, 2018
Start Time: **1:00 PM ET**
End Time: **3:00 PM ET**
Program Chair: **Adam P. Dicker, MD, PhD, FASTRO**
Program Co-Chairs: **Matthew F. Hudson, PhD, MPH and Debra Ritzwoller, PhD**

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

1. Illustrate how healthcare organizations are using digital tools not only to monitor but also to treat and intervene with patients
2. Understand how connected health tools have enabled clinical goals and health science research
3. Demonstrate how digital health programs have improved access, care, and collaboration

Educational Needs:

To provide a conceptual framework for better mechanistic understanding of the pathway(s) by which digital tools can impact cancer care.

MINISYMPOSIUM AGENDA

1:00-1:05 pm	Welcome and Introduction	Adam P. Dicker, MD, PhD, FASTRO
1:05-1:20 pm	Emerging Trends in Cancer Research Using Patient-Generated Data	Heather S. Jim, PhD
1:20-1:35 pm	FDA Oncology Center of Excellence: Core Patient Outcomes and Digital Health	Paul G. Kluetz, MD
1:35-1:50 pm	Platforms for Patient Engagement and Research	Amir Kishon, PhD
1:50-2:00 pm	Q&A	
2:00-2:15 pm	Technology APPlications for Digital Safety and Compliance in Drug Development	S. Percy Ivy, MD
2:15-2:30 pm	Harnessing Patient-Reported Outcomes and Digital Phenotyping to Improve Cancer Care	Alexi Wright, MD, MPH
2:30-2:45 pm	Improving Cancer Outcomes through Connected Health	Bradford W. Hesse, PhD
2:45-3:00 pm	Q&A and Closing Discussion	

Intervening on the Financial Toxicity of Cancer Care

Friday, July 13, 2018

7a.m. – 9a.m.

Presented by Yousuf Zafar, MD, MHS

Associate Professor of Medicine and Public Policy

Duke Cancer Institute

According to the Centers for Disease Control and Prevention, one in three Americans experience financial burden as a result of medical care. The burden is greater for cancer patients, who pay more out of pocket for care than those with other chronic illnesses. Indeed, 13% of nonelderly cancer patients spend at least 20% of their income on out-of-pocket expenses. Fifty percent of Medicare beneficiaries with cancer pay at least 10% of their income towards cancer treatment-related out-of-pocket costs. In other words, half of elderly cancer patents are underinsured.

This workshop at the July NRG Oncology Semiannual Meeting in Philadelphia will focus both on long term solutions including policy changes to reduce unsustainable drug prices and promote innovative insurance models as well as more immediate solutions.

Be sure to register for this special workshop to improve understanding and engagement through increased knowledge of available resources, discussion of the value of care delivered and communication-based interventions for physician and patient interactions.

Dr. Zafar is a gastrointestinal medical oncologist and healthcare delivery researcher. He is an Associate Professor of Medicine and Public Policy at the Duke Cancer Institute and Sanford School of Public Policy. He serves as Director of the Center for Applied Cancer Health Policy at the Duke Cancer Institute. Dr. Zafar's research explores ways to improve cancer care delivery with a primary focus on improving the affordability of cancer treatment. He approaches this issue from both patient–focused and policy perspectives. He has over 80 publications in top peer–reviewed journals including the *New England Journal of Medicine*, the *Journal of Clinical Oncology,* and *JAMA Oncology*. Dr. Zafar also serves as Clinical Associate Director of Duke Forge (Health Data Science Center), and Co–Leader for Duke Cancer Institute's Healthcare Delivery Research Focus Area. His research has been funded by the National Institutes of Health and the American Cancer Society, among others. His work has been covered by national media outlets including *Forbes*, *New York Times*, *Wall Street Journal*, *NPR*, and *Washington Post*.

NRG Scientific Session
NRG Oncology Research Review

Date: **Friday, July 13, 2018**
Start and End Time: **8:00 am – 10:00 am**
Co-Chairs **Deborah W Bruner, PhD; Elizabeth M Gore, MD; Thomas B Julian, MD (Moderator); and Krishnansu S Tewari, MD**

Learning Objectives:

Following this activity, participants will be better able to:

1. Examine the effectiveness of chemotherapy (CT) after local therapy for Isolated Locoregional Recurrence (ILRR).
2. Discuss how to optimize radiation therapy techniques for localized prostate cancer to impact patient outcomes.
3. Distinguish between the use of chemotherapy with and without concurrent BEV, and with concurrent BEV followed by maintenance BEV for advanced stage ovarian carcinoma.
4. Describe 5-year results to understand how potential late events may influence the utility of Stereotactic Body Radiation Therapy (SBRT) in medically inoperable patients with clinically staged early lung cancer.
5. Explain the association between MLH1 expression and survival in patients who underwent resection of pancreatic cancer and received adjuvant chemoradiation.
6. Understand the patient-reported acute toxicity and health-related quality of life (QOL) during treatment with standard pelvic radiation or Intensity-modulated radiation therapy (IMRT) in women with cervical and endometrial cancer.
7. Educate members regarding the Quantitative Imaging Network and its role in the development, validation and application of quantitative image analysis tools for advancement of multi-institutional clinical trials.

WORKSHOP AGENDA

8:00 – 8:05 am	Welcome	Thomas B Julian, MD
8:05 – 8:15 am	Efficacy of chemotherapy for ER-negative and ER-positive isolated locoregional recurrence of breast cancer: Final analysis of the CALOR Trial.	Irene L Wapnir, MD
8:15 – 8:20 am	Discussant	Ruth O'Regan, MD
8:20 – 8:30 am	NRG Oncology RTOG 0126: A randomized phase III trial comparing standard and dose escalated radiation therapy for patients with intermediate risk prostate cancer.	Jeff Michalski, MD
8:30 – 8:35 am	Discussant	Leonard Gomella, MD
8:35 – 8:45 am	Final Overall Survival (OS) Analysis of an International Randomized Trial Evaluating Bevacizumab (BEV) in the Primary Treatment of Advanced Ovarian Cancer: A NRG Oncology/Gynecologic Oncology Group (GOG) study	Krishnansu S. Tewari, MD (R Burger 1st author)
8:45 – 8:50 am	Discussant	Kathleen Moore, MD
8:50 – 9:00 am	Long-term Results of NRG Oncology RTOG 0236: A Phase II Trial of Stereotactic Body Radiation Therapy (SBRT) in Medically Inoperable Stage I Non-Small Cell Lung Cancer.	Robert Timmerman, MD
9:00 – 9:05 am	Discussant	Clifford Robinson, MD
9:05 – 9:15 am	Expression of the DNA repair gene MLH1 correlates with survival in patients who have resected pancreatic cancer and have received adjuvant chemoradiation: NRG Oncology RTOG Study 9704.	Chandan Guha, MD (Y Lawrence 1st author)
9:15 – 9:20 am	Discussant	Terence Williams, MD
9:20 – 9:30 am	Patient-reported toxicity during pelvic IMRT: NRG Oncology-RTOG 1203	Ann H Klopp, MD
9:30 – 9:35 am	Discussant	Patricia Ganz, MD
9:35 – 9:50 am	Quantitative Imaging Network (QIN) presentation	John Buatti, MD
9:50 – 10:00 am	Q&A	

Social Media Workshop

Presented by the NRG Oncology Communications Committee

Friday, July 13, 2018
10-11:30 AM ET

NRG Oncology July 2018 Semiannual Meeting
Philadelphia Marriott Downtown

NRG ONCOLOGY

Advancing Research. Improving Lives.™

SPEAKERS

Thomas Julian, MD
Allegheny Health Network
Welcome and Introductions

Merry Jennifer Markham, MD
University of Florida Health
@DrMarkham
"Networking and Professional Development Through Social Media"

Michael Cowher, MD
Allegheny Health Network
@MikeCowher
"Pitfalls and Risks of Social Media Use"

Thomas George, MD
University of Florida Health
@TGeorgeMD
"Social Media for Patient Engagement in Clinical Trials"

Kara Smigel-Croker
National Cancer Institute
@KaraSmigel
"Social Media and the NCI"

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

#NRG18

Register for the semiannual meeting on the NRG Oncology website

Social Media Workshop Agenda

Date: Friday, July 13, 2018
Start and End Time: 10:00 am to 11:30 am (EST) (tentative)
Chair: Merry-Jennifer Markham, MD

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

1. Recognize that social media is an increasingly important communication tool for health professionals.
2. Appreciate the potential value of social media for professional development.
3. Identify potential risks and barriers to social media use in professional practice.
4. Appreciate potential methods for utilizing social media as part of clinical trial outreach and awareness.

WORKSHOP AGENDA

A.	10:00 – 10:10 – Welcome and Introduction –	Thomas Julian, MD
B.	10:10 – 10:25 – Networking and Professional Development thru Social Media	Merry-Jennifer Markham, MD
C.	10:25 – 10:40 – Pitfalls and Risks of Social Media Use	Michael Cowher, MD
D.	10:40 – 10:55 – Social Media for Patient Engagement in Clinical Trials	Thomas George, MD
E.	10:55 – 11:10 – Social Media and the NCI	Kara Smigel-Croker
F.	11:10 – 11:20 – Questions/Open Discussion	
G.	11:20 – 11:30 – Brief Demo: Twitter Basics	

Welcome to Philadelphia!

NRG Oncology Welcome Reception

Friday, July 13, 2018
6 pm - 8 pm
Salon EF (5th floor)

NRG ONCOLOGY

Advancing Research. Improving Lives.

Workshops Agendas (CME)

Breast Cancer Rare and Genetically-Linked Subcommittee Workshop

Date: **Friday, July 13, 2018**
Start and End Time: **11:30 am - 1:00 pm**
Chair: **Alexandra Thomas**

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

1. Identify and describe opportunities for trial concept development in metaplastic breast cancer
2. Identify and describe opportunities study and prevent brain metastases in breast cancer
3. Identify and describe opportunites for secondary analyses of NSABP trials and analyses in other large datasets
4. Identify and describe mechanisms by which to assess trial proposals on rare and genetically-linked breast cancers

WORKSHOP AGENDA

11:30- 11:40 Committee Updates

- Update from the Working Group
- Speakers for future meetings
- BR1703 Metaplastic Concept Update

11:40– 12:00 Trial Concept
- Prevention of brain metastases in high-risk breast cancer **Alexandra Zimmer, MD**

12:00 –12:20 *Trial Concept (Tentative)*
- *BRCA Concept* ***Simona Shaitelman, MD***

12:20- 12:30 Committee Discussion of Mechanisms to Develop Trial Concepts
- Technology/Big Data
- GOG Experience

12:30- 12:55 Secondary analyses **Karen Daily, DO and Joseph P. Costantino DrPH**
- Concepts which mine exisiting legacay or NRF data to build new knowledge on rare tumors or genetically linked tumors
- Challenges to date
- Funding sources (possibility outside NCI?)

12:55- 1:00 Committee Discussion
- Follow-up on previous discussions
- Future directions

Canadian Members Workshop

Date: **Saturday, July 14, 2018**
Start and End Time: **7:00 am – 8:00 am EST**
Chair: **Jean-Paul Bahary, MD**
Co-Chairs: **Andre Robidoux, MD; Al Covens, MD**
NRG Oncology Operations: **Kate Wiser (back-up representative – Erica Field and Judy Langer)**

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

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

WORKSHOP AGENDA

I. General
a. Overview of Workshop Agenda and Disclosures and Potential Conflict(s) of Interest

II. Status of NRG Oncology trials open to accrual – *discussion lead NRG Oncology Regulatory*
a. Accrual Update (January 2018 – June 2018)
b. Membership Status due to low accrual

III. Continuing Discussion Regarding Consent Form Reviews (Following the NCI Template) and any Other Audit-related Issues
Discussion with Mimi Passarello, MBA, Associate Director, Membership Affairs and Quality Assurance NRG Oncology Statistics and Data Management Center

IV. Optimizing accrual or identifying obstacles to accrual in Canada - Discuss best practices for optimizing accrual among Canadian sites.
Discussion lead Jean-Paul Bahary, MD, Andre Robidoux, MD Al Covens, MD
a. Disease Sites of interest
b. Review previously collected site data to support enrollment in these specific disease sites

V. New concepts and protocols

a. NRG-GY018: A Randomized Phase III Study of Paclitaxel and Carboplatin with or without Pembrolizumab (MK-3475) for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer
b. NRG-_____:
c. Canadian Review Board – *discussion lead*

Jean-Paul Bahary, MD, Andre Robidoux, MD Al Covens, MD

VI. New Business, General Questions, Discussion
a.

Discussion lead Jean-Paul Bahary, MD, Andre Robidoux, MD Al Covens, MD

VII. Evaluation

Cancer Prevention and Control Workshop

Chair: Lisa Kachnic, MD

Session I: Friday, July 13, 2018 11:00 am – 12:00 pm GOG-225 Informational Session
Session II: Friday, July 13, 2018 2:30 pm – 5:30 pm CPC Workshop
Session III: Saturday, July 14, 2018 10:00 am – 12:00 pm GOG-225 Workshop

SESSION I – GOG-0225, Information Session – *CMEs are not provided*
Friday, July 13, 2018 11:00 am – 12:00 pm

GOG-225: The Lifestyle Intervention for ovarian cancer Enhanced Survival (LIVES) Study
Presentations with a question and answer session

Cynthia Thomson, PhD, RD, CSO, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona
Tracy Crane, MS, RD, Research Specialist, Sr., LIvES Study Coordinator -Study co-chair and coordinator will be available to answer questions regarding ongoing study

SESSION II – NRG CPC Committee Workshop
Friday, July 13, 2018 2:30 pm – 5:30 pm

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

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

A. Introduction

B. Review of Open Studies:

- **GOG-0225:** Can Diet and Physical Activity Modulate Ovarian Cancer Progression Free Survival? (D. Alberts)
- **GOG-0237:** Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papillomavirus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC) (S-Y. Liao)
- **GOG 0278:** Before/after Non-radical Surgery Physical function and QOL (A. Covens)
- **NRG-CC003:** Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC (V. Gondi), *temporarily closed for analysis*
- **NRG-CC004:** Phase II Double Blind Dose Finding Trial of Bupropion vs. Placebo for Sexual Desire in Women with Breast or Gynecologic Cancer (D. Barton)

C. Review of Concepts & Protocols in Development:

- NRG-CC005: FORTE – Five or Ten Year Colonoscopy for 1-2 Non-advanced Adenomatous Polyps (R. Schoen)
- NRG-CC007CD: Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy (R. Chen)
- NRG-CC1819: A Randomized Trial of IADL-Based Dose-Adjusted Pegylated Liposomal Doxorubicin Every 28 Days with Bevacizumab 10 mg/kg Every 2 Weeks versus Standard of Care Dosing of Chemotherapy in Elderly Recurrent Ovarian Cancer Patients (D. Chase)

- NRG-CC1820: A Three-Arm Cohort Study of Salpingectomy to Reduce the Risk of High-Grade Serous Carcinoma Among Premenopausal *BRCA1* Carriers (D. Levine)
- Impact of Sentinel Lymph Node Mapping on Lymphedema and Health Related Quality of Life in Endometrial Cancer (E. Tanner)
- NRG-CC1742: Adaptive Intervention for Smoking Cessation in Women with Breast, Cervical, Endometrial and Vaginal Cancer prior to Radiation Therapy (T. Crane)
- Utility of gonadotropin-releasing Hormone Agonists (GnRHa) to Protect Ovarian Reserve for Women Undergoing Chemotherapy (H. Burks, L. Landrum, J. Walker)
- NRG-CC1836 : Evaluation of Lymphedema and QOL after Sentinel Lymph Node Biopsy Alone in Patients with Early Stage Cervical Cancer (Allan Covens)

D. Other Updates

- New Pilot Project Awardees
- C. Xiao and K. Sturgeon – Pilot project update
- A. Dicker and K. Hutchinson – pilot project update

SESSION III – CPC Training GOG-0225
Saturday, July 14, 2018 10:00 am –12:00 am GOG-225 Workshop

GOG-0225: The Lifestyle Intervention for ovarian cancer Enhanced Survival (LIVES) Study

Training Objectives:

- "Hands on" anthropometric training will be available with live models
- Overview of the study instruments and data collection time points
- Introduction to study questionnaires
- Orientation to coaching for behavior change

Presentations:

Cynthia Thomson, PhD, RD, CSO, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona
Tracy Crane, MS, RD, Research Specialist, Sr., LIvES Study Coordinator

QUESTIONS/DISCUSSION
EVALUATION

Cervix Workshop Agenda

Date: **Friday, July 13, 2018**
Start and End Time: **10:00am – 12:00 (Session I)**

Date: **Saturday, July 14, 2018**
Start and End Time: **10:00am – 11:00 (Session II)**

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

Educational Need:

To provide both a national and international forum for development and monitoring of cooperative group clinical trials in cervical and vulvar cancers, with content and format based on evaluations and discussions from prior meetings.

WORKSHOP AGENDA

Session I: **Friday July 13, 2018 (Scientific Developmental Focus) 10:00 am – 12:00 pm**

A. Introduction (10:00 – 10:10)
   a. Welcome, introduction of new members and chairs, committee membership and rotation plan and review of January 2018 minutes
B. Scientific updates (10:10 – 10:45)
   a. Upcoming Cervical Cancer Clinical Trials Planning Meeting (Ritu Salani)
   b. Cervical Cancer Task Force Update (Anuja Jhingran)
   c. CTEP Update (Charles Kunos, MD, PhD)
   d. Radiation and immunotherapy (Marka Crittenden MD, PhD)
C. Previously committee approved/reviewed concepts – current updates and future directions
   a. NRG-GY017 (PI1727): 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)
   b. NRG CV1748: Groningen International Study on Sentinel Nodes in Vulvar Cancer – GROINSS VIII – A prospective phase II trial (SLN + macroscopic). (Brian Slomovitz)
   c. NRG CC1836: Evaluation of lymphedema and QOL after sentinel lymph node biopsy only in women with early stage cervical cancer. (Al Covens)
      i. Tabled from July 2017
      ii. GOG-0244 presented at SGO 2018 – how does this inform protocol development
   d. CV1649: A randomized phase II trial of cisplatin, paclitaxel and bevacizumab vs. cisplatin, paclitaxel, bevacizumab, and anti-PD1 ligand in patients with Stage IVB recurrent or persistent carcinoma of the cervix. (Katherine Moxley, Scott Richard)
      i. Transitioned to GCIG

e. SWOG DART (Dual anti-CTLA-4 & Anti-PD-1 blockade in Rare Tumors) – Ipilimumab and Nivolumab (Gyn Champion – Lilian Gien)
f. Radical treatment of oligometastatic cervix cancer (Kim, Chino)
g. CV1807: Phase I/II trial considering efficacy of concurrent immunotherapy with weekly cisplatin and radiation then maintenance immunotherapy vs. weekly cisplatin and radiation in locally advanced cervical cancer. (Haider Mahdi)
    i. Not supported at January 2018, although committee very interested in developing immunotherapy protocols for primary disease therapy
h. Other

D. New proposed concepts
a. CV1834 Robotic versus Open Hysterectomy for Cervical Cancer (ROCC Trial): A Randomized Controlled Phase III Trial. (Kristin Bixel)
b. CV1840 Randomized Phase II Study of Stereotactic Body Radiotherapy + Anti-PD1 Antibody (Pembrolizumab) in Recurrent or Persistent Metastatic Cervical Cancer. (L Gien)
c. CV1842 A Phase II Study of Epacadostat plus Pembrolizumab in patients with recurrent cervical cancer (J Farley)
d. CV1848 A Phase II trial of tumor directed Surgery or Radiotherapy followed by Cisplatin, Paclitaxel, and Bevacizumab, with or without Pembrolizumab for women with Oligometastatic Cervical Cancer. (Junzo Chino)
e. 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)

Session II Saturday July 14, 2018 (Operational management of on-going NRG trials) 10:00 am – 11:00 am

E. Closed Studies

Protocols: 101, 120, 205, 222, 141, 173, 179, 204, 206, 204, 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 172/285 (60.4%)
b. GOG-0263: Randomized clinical trial for adjuvant chemoradiation in post-operative cervical cancer patients with intermediate risk factors (Sang Young Ryu, Wui-Jin Koh)
    i. Opened April 2010
    ii. Amended Nov 2017 to decrease accrual from 534 to 360
    iii. Accrual 279/360 (79.7%)
c. GOG-0270: Groningen International Study on Sentinel nodes in vulvar cancer (GROINSS-VII) – An observational study (Brian Slomovitz)
    i. NRG Opened January 2012; NRG target accrual 140
    ii. Amendment for treatment of SLN macro-metastatic disease
    iii. Amendment for IMRT approved July 2015 by GROINSS, NOT by CTEP
    iv. Accrual completed (NRG accrual 148)
d. GOG-0274: A phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: GOG collaboration with the OUTBACK trial (ANZGOG 0902/GOG 0274 / RTOG 1174). (Kathleen Moore)
    i. Opened January 2012; NRG target accrual 500
    ii. Expanded target accrual to 900 patients
    iii. Accrual completed May 2017
    iv. Study closed 6/1/2017 – 924/900 accrued – NRG accrual 627

e. GOG-0278: Evaluation of physical function and quality of life (QOL) before and after non-radical surgical therapy for stage IA1-IB1 (≤2cm) cervical cancer. (Al Covens)
    i. Opened October 1, 2012
    ii. PET imaging amendment approved July 2015
    iii. Accrual 161/220 (80.5%)
f. GOG-0279: A phase II trial evaluating cisplatin and gemcitabine concurrently with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva. (Neil S. Horowitz)
    i. Opened July 2, 2012
    ii. Temporarily Closed June 15,2015 after enrolling 28 in 1st stage
    iii. 2nd stage re-opened July 2016
    iv. Accrual 36/52 total (69.2%)
g. NRG-GY006: A randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, stage II, IIIB, or IVA Cancer of the uterine cervix or Stage II-IVA vaginal cancer. (Trey Leath, Loren Mell)
    i. Opened January 15, 2016
    ii. Temporarily closed June 30, 2017 for NCI to manufacturer drug
    iii. Accrual 101/188 (53.7%)

G. Reports from Other Committees and Groups
    a. Publications Subcommittee
    b. Patient Centered Outcomes Research Committee
    c. Ancillary Data Committee
    d. Cancer Prevention and Control
    e. Rare Tumor Committee
    f. Vaccine Subcommittee
    g. Pathology Committee
    h. Radiation Committee
    i. SPORE Committee
    j. Nursing
    k. Medical Oncology
    l. Patient/Community/Advocacy

H. Concluding Remarks and Wrap-up

I. Next Semi-Annual Meeting – February 7-9, 2019 Phoenix Convention Center, Phoenix, Arizona

QUESTIONS / DISCUSSION

Gastrointestinal Cancer Committee Workshop Agenda

Date:	**Saturday, July 14, 2018**
Start and End Time:	**1:00 pm – 3:00 pm**
Colorectal Chair:	**Thomas George, MD, FACP**
Colorectal Co-Chair:	**Scott Kopetz, MD, PhD**
Non-colorectal Chair:	**Christopher Crane, MD**
Non-colorectal Co-Chair:	**David Ilson, MD**

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

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

WORKSHOP AGENDA

1:00 – 1:05	Introduction and Opening Remarks	Christopher Crane, MD Thomas George, MD
1:05 – 1:15	**CRC SUBCOMMITTEE - Review of Developing Trials**	
	NRG-GI005: Use of cfDNA as a decision tool for stage II colon cancer treatment	Van Karlyle Morris, MD
1:15 – 2:00	**Active Studies**	
	N1048 (PROSPECT): Intergroup Selective Radiotherapy Elimination Trial	Harvey Mamon, MD
	NRG-GI002: TNT Trial Update	Thomas George, MD
	S0820 (PACES): Eflornithine & Sulindac for polyp prevention after CRC	Jenny Dorth, MD
	A021502 (ATOMIC): MSI-H colon adjuvant trial FOLFOX +/- Atezolizumab	Asha Dhanarajan, MD
	NRG-GI004 / S1610 (COMMIT): Metastatic MSI-H CRC Immunotherapy Study	James Lee, MD, PhD
	S1613: A Randomized Phase II Study of Pertuzumab and Trastuzumab vs Cetuximab and Irinotecan in Advanced/mCRC with HER2 Amplification	Marwan Fakih, MD
2:00 – 2:20	**NON-CRC SUBCOMMITTEE**	
	0848: A Phase III Trial Evaluation ChemoradiationAs Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma	Ross Abrams, MD
	1112: Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma	Theodore Hong, MD
	NRG GI001: Ph II/III Chemo +/- Hypofractionated XRT intrahepatic cholangioca	Theodore Hong, MD
	NRG GI003: Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma	Theodore Hong, MD
2:20 – 3:00	**Review of Developing Trials**	
	Phase II study of durvalumab and PET-guided chemo for GEJ adenocarcinoma followed by adjuvant durvalumab/ tremelimumab	Geoffrey Ku, MD
	A Randomized Phase II of Local Treatment Targeted Sensitization Wee1 vs PARPi	Chris Crane, MD
	Phase I trial of chemoradiation and telomolysin for inoperable esophageal and GEJ ACA	Geoff Ku, MD

GYNECOLOGIC CANCER WORKSHOP AGENDA

Date: **Saturday, July 14, 2018**
Start and End Time: **1-3 PM**
Chair: **Carol Aghajanian, MD**
Co-Chairs: **Paul DiSilvestro & William Small, MD**
Translational Co-Chair: **Heather Lankes, PhD**

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 2018
C. Symposia (Alvarez)
D. Report from Health Disparities Committee (Brown)
E. Report from HRC (Creasman)
F. Report from Scientific Publications Committee (Tewari)

II. Committee Descriptions

Gynecologic Cancer Committee

Cervix/Vulvar Cancer Subcommittee

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

Ovarian Cancer Subcommittee

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

Rare Tumor Subcommittee

- Clear Cell Tumors
- Germ Cell Tumors

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

Uterine Corpus Cancer Subcommittee

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

<u>GYN Developmental Therapeutics Committee</u>

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

GYN Phase I Subcommittee

- Safety lead-ins
- Phase I

<u>Other NCTN Group Trials & Study Champions</u>

S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors
-Fibromixoma and low grade mucinous adenocarcinoma (pseudomyxoma peritonei) – appendix and ovary
-Non-epithelial tumors of the ovary (germ cell tumors, mullerian mixed tumor, adenosarcoma)
-Trophoblastic tumor (choriocarcinoma)
-Adenoid cystic carcinoma
-Vulvar cancer
-Not otherwise categorized (NOC) rare tumors – after discussion with Study Chairs

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: David Gershenson, MD

III. Cervix/Vulvar Cancer Subcommittee

New Concepts

a) **CV1834** Robotic versus Open Hysterectomy for Cervical Cancer (ROCC Trial): A Randomized Controlled Phase III Trial. (Kristin Bixel)

b) **CC1836** Evaluation of Lymphedema and QOL after Sentinel Lymph Node Biopsy Alone in Patients with Early Stage Cervical Cancer (Allan Covens)

c) **CV1840** Randomized Phase II Study of Stereotactic Body Radiotherapy + Anti-PD1 Antibody (Pembrolizumab) in Recurrent or Persistent Metastatic Cervical Cancer (L Gien)

d) **CV1842** A Phase II Study of Epacadostat plus Pembrolizumab in patients with recurrent cervical cancer (J Farley)

e) **CV1848** A Phase II trial of tumor directed Surgery or Radiotherapy followed by Cisplatin, Paclitaxel, and Bevacizumab, with or without Pembrolizumab for women with Oligometastatic Cervical Cancer. (Junzo Chino)

Studies Under Development

a. **CV1748**, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III- A Prospective Phase II Treatment Trial. (NRG Oncology PI: Brian Slomovitz; Global PI: Maaike Oonk, MD, Dutch Gynaecological Oncology Group (DGOG))

Active Studies: **Accrual as of 6/18/18**

a. **GOG0263**, 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) **283/360**

b. **RTOG0724**, 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) **172/285**

c. **GOG0278**, Evaluation of Physical Function and QoL Before and After Non-Radical Surgical Therapy for Stage IA1 (LVSI+) and IA2-IB1 Cervical Cancer. (Allan L Covens) **165/200**

d. **GOG0279**, A Phase II Trial Evaluating Cisplatin and Gemcitabine Concurrent with Intensity-Modulated Radiation Therapy (IMRT) for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva. (Neil S Horowitz) **36/52**

e. **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. (Charles Leath) **117/188**

Closed Studies: 270, THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174)
Terminations:

Rare Tumor Subcommittee
Studies Under Development

a. **RT1531**, A randomized phase II trial of Temozolomide and Cisplatin versus Pembrolizumab in patients with completely resected mucosal melanoma. (GYN Chair: Danielle Vicus, GI Chair: Chris Barker, H&N Chair: Min Yao, TS Chair: Samir Khleif)

GYN Developmental Therapeutics Committee - Cervical Cancer
Studies Under Development

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

Active Studies:
Closed Studies: 9926, 9929, 265, GY002
Terminations:

Translational Science

a. **NRG GY TS012**, Glycan and Glycoprotein Biomarkers of Para aortic Lymph Node Metastases in GOG221 Specimens. (Doris Benbrook)

IV. Ovarian Cancer Subcommittee

New Concepts

Front line:

a) DT1846 A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with neoadjuvant and postsurgical chemotherapy in patients with newly-diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (D Zamarin)

b) OV1847 A randomized controlled study of the effectiveness of neoadjuvant chemotherapy (carboplatin and paclitaxel) versus chemo-immunotherapy (carboplatin, paclitaxel and oregovomab) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. (R Previs, A Secord)

c) OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (M Birrer/ K Moore)

d) OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery

with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins)

Platinum Sensitive

e) OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)

f) OV1851 **B**iomarker-directed Therapy for Platinum-Sensitive **R**ecurrent **O**varian **C**ancer (BROC protocol) (A Secord/D O'Malley)

Platinum Resistant

g) OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)

h) PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)

Rare Tumors/Other

i) 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)

J) RT1835 Ph II/III Trial of Adjuvant Combination Radiotherapy and Immunotherapy for Clear Cell Ovarian Carcinoma (CCOC) (Kosei Hasegawa)

k) RT1841 A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien)

l) RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus)

Studies Under Development

a. OV1821/OV1719, A randomized phase II trial of olaparib +tremelimumab vs platinum-based physician choice chemotherapy in platinum-sensitive recurrent ovarian cancer with and without homologous repair deficiency. (Sarah Adams)

b. OV1741, Surgery and chemotherapy vs chemotherapy alone as primary treatment of elderly women with advanced stage ovarian, fallopian tube or primary peritoneal serous carcinomas. (Amina Ahmed/Amy Bregar) - Elderly & Special Populations Working Group and Cancer Care Delivery (Health Disparities Committee)

Active Studies:

a. GY004, A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with

Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer. (Joyce Liu). *Closed to non-Japanese sites 11.10.17.*

b. **GY005**, A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS). (Jung-Min Lee). *Temporarily closed to accrual 6/16/17*

c. **GY007**, A Phase I/II Study of Ruxolitinib with Front-Line Neoadjuvant and Post-Surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer. (Robert Burger)

d. **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)

Closed Studies: 212, 213, 218, 252, 262, 273
Terminations:

<u>Rare Tumor Subcommittee</u>
<u>Studies Under Development</u>

a. GY016, Randomized phase II evaluation pembrolizumab + epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)

b. RT1753, 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/David Gershenson)

c. A Randomized Phase II Study of Pegylated Liposomal Doxorubicin (PLD) in Combination with M3814 or Placebo in Patients with Recurrent Low Grade Serous Ovarian Cancer (Rachel Grisham/Kathleen Moore)

Active Studies:

a. GOG0264, A Randomized Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide and Cisplatin for Newly Diagnosed Advanced Stage and Recurrent Chemo-Naive Sex Cord-Stromal Tumors of the Ovary. (Jubilee Brown) **50/128**

Closed Studies: 239, 241, 254, 268, 281, 283, GY001
Terminations:

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

a. **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: 9923, 170R, 186G, 186H, 186K, 255, 260, GY003
Terminations:

NCORP

a. **CC1820**, Premenopausal BRCA 1/2 Carriers – Risk Reducing Salpingectomy (Douglas Levine)
b. **CC1819**, Elderly Platinum-Resistant Ovarian Cancer Patients (Chase)

Translational Science

a. **TS1514**, ImmunoScore determination as predictive biomarkers for clinical outcome in GOG0262 population. (Samir Khleif)
b. **NRG GY TS013**, Biomarker Discovery to Direct Bevacizumab Therapy in Ovarian Cancer – Blood based Angiome Profiling in samples from women enrolled on the Gynecologic Oncology Group (GOG) 0218 trial (Angeles Secord)
c. **NRG GY TS###**, Evaluation of clear cell histologic subtypes of ovarian and uterine malignancies with anti-PD-L1 and anti-PD1 immunohistochemical staining and correlation with stage and survival. (Jill Alldredge)

V. Uterine Corpus Cancer Subcommitee

New Concepts

a.**UC1837** Phase III Trial of Adjuvant doxorubicin plus olaratumab: pivotal trial for uterine leiomyosarcoma (ADOPT-FUL) (Elizabeth Loggers)
b.**UC1843** Efficacy of first line immunotherapy with checkpoint inhibitors (CPI) vs. standard chemotherapy in patients with stage IV or recurrent endometrial carcinoma with deficient mismatch repair system: randomized phase II study. (H Mahdi)
c. UC1844 Phase II study of efficacy of second line treatment with immunotherapy comparing combined regimen (PD1/PDL1
and CTLA-4 inhibitors) vs. PD1 /PDL1 monotherapy in patients with recurrent endometrial carcinoma with deficient mismatch repair system. (H Mahdi)
d.**UC1853** EmBATTLE: **EndoMetrial Cancer and Tumor Biopsy Assigned Targeted Therapy Based on MoLecular AltErations** (B Pothuri)

Studies Under Development

a. **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. **UC1644**, A Randomized Phase II Study of Letrozole Versus Observation in Patients with Newly Diagnosed Estrogen Receptor Positive Uterine Leiomyosarcoma (Brian Slomovitz)

c. **GY018**, A randomized phase III study of paclitaxel and carboplatin with or without pembrolizumab for measurable stage III or IVA, stage IVB or recurrent endometrial cancer. (Ramez N. Eskander)
d. **UC1731**, Medroxyprogesterone and entinostat in PR+ low grade endometrioid endometrial cancer: a randomized phase II study. (Katarzyna Jerzak/Helen Mackay/Linda Duska)
e. **UC1744**, Randomized Phase II Study of Conventional versus Hypofractionated Pelvic RT for adjuvant treatment of endometrial cancer with endpoint of toxicity (Camille Gunderson/ Mark Bernard)
f. **UC1805**, Randomized phase III trial of radiation +/- checkpoint inhibitor for high intermediate risk mismatch repair deficient (dMMR) endometrioid endometrial cancer (Floor Backes, David Cohn)
g. **UC1814**, A phase II/III randomized study of carboplatin, paclitaxel, atezolizumab, and bevacizumab plus atezolizumab and bevacizumab maintenance versus carboplatin and paclitaxel as initial therapy in measurable stage III or IVA, stage IVB or recurrent endometrial cancer (Debra Richardson)
h. **UC1815**, A phase II randomized study of standard IMRT versus scanning beam proton radiation therapy for post-operative treatment of endometrial and cervical cancer (Ann Klopp, Lilie Lin)

Active Studies:

a. **GOG0238**, A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus. (Jonathan Micha Feddock) **133/210**

Closed Studies: 188, 209, 210, 249, 258, 261, 275, 277, 286B
Terminations:

<u>GYN Developmental Therapeutics Committee - Endometrial Cancer</u>
<u>New Concepts</u>

a) **DT1831**: A Phase II study of combination pegylated liposomal doxorubicin (PLD) with durvalumab in women with microsatellite stable recurrent endometrial cancer. (B Corr)
b) **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)

<u>Studies Under Development</u>

a. **DT1737**, Phase I/II study of megestrol acetate, entinostat, and SGI-110 in advanced, persistent, or recurrent endometrial carcinoma. (Carolyn McCourt)
b. **DT1806**, Gemcitabine and Wee1 Inhibitor in persistent or recurrent endometrial malignancy: a phase II study (Megan McDonald, David Bender, MD, Kimberly Leslie)

Active Studies:

a. GY008, A Phase II Evaluation of Copanlisib (BAY 80-6946), a Selective Inhibitor of PI3KCA, in Patients with Persistent or Recurrent Endometrial Carcinoma Harboring PIK3CA Hotspot Mutations. (Alessandro Santin). *Temporarily closed to accrual*

Closed Studies: 86P, 229O, GY011
Terminations:

Translational Science

a. UC1506, Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine)
b. NRG GY TS001, The Relationship of Racial Genetic Admixture and its Association with High Risk Endometrial Cancer Outcomes. (Rod Rocconi)
c. NRG GY TS###, Expression of L1CAM in serum and metastatic samples of recurrent and advanced stage endometrial cancer patients. (Thanh Dellinger)
d. NRG GY TS###, Immunoscore in Endometrial Cancer: Analysis of a cohort from GOG 210 (Debra Richardson)

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

New concepts:

1. 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)
2. UC1837 Phase III Trial of Adjuvant doxorubicin plus olaratumab: pivotal trial for uterine leiomyosarcoma (ADOPT-FUL) (Elizabeth Loggers)
3. OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
4. OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
5. UC1843: Efficacy of first line immunotherapy with checkpoint inhibitors (CPI) vs. standard chemotherapy in patients with stage IV or recurrent endometrial carcinoma with deficient mismatch repair system: randomized phase II study (H Mahdi)
6. UC1844 Phase II study of efficacy of second line treatment with immunotherapy comparing combined regimen (PD1/PDL1 and CTLA-4 inhibitors) vs. PD1 /PDL1 monotherapy in patients with recurrent endometrial carcinoma with deficient mismatch repair system. (H Mahdi)
7. PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)
8. OV1847 A randomized controlled study of the effectiveness of neoadjuvant chemotherapy (carboplatin and paclitaxel) versus chemo-immunotherapy (carboplatin, paclitaxel and

oregovomab) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. (R Previs, A Secord)

9. OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (M Birrer/ K Moore)
10. OV1851 **B**iomarker-directed Therapy for Platinum-Sensitive **R**ecurrent **O**varian **C**ancer (**BROC** protocol) (A Secord/D O'Malley)
11. OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins)
12. UC1644: Biomarker Driven Adjuvant Therapy for High-Risk Uterine Leiomyosarcoma (ALDO study) (E Loggers/B Slomovitz)

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

VIII. Translational Science Committee Report (Birrer)

New concepts:

1. 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)
2. RT1835 Ph II/III Trial of Adjuvant Combination Radiotherapy and Immunotherapy for Clear Cell Ovarian Carcinoma (CCOC) (Kosei Hasegawa)
3. UC1837 Phase III Trial of Adjuvant doxorubicin plus olaratumab: pivotal trial for uterine leiomyosarcoma (ADOPT-FUL) (Elizabeth Loggers)
4. OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
5. OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
6. CV1840 Randomized Phase II Study of Stereotactic Body Radiotherapy + Anti-PD1 Antibody (Pembrolizumab) in Recurrent or Persistent Metastatic Cervical Cancer (L Gien)
7. RT1841 A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien)
8. CV1842 A Phase II Study of Epacadostat plus Pembrolizumab in patients with recurrent cervical cancer (J Farley)

9. UC1843: Efficacy of first line immunotherapy with checkpoint inhibitors (CPI) vs. standard chemotherapy in patients with stage IV or recurrent endometrial carcinoma with deficient mismatch repair system: randomized phase II study (H Mahdi)
10. UC1844 Phase II study of efficacy of second line treatment with immunotherapy comparing combined regimen (PD1/PDL1 and CTLA-4 inhibitors) vs. PD1 /PDL1 monotherapy in patients with recurrent endometrial carcinoma with deficient mismatch repair system. (H Mahdi)
11. PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)
12. OV1847 A randomized controlled study of the effectiveness of neoadjuvant chemotherapy (carboplatin and paclitaxel) versus chemo-immunotherapy (carboplatin, paclitaxel and oregovomab) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. (R Previs, A Secord)
13. CV1848 A Phase II trial of tumor directed Surgery or Radiotherapy followed by Cisplatin, Paclitaxel, and Bevacizumab, with or without Pembrolizumab for women with Oligometastatic Cervical Cancer. (Junzo Chino)
14. RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus)
15. OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (M Birrer/ K Moore)
16. OV1851 **B**iomarker-directed Therapy for Platinum-Sensitive **R**ecurrent **O**varian **C**ancer (**BROC** protocol) (A Secord/D O'Malley)
17. OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins)
18. UC1853 EmBATTLE: **EndoMetrial Cancer and Tumor Biopsy Assigned Targeted Therapy Based on MoLecular AltErations** (B Pothuri)
19. UC1644: Biomarker Driven Adjuvant Therapy for High-Risk Uterine Leiomyosarcoma (ALDO study) (E Loggers/B Slomovitz)

Active Studies: 8015, 8016, 8020, 8025, 8031, 8034, 8039
Closed Studies:
Terminations:

IX. Cancer Prevention and Control Committee Report (Walker)

New concept:
NRG-CC1836 : Evaluation of Lymphedema and QOL after Sentinel Lymph Node Biopsy Alone in Patients with Early Stage Cervical Cancer (Allan Covens)
Active Studies: 225, 237, 278
Closed Studies: 199, 214, 244, 8199
Terminations:

QUESTIONS / DISCUSSION

GYN Developmental Therapeutics/Phase I/Translational Science Workshop

Date:	**Thursday, July 12, 2018**
Start and End Time:	**4:00 PM – 6:00 PM**
Chairs:	**Roisin O'Cearbhaill, MD (Developmental Therapeutics)** **Michael Birrer, MD, PhD (Translational Science)**
Translational Research Chair:	**Pan. Konstantinopoulos, MD, PhD (Dev. Therapeutics)**
Co-Chairs:	**Floor Backes, MD; Russell Schilder, MD** **Stephanie Gaillard, MD, PhD (Phase I)**

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

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

WORKSHOP AGENDA

Thursday, July 12, 2018
Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

4:00 PM – 4:10 PM	Introduction, Drs. O'Cearbhaill and Birrer
4:10 PM – 4:30 PM	CTEP Early Drug Development Update, Charles Kunos, MD, PhD, Medical Officer and Coordinator, Investigational Therapeutics & Radiation, Investigational Drug Branch, CTEP
4:30 PM – 4:45 PM	Novel statistical design for window, Phase I and single arm Phase II trials, Michael Sill, PhD, NRG Oncology
4:45 PM – 5:00 PM	Opportunity for window trials, Linda Duska, MD, Professor of Obstetrics and Gynecology, University of Virginia
5:00 PM – 5:30 PM	Translational research in early phase trials, Panagiotis Konstantinopoulos, MD, PhD, Director of Translational Research and attending oncologist in the Gynecologic Oncology Program at Dana-Farber Cancer Institute
5:30 PM – 6:00 PM	Review of new concepts • 5-10 minute presentation of concept (by proposing investigator) • Review of concept

New Concepts: DT/Ph I

1. **DT1831**: A Phase II study of combination pegylated liposomal doxorubicin (PLD) with durvalumab in women with microsatellite stable recurrent endometrial cancer. (B Corr)

2. **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)

3. **PI1845** Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)

4. **DT1846** A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with neoadjuvant and postsurgical chemotherapy in patients with newly-diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (D Zamarin)

GYN Developmental Therapeutics/Phase I Workshop

Date:	**Saturday, July 14, 2018**
Start and End Time:	**8:00 AM – 10:00 AM**
Chair:	**Roisin O'Cearbhaill, MD (Developmental Therapeutics)**
Translational Research Chair:	**Panagiotis Konstantinopoulos, MD, PhD (Dev. Therapeutics)**
Co-Chairs:	**Floor Backes, MD; Russell Schilder, MD** **Stephanie Gaillard, MD, PhD (Phase I)**

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

1. Participants will become familiar with the current status of phase I and phase II studies that are under development and activated for accrual.
2. Immune Therapy and Immune Modulation workshop will present an update from Thursday, July 12, 2018 (2:00 – 4:00 PM) and plan for integration and prioritization.
3. Integration and prioritization of studies will be reviewed and reference to Cervix/Vulva Cancer, Ovarian Cancer and Uterine Corpus Cancer workshops and the Translational Science workshop.
4. Recommendations for action by the GYN Cancer Committee will be summarized.

Saturday, January 27, 2018
Review of Phase I Studies (Active, Under Development, and New Concepts):
8:00 AM - 9:00 AM **Russell Schilder, MD and Stephanie Gaillard, MD, PhD**

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

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

9:00 AM – 9:15 AM **Cervical Cancer (Dmitriy Zamarin, MD, PhD)**

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

9:15 AM - 9:30 AM **Endometrial Cancer (Floor Backes, MD)**

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

9:30 AM – 9:45 AM **Ovarian Cancer (Roisin O'Cearbhaill, MD)**

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

9:45 AM – 10:00 AM **Sarcomas (Martee Hensley, MD)**

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

Head and Neck Cancer Workshop Agenda

Date:	**Saturday, July 14, 2018**
Start and End Time:	**10:00 am – 12:00 pm**
Chair:	**Quynh-Thu Le, MD**
Co-Chairs:	**Erich Sturgis, MD-MPH; Stuart Wong, MD, Andy Trotti, MD**

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

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

WORKSHOP AGENDA

10:00 – 10:10	**Report on publications and protocol closed to active accrual**	**Quynh-Thu Le, MD**
10:10 – 10:30	**Review of Active Studies**	
RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-IIIR)	**Cristina Rodriguez, MD**
RTOG 1216	RT-cisplatin vs. RT-Docetaxel vs. RT-Docetaxel + Cetuximab for "high risk" resected HNSCC (Phase IIR-III)	**David Rosenthal, MD**
NRG HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III)	**Nancy Lee, MD**
NRG HN003	Phase I of Adjuvant Chemoradiotherapy +/- Pembrolizumab in High Risk, HPV(-) HNSCC	**Julie Bauman, MD, MPH**
RTOG 3504	Phase I/IIIR of CRT +/- Nivolumab in intermediate/high risk HNSCC	**Maura Gillison, MD, PhD**
NRG HN004	Phase IIR RT+ Cetuximab vs. RT + PD-L1 antibody in patients who cannot tolerate cisplatin with locally advanced HNSCC	**Loren Mell, MD**
NRG 1707/ NRG HN005	Phase II-IIIR of reduced field RT +/- systemic therapy for good risk HPV(+) cancer	**Sue Yom, MD**
10:30-10:40	**Review of recently completed study**	
NRG HN002	Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good-Prognosis Advanced-Stage Oropharyngeal Cancer	**Sue Yom, MD**

RTOG 0912	Concurrent radiation + chemotherapy + pazopanib for Anaplastic Thyroid Cancer (Phase II-R)	**Eric Sherman, MD**
RTOG 3501	Phase II R study of CRT +/- Lapatinib in high risk HNSCC	**Stuart Wong, MD** RTOG
0920	IMRT/IGRT + cetuximab for "intermediate risk" resected HNSCC (Phase III)	**Mitchell Machtay, MD**

10:40 – 11:30 Review of developing studies and ECOG studies

RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	**Stuart Wong, MD**
NRG 1706	Clinically N0 Oral cavity cancer: ND vs. sentinel node biopsy	**Stephen Lai, MD,PhD**
NRG 1801	Phase II-IIIR of M3814 (DNA-PK inhibitor) + Avelumab vs. cisplatin + Avelumab vs. Cisplatin alone in stage 3-4 local-regionally advanced HPV-negative HNSCC	**Maura Gillison, MD, PhD/ Michael Samuels**
NRG ?	Phase III trial of cisplatin/gemcitabine chemo +/- anti PD1/PDL1 for first line recurrent/metastatic NPC	**Quynh Le (**Brigette Ma, MD/ Zhang Li, MD)
ECOG trials	E3132 PORT +/- Cisplatin in intermediate risk pts with disruptive P53 mutation E3163 Sinonasal carcinoma	**Christine Chung, MD, PhD Nabil Saba, MD**

11:30 – 11:50 Presentations & Updates

Translational Research Program update	**Neil Hayes, MD, MPH**
HNSC update	**Maura Gillison**

11:50 – 12:00 New Business

NCI-QIN Program and imaging tools	**Mitchell Machtay, MD**

Health Disparities Committee Workshop Agenda

Date: **Friday, July 13, 2018**
Start and End Time: **7:00 am – 9:00 am**
Chair: **Kathie-Ann Joseph, MD, MPH**

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

1. Understand the relationship between financial toxicity and patient well-being, health-related quality of life and its harm on the quality of cancer care.
2. Recognize the need for physicians to seek knowledge on the value of cancer care delivered.
3. Initiating the conversation earlier in the course of patients' treatment.
4. Utilize communication-based interventions to promote discussions about out-of-pocket costs between patients and physicians.
5. Improve patients' conceptual knowledge of health and finance (health literacy).

WORKSHOP AGENDA

Session I

A. **Intervening on the Financial Toxicity of Cancer Care**

According to the Centers for Disease Control and Prevention, one in three Americans experience financial burden as a result of medical care. The burden is greater for cancer patients, who pay more out of pocket for care than those with other chronic illnesses. Indeed, 13% of nonelderly cancer patients spend at least 20% of their income on out-of-pocket expenses. Fifty percent of Medicare beneficiaries with cancer pay at least 10% of their income towards cancer treatment-related out-of-pocket costs. In other words, half of elderly cancer patents are underinsured.
This workshop will focus both on long term solutions including policy changes to reduce unsustainable drug prices and promote innovative insurance models as well as more immediate solutions. Looking to the oncologist and patient, the discussion will focus on the value of care delivered, encouragement of patient engagement in the topic of costs, as well as the financial resources available to patients.

Introduction	**Kathie-Ann Joseph, MD, MPH**
Lecture	**Yousuf Zafar, MD, MHS** Associate Professor of Medicine and Public Policy Duke University School of Medicine and Sanford School of Public Policy
Q&A-moderated by	**Kathie -Ann Joseph, MD, MPH**
Post Assessment	

International Members Workshop

Date: **Friday, July 13, 2018**
Start and End Time: **10:00 am – 11:00 am EST**
Chairs: **Ben Corn, MD; Stephan Bodis, MD**
NRG Operations: **Erica Field**

Learning Objectives:

Following this activity, participants will be better able to:

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

I. General

a. Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest
b. News from NRG leadership for intl. members

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

III. Optimizing accrual - Discuss best practices for optimizing accrual among International sites – *Ben Corn and Stephan Bodis*
a. Disease Sites of interest
b. RT only protocols (overview)
c. Study protocols with RT and systemic chemotherapy, targeted, immunotherapy: involvement of pharmaceutical sponsor upfront early during protocol development if trial opened for international members

IV. New concepts and protocols
a. Development of International concept/proposal – *Ben Corn*

V. New Business, General Questions, Discussion - *discussion lead Ben Corn, MD; Stephan Bodis, MD*
a. Goals and milestones
b. Input from international members

VI. Evaluation

Local Regional Breast Cancer Subcommittee

Date: Friday, July 13, 2018
Start and End Time: 7:00 am – 8:00 am
Chair: Thomas Julian, M.D.
Co-Chair: Doug Arthur, M.D.

Learning Objectives:

Following this activity, participant will be better able to:

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

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

Workshop Agenda:

7:00 – 7:05	Welcome/Introduction Presentation of Alliance Locoregional trial	Thomas Julian, M.D & Doug Arthur, M.D.
7:05 – 7:20	NRG 1014 re-treatment Follow-up study	Atif Kahn, MD
7:20– 7:35	Pre-OP RT Update of institutional experience	Simona Shaitelman, MD & Janet Horton, MD Elizabeth Nichols, MD
7:35 –8:00	Call for new ideas	Lead by Thomas Julian, M.D & Doug Arthur, M.D.

Medical Oncology Workshop Agenda

Date: **Saturday, July 14, 2018**
Start and End Time: **7:00 am - 8:00 am**
Chairs: **Corey Langer, MD; Deborah Armstrong, MD**

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

1. **Address clinical trial guidelines to use of nutritional supplements**
2. **Discuss the focus of current cooperative group Phase I clinical trials**
3. **Update clinical trial outcomes in major disease entities from ASCO 2018**
4. **Provide updates on NRG clinical trial developments**

WORKSHOP AGENDA

I.	Introductions	**Corey Langer, MD**
II.	Pharmacy Subcommittee A. Nutritional Supplement Use Guidelines B. Survey on differences in dosing/regimens in clinical practice: C. Update on Protocol Drug Information Database/Forms	**Judith Smith Pharm MD**
III.	Phase I Subcommittee Review	**Russell Schilder**
IV.	Critical post-ASCO updates	**Corey Langer, MD; Deborah Armstrong, MD**
V.	Other business	**Corey Langer, MD; Deborah Armstrong, MD**

QUESTIONS / DISCUSSION

NRG Protocol Workshop: NRG-BR003, NRG-BR004 and NSABP B-55

Date: **Friday, July 13, 2018**
Start and End Time: **10:00 am – 11:00 am**

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

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

WORKSHOP AGENDA

10:00-10:25 Overview of NRG-BR004 **Priya Rastogi, MD**
A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer

10:25-10:35 Overview of NRG-BR003 **Kristen Kotsko, RN, BSN**
A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel With or Without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Breast Cancer

10:35-10:40 Clinical Logistics **Kristen Kotsko RN, BSN**

10:40-10:50 Overview of NSABP B-55/BIG 6-13 Lynne Suhayda, RN, MSEd.
A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multicenter Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy

10:50-10:55 Questions/Discussion

10:55-11:00 Evaluation

NRG Oncology Protocol NRG-BR005 Workshop

Date: Saturday, July 14, 2018
Start and End Time: 8:00 am- 9:00 am

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

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

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

WORKSHOP AGENDA

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

NRG Oncology Protocol GI004 and Protocol GI002 Workshop

Date: **Friday, July 13, 2018**
Start and End Time: **11:30 am – 1:00 pm**

Presenters:
Thomas George, MD, FACP
James J. Lee, MD, PhD
Mary Pat Matisko, RN, BSN
Lynne Suhayda, RN, BSN, MSEd

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

1. Discuss the study design and key inclusion criteria of the clinical trials.
2. Discuss common eligibility and treatment questions.

WORKSHOP AGENDA

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

and

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

11:30 am - 12:00 pm	Overview of GI004	James Lee, MD, PhD
12:00 pm - 12:10 pm	Clinical Logistics	Mary Pat Matisko, RN, BSN
12:10 pm - 12:20 pm	Questions & Answers	James Lee, MD, PhD Mary Pat Matisko, RN, BSN
12:20 pm - 12:40 pm	Overview of GI002	Thomas George, MD
12:40 pm - 12:50 pm	Frequently Asked Questions	Lynne Suhayda RN, BSN, MSEd
12:50 pm - 1:00 pm	Questions & Answers	Thomas George, MD Lynne Suhayda, RN, BSN, MSEd

Questions/Discussion

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

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

Date: **Friday, July 13, 2018**
Start and End Time: **11:30am – 1:00pm EST**

Learning Objectives:

Following this activity, participants will be better able to:

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

Agenda

Welcome and Introductions – ***Erica Field, NRG Oncology***

Background to Non-Small Cell Lung Cancer Trials – ***Jeff Bradley, MD, NRG Oncology Lung Cancer Committee Chair***

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

Blood Assay and Tissue Analysis – ***Jennifer Webster, Foundation of Medicine***

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

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

AE/SAE Reporting – ***Sara McCartney, SAE Administrator, NRG Oncology***

Question and Answer Session

Ovarian Workshop Agenda

Date:	**Friday, July 13, 2018**	**Saturday, July 14, 2018**
Start and End Time:	**8:00 am - 10:00 am**	**10:00 am - 11:00 am**
Chair:	**Kathleen Moore, MD**	**Kathleen Moore, MD**
Co-Chair:	**Robert Burger, MD**	**Robert Burger, MD**

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

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

WORKSHOP AGENDA

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

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

B. Summary of Key Discussion Items (from this Agenda)
- Update regarding international studies from GCIG June 2018 (Kathleen Moore)
- Update on approved trials for low grade serous ovarian cancer RT1713 to evaluate an aromatase inhibitor in front line LGSC (Amanda Nickles-Fader) and new PTMA trial of M3814 + PLD in recurrent LGSOC (Rachel Grisham)
- Commentary on SCORPION and JCOG 0602 and GOG 218 data from ASCO 2018: how does this impact front line study design in terms of surgery/mandatory bevacizumab? ((Mario Leitao/Tom Herzog)
- Commentary on designs of platinum sensitive recurrent trials in the era of approved PARPi and bevacizumab – discussion of OV1821 (Sarah Adams) and discussion of GOG 213/OVAR Desktop (Rob Coleman)
- Discussion of protocol violations on GY004 (Joyce Liu)
- Discussion of development of trials for older/vulnerable ovarian cancer patients (CC1720 Elderly Platinum-Resistant Ovarian Cancer Patients (Dana Chase)) and OV1741, a randomized evaluation of interval cytoreductive surgery in elderly patients receiving neoadjuvant chemotherapy, in collaboration with the Elderly Working Group (Amina Ahmed, Amy Bregar, Helen Huang, et al.)
- Discussion of EAE161: Perfusion CT to predict progression free survival and response rate in bevacizumab and paclitaxel treatment of platinum resistant, persistent or recurrent epithelial ovarian cancer (Russ Schilder).

C. Review of Closed Studies (non-terminated)
- GOG0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Larry J Copeland)
- GOG0213 A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive,

recurrent ovarian, peritoneal primary and fallopian tube cancer (Robert Coleman). Accrual to surgical component completed and study closed JUN2017, awaiting events for primary analysis

- GOG0218 A Phase III trial of carboplatin and paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent bevacizumab (NSC #704865, IND #7921) followed by placebo, versus carboplatin and paclitaxel plus concurrent and extended bevacizumab, in women with newly diagnosed, previously untreated, stage III and IV epithelial ovarian, primary peritoneal or fallopian tube cancer (Robert A Burger).
- GOG0252 Phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma (Joan L Walker) Awaiting publication
- GOG0262 A randomized phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III or IV epithelial ovarian, peritoneal or fallopian tube cancer (John K Chan)
- GOG0273 Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen) Modified dose dense cohort not yet presented/published.
- GOG3001 A phase 3 randomized, double-blind, placebo-controlled, multi-center study of AMG 386 with paclitaxel and carboplatin as first-line treatment of subjects with FIGO stage III-IV epithelial ovarian, primary peritoneal or fallopian tube cancers (Amgen TRINOVA-3 NCT01493505) (Bradley J Monk)
- GOG3004 (SOLO1) A phase III, randomised, double blind, placebo controlled, multicentre study of olaparib maintenance monotherapy in patients with BRCA mutated advanced (FIGO stage III-IV) ovarian cancer following first line platinum based chemotherapy. (Paul A DiSilvestro and Kathleen Moore). Anticipate primary analysis 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).
- NRG-GY003 Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (Bob Burger)
    - Activated 29JUN2015, 49 patients on first stage, temporary closure 07OCT2015
    - Re-activated 22MAY2017, 51 accrued on second stage (total = 100), closed 28AUG2017
- 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
    - Reminder to sites regarding completion of scheduled QOL assessments

D. Review of Active Studies

- GOG0264 RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Carol Brown)
    - Activated 08FEB2010
- GOG0281 RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson)
    - Activated 27FEB2014, closed to US sites 01MAY2017 with 178 enrolled, ongoing accrual in UK (slow), amendment approved to re-open for 20 additional patients at US sites
- NRG-GY005: A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Jung-Min Lee and Angeles Alvarez Secord)
    - Suspended 17JUN2017 (n = 213) for analysis of randomized phase II component (estimated mid-2018)
    - Reminder to sites regarding completion of scheduled QOL assessments
- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer. Activated for Phase I accrual. (Robert A Burger)
    - Tentative dose established for randomized phase II, pending reactivation as of 6/2018

- NRG-GY009 A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab *vs* Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab *vs* Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Roisin O'Cearbhaill, Carol Aghajanian).
    - Activated in Phase I Working Group for initial safety lead-in 12MAY2017 (9 patients)
    - Second-stage safety lead-in (all three arms) opened 14NOV2017
    - Group-wide activation 6/18/2018
- AGCT1531 (RT1205) Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, Al Covens NRG)
    - Activated group-wide 30MAY2017

E. Review of Approved Concepts under Development

- NRG-GY014 (DT1718) A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. Protocol consensus review in progress. (Ramez Eskander and David Hyman)
    - Approved PDC 2/17 RSC 2/17. CPAC 3/6/17. CRDL LOI submitted 3/15/17. Review call 4/27/17 was positive with responses provided by Study Team. Revised LOI submitted 05/02/2017. LOI provisionally approved 5/30 and sent by CTEP to Epizyme for review and approval to supply Tazemetostat. LOI fully approved, protocol docs sent to team. Eskander circulated first draft 8/8/17 BRC consensus review rec'd 8/14/17. Protocol to CTEP 9/22/17. PRC review on 10/19/17. CR received 11/7/17. OEWG conference call on 11/15 to review Major Issues on CR.
    - Consensus Review response to CTEP 11/30/17. Possible Canadian participation. 3/14/18: CIRB Approved and CTEP Approval-on-Hold (awaiting IND approval, 30-days since submission is 5/10/18). Submitted Pre-activation amendment 4/19/18.
- NRG-GY015 (OVM1629) A randomized phase II study of metformin combined with and maintained following front-line neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Diane Yamada and U Chicago SPORE). Submitted to CTEP 2/02/18. Disapproved 3/02/18
- NRG-GY016 (RT1627) Randomized phase II evaluation pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. LOI approved 02OCT02017, preparing protocol for submission (n = 58) (L Gien and Robert Coleman)
- OVM1505 Randomized Phase II study of paclitaxel/carboplatin +/- OMP-54F28 (a receptor decoy of Wnt ligands) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer receiving front-line neoadjuvant chemotherapy (Kathleen N Moore). Company discontinued development of ipifracept.
- NRG-GY019 (RT1753) A Phase III Randomized Three Arm trial of paclitaxel/carboplatin compared to paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV primary low-grade serous carcinoma of the ovary or peritoneum. (Amanda Nickles-Fader). GCSC review 21SEP2017, anticipate revision of study design using 2 arms. International interest from GCIG (AGO, AGO-Austria, GINECO, MRC-UK, NSGO) GCSC approved 5/7/2018
- TS1514 Immunoscore determination as predictive biomarkers for clinical outcomes in GOG-0262. Awaiting amendment of data sharing plan (Samir Khleif).
- CC1819 Elderly Platinum-Resistant Ovarian Cancer Patients (Dana Chase). Not approved by NCI, undergoing revision in collaboration with DCPC and Elderly Working Group. Redesigned as randomized trial with physician's determined dosing of PLD as control arm. Approved Jan '18 NCORP. Preparing for DCP submission
- OV1821 Randomized Phase II Trial of olaparib + tremelimumab *vs* platinum based physicians' choice chemotherapy in platinum sensitive recurrent ovarian cancer/HRD+ and HRD- (n = 420). (Sarah Adams). Resubmitted for GCSC review May 2018
- OV1741 Randomized evaluation of interval cytoreductive surgery in elderly patients receiving neoadjuvant chemotherapy. Coordinated development with Elderly Working Group, plan for initial OTF GCSC submission after JAN2018 (Amina Ahmed, Amy Breggar, Helen Huang, et al.)
- NC1427 (CPC1206) Risk reducing salpingectomy in premenopausal BRCA1/2 carriers (Doug Levine). To be submitted for NCORP review

F. Review of New Concepts and Future Request for Proposals

Front line:

- DT1846 A randomized phase II study with safety lead-in of nivolumab and nivolumab with ipilimumab in combination with neoadjuvant and postsurgical chemotherapy in patients with newly-diagnosed advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer. (D Zamarin)
- OV1847 A randomized controlled study of the effectiveness of neoadjuvant chemotherapy (carboplatin and paclitaxel) versus chemo-immunotherapy (carboplatin, paclitaxel and oregovomab) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. (R Previs, A Secord)
- OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (M Birrer/ K Moore)
- OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins)

Platinum Sensitive

- OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
- OV1851 **B**iomarker-directed Therapy for Platinum-Sensitive **R**ecurrent **O**varian **C**ancer (BROC protocol) (A Secord/D O'Malley)

Platinum Resistant

- OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
- PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)

Rare Tumors/Other

- 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)
- RT1835 Ph II/III Trial of Adjuvant Combination Radiotherapy and Immunotherapy for Clear Cell Ovarian Carcinoma (CCOC) (Kosei Hasegawa)
- RT1841 A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien)
- RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus)

QUESTIONS / DISCUSSION

Pathology Committee Workshop Agenda

Date:	**Friday, July 13, 2018**
Start and End Time:	**8:00 am -12:00 pm**
Chair:	**William H Rodgers, MD, PhD**
Co-Chair:	**Jeff Simko, MD, PhD**

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

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

WORKSHOP AGENDA

Session I

A. Discussion Topic - Current priorities of the Committee; Background, status, and significance of pathology eligibility for active and future protocols
B. Discussion Topic – Future organization, membership and role of Pathology Committee
C. Reports:
   - NRG Biorepositories
   - Gynecologic Cancer Intergroup (GCIG) Pathology Liaison Group (Joint GCIG ISGYP meeting 3/2018)
D. Orientation for new members

QUESTIONS / DISCUSSION
LUNCH: 12:00-1:00

ATTACH List of Concepts – see disease organ site committee agendas

Patient Centered Outcomes Research (PCOR) Workshop

Date: **Thursday, July 12, 2018**
Start and End Time: **4:00 pm – 6:00 pm**
Co-Chairs: **Patricia Ganz, MD; Benjamin Movsas, MD; Lari Wenzel, PhD**

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

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

WORKSHOP AGENDA

4:00 –4:25	**II. PCOR Compliance Update** Comments/Audience Q & A	Ron Chen, MD
4:25 –5:30	**I. Concepts in Development** **BR1745:** A Randomized, Phase III Clinical Trial to Compare Axillary Local Treatment Compared to No Axillary Local Treatment in Patients with HER2-Negative, ER-Positive and/or PgR-Positive Clinically Node-Negative Invasive Breast Cancer **GU1826:** Randomized Trial of Molecular Imaging vs No Molecular Imaging in High-Risk and Unfavorable-Intermediate Risk Prostate Cancer **HN1801:** Randomized, 3-arm, Phase 2 Trial of DNA-PK Inhibition or Cisplatin with PD-L1 Checkpoint Blockade vs. Cisplatin and IMRT in Stage 3-4 Local-Regionally Advanced HPV-Negative HNSCC **NC1744 (0249r):** Randomized Phase II Conventional vs Hypofractionated Pelvic Radiation Therapy for Adjuvant Treatment of Endometrial Carcinoma with Toxicity as Endpoint **OV1821 (1719):** A Randomized Phase II Trial of Olaparib + Tremelimumab vs Platinum-Based Physician Choice Chemotherapy in HRD+ and HRD - Platinum Sensitive Recurrent Ovarian Cancer **OV1741:** Assessing the Role of Minimally Invasive Surgery in Patients Undergoing Neo-Adjuvant Chemo for Ovarian Cancer **II. Protocols in Development** **BR004:** A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2-Positive Metastatic Breast Cancer **GI006:** Phase III Randomized Trial of Proton Beam Therapy (PBT) Versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer **GY018:** A Randomized Phase III Study of Paclitaxel and Carboplatin with or without Pembrolizumab (MK-3475, NSC #776864) for Measurable Stage III or IVa, Stage IVb or Recurrent Endometrial Cancer **HN004:** Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Stage III-IVB Head and Neck Cancer with a Contraindication to Cisplatin	Patricia Ganz, MD Ben Movsas, MD Lari Wenzel, PhD

	LU005: Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab	
5:30 –5:45	**III. NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates**	Patricia Ganz, MD Ben Movsas, MD Lari Wenzel, PhD
5:45 –6:00	**IV. Other Business**	Patricia Ganz, MD Ben Movsas, MD Lari Wenzel, PhD

Activated Studies with PCOR/CER Endpoints

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

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

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

NRG-CC001: Phase III Trial of Memantine and Whole-Brain Radiotherapy with or without Hippocampal Avoidance for Patients with Brain Metastases (activated 7/15)

NRG-CC002: Pre-operative assessment and post-operative outcomes of elderly women with gynecologic cancers (activated 2/15)

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

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

NRG-GI004: Colorectal Cancer Metastatic dMMR Immuno-Therapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/Bevacizumab Combination Chemotherapy with or without Atezolizumab or Atezolizumab Monotherapy in the First-Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer (activated 11/17)

NRG-GU003: A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) versus Conventional Post-Prostatectomy Radiation Therapy (COPORT) (activated 7/17)

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

NRG-GY004: A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (activated 2/16)

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

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

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

NRG-HN002: A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer (activated 10/14)

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

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

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

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

New Concepts from GYN for review

1. 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)
2. UC1837 Phase III Trial of Adjuvant doxorubicin plus olaratumab: pivotal trial for uterine leiomyosarcoma (ADOPT-FUL) (Elizabeth Loggers)
3. OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
4. OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
5. UC1843: Efficacy of first line immunotherapy with checkpoint inhibitors (CPI) vs. standard chemotherapy in patients with stage IV or recurrent endometrial carcinoma with deficient mismatch repair system: randomized phase II study (H Mahdi)
6. UC1844 Phase II study of efficacy of second line treatment with immunotherapy comparing combined regimen (PD1/PDL1 and CTLA-4 inhibitors) vs. PD1 /PDL1 monotherapy in patients with recurrent endometrial carcinoma with deficient mismatch repair system. (H Mahdi)
7. PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)
8. OV1847 A randomized controlled study of the effectiveness of neoadjuvant chemotherapy (carboplatin and paclitaxel) versus chemo-immunotherapy (carboplatin, paclitaxel and oregovomab) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. (R Previs, A Secord)
9. OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (M Birrer/ K Moore)
10. OV1851 **B**iomarker-directed Therapy for Platinum-Sensitive **R**ecurrent **O**varian **C**ancer (**BROC** protocol) (A Secord/D O'Malley)
11. OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins)
12. UC1644: Biomarker Driven Adjuvant Therapy for High-Risk Uterine Leiomyosarcoma (ALDO study) (E Loggers/B Slomovitz)

Pharmacy Subcommittee Workshop

Date:	**Friday, July 13, 2018**
Start and End Time:	**12:00 pm – 1:00 pm**
Chair:	**Judith Smith, Pharm.D.**

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

1. **Describe the common adverse effects associated with immunotherapy.**
2. **Compare and contrast the monitoring, prevention and treatment of immunotherapy adverse effects.**
3. **Understand the rationale and benefits of standardizing drug information for research protocols.**
4. **Explain the primary aspects for standardizing patient variables for dosing carboplatin.**
5. **Discuss acceptable nutritional supplements use in cancer research patients.**

WORKSHOP AGENDA

I. Introduction **(2 min)**
   a. Committee purpose and goals

II. CE Presentation: ""*Treatment Guidelines for Immunotherapy-related Adverse Effects*" **(30 min)**
   –presented by Patrick Medina, Pharm.D., BCOP,

III. Update on Protocol Review Process for Pharmacy Subcommittee **(3 min)**

IV. Protocol Drug Information Update **(15 min)**
   a. To be reviewed/approved at this meeting:
      - Liposomal doxorubicin
      - Etoposide
      - Oxalitplatin
      - Paclitaxel Albumin Bound (Abraxane)
      - Temozolomide
      - Topotecan
      - Ado-Trastuzumab
      - Cetuximab
      - Carboplatin
      - Ramucirumab
      - Trastuzumab
   b. Approval of standardized language/position on use of herbal/nutritional supplements

V. Carboplatin Position Paper Update **(5 min)**

VI. Updates/Discussion of any Pharmacy Related Issues Identified in Other NRG Committee Meetings **(5 min)**
   a. Any issues that the Pharmacy Subcommittee should follow up on regarding new protocol proposals presented at the other committee meetings.

VII. Evaluation[i]

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

Date:	**Thursday, July 12, 2018**
Start and End Time:	**8:00 am – 12:00 pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Program Facilitator:	**Sally Brown RN, BSN, MGA, Melinda Weiblen, BS**

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

1. Discuss the purpose of DQP
2. Describe the difference between histology and cytology
3. List two changes to the AJCC Staging System

AGENDA

Time	**Topic**	**Speakers**
8:00am-8:10am	Introduction	Sally Brown, RN, BSN, MGA,
8:10am- 8:20am	Introduction	Kati Stoermer MSBA
8:20am- 8:35am	Update from SDMC. Lost to Follow up	Roseann Bonanni, CTR, CCRP
8:35am – 9:05am	CTSU – In's and Out's of DQP	Ginger Riley
9:050am-9:35am	CTCAE – version 5 versus version 4	Sara McCartney, RN, MS
9:35 am-10:10 am	Pathology 101	Jeff Simko PhD, MD
10:10am-10:25am	Break	
10:25 am-11:00am	Genomic Profiling 101	Terrence Cesscon M.D.
11:00am-11:35am	Changes in the staging manual	Diana B Lin, RN, MPH

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee CTN/CRA Workshop – Educational Session (LUNCH provided)

Date:	**Thursday, July 12, 2018**
Start and End Time:	**12:00 pm – 1:00 pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Program Facilitator:	**Sally Brown RN, BSN, Melinda Weiblen, BS**

Learning Objectives

Following this activity, participants will be better able to:

1. Describe the basic concept of Reiki therapy
2. Define Chakras

AGENDA

Time	Topic	Speakers
12:00-12:05	Welcome and Introduction	**Sally Brown**
12:05-12:50	An Introduction to Reiki and More	**Judith M. Fannelli, BA, RN, CCRP**
12:50-1:00	QUESTIONS/DISCUSSION EVALUATION	

Protocol Support Committee Workshop
CTN/CRA Educational Session- Roundtables

Date:	**Thursday, July 12, 2018**
Start and End Time:	**1:30 pm – 4:30 pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Program Facilitator:	**Melinda Weiblen, BS, Sally Brown RN, BSN**

Learning Objectives

Following this activity, participants will be better able to:

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

AGENDA

Topic	Speakers
Brain Protocols	Liz Wise CCRC, Sylvia Solokov MS, RN, Denise Manfredi BS, RT (T)
Breast (BR001/BR002)	Debora Grant RN, MSN, Susan McNulty CMD, BS (R)(T),
GI Non Colorectal Protocols	Debora Grant RN, MSN, Susan McNulty CMD, BS (R)(T), Wendy Bergantz,RN
Breast Topics (BR005/BR003)	Lynn Suhayda RN, MSEd, Kristen Kotsko,RN, BSN
GI (GI002/GI004)	Martha Duncan RN, MSN, Mary Pat Matisko RN, BSN
GU Protocols	Elaine Motyka-Welsh, RN, MSN, CCRP, Margaret Kennish AS, CCRC, Joanne Hunter, BS, RT (R) (T)
Head & Neck Protocols	Janelle Robinson, BA, CCRP, Vanita Patel, MS, Nancy LInnemann BS, RT (R) (T)
Lung Protocols	Jeffrey Serrianni BS, Amy Krystkiewicz, RN, Jennifer Presley, RT (R) (M) (T)
NCOR & QOL	Roseann Bonanni, CTR, CCRP, George Ballinger RT (R) (T), Tiffany Small RN
Neurocognitive Testing	Catherine Sullaway
Gyn Protocols- Ovarian	Chrisann Winslow RN, MSN
Gyn Protocols – Cervix, Uterine Corpus	Izabela Frak, Mphil, Dolly Kirschner, MPH, BS, BA Lisa Barry, MAEd, BS
NRG Oncology Membership/Payments	Mimi Passarello, MBA, Julie Kardell, Rebecca Dymond
NRG Oncology Audit	Mimi Passarello, MBA, Tamara McLaughlin MHA, MPH, Jerry Koss RN, BSN Carole Donnelly, Linda Gilarski
NRG Oncology Biospecimen Bank	Sandy DeVries MA, Melanie Finnigan BS, Lisa Beaverson BA, CCRP Heather Lankes PhD, MPH, Lisa DeNero

CTCAE Version 5 AE'SAE reporting	Sara McCartney, MS, RN
CTSU-Data Quality, DTL, Central monitoring and source documents, Website updates, IROC integration	Ginger Riley
McKesson	Erica Field, MPH, MHA, CCRP
IROC RT	Denise Manfredi, BS, RT (T), Jessica Lowenstein, MS, DABR
IROC DI	Christine Davis, Leslie Sears
PMB	Donna Shriner, RPH, Pharm D, Tali Johnson, Pharm D, BCOP
Best Practices for study implementation and management	Cynthia Licavole RN, BSN, MA, HeeSun Kim-Suh RN, BSN, OCN Tiffany Elsea, Mallory Matuszek
PSC/CTN/CRA	Nancy Knudsen RN, BSN, Susan Nolte CRNP, PhD, Terry Thomas MS, CCRC
NRG/RTOG Legacy data submission	Nick Barror, Charleen Davis, Laura Hall

QUESTIONS/DISCUSSION
EVALUATION

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

Date:	**Thursday, July 12, 2018**
Start and End Time:	**4:30 pm – 6:00 pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitator	**Sally Brown RN, BSN, MGA, Melinda Weiblen, BS**

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

1. Discuss alternative methods of education
2. Provide the PSC with potential topics and speakers for 2018 meetings

WORKSHOP AGENDA

1. Welcome
2. Announcements of open positions
3. Discuss concepts for alternative methods of education
    a. Form sub-group
4. Discuss plans for winter 2018 meeting
    a. Sub working group
5. Suggestions for summer 2018 meeting
    a. Sub working group

QUESTIONS/DISCUSSION/EVALUATION

Protocol Support Committee Workshop
Mentorship Working Group (CLOSED)

Date:	**Thursday, July 12, 2018**
Start and End Time:	**4:30 pm – 6:00 pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitator	**Nancy Fusco RN, BSN**
Working Group Co-Facilitator	**Sue Eaton CCRP**

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

1. Identify potential new topics for the Mentorship Welcome Packet
2. Discuss plans to develop the Mentor Program

WORKSHOP AGENDA:

1. Roll call of Mentorship Working Group members
2. Update from Quality Control Working Group Liaison
3. Announcements
4. Approval of minutes from most recent conference calls
5. Review committee member number of participants
6. Review current projects for the working group:
    a. Introductory Materials For NRG Oncology Clinical Trials Coordinators:
        i. Discuss new topics to include
        ii. Quality Assurance and Audit Team & Quality Control Working Group: recommendation of materials for institutions in need
    b. Develop Mentor Program:
        i. Review temporary mentor plan and effectiveness
        ii. Development of Mentorship Program tools
        iii. Review Mentor applications if received
7. Meeting Plan: Conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

QUESTIONS/DISCUSSION/EVALUATION

Protocol Support Committee Workshop
Protocol Review Working Group (CLOSED)

Date:	**Thursday, July 12, 2018**
Start and End Time:	**4:30pm – 6:00pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitator	**Terry Thomas MS, CCRC**
Working Group Co-Facilitator	**Nancy Knudsen RN, BSN**

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

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

WORKSHOP AGENDA

1. Review current Protocol review process
2. Update from the Protocol Development team. Any upcoming studies – it has been a slow few months?
3. CIRB update if member can attend
4. Replacement members – review current roster, introduce new members
5. Update from Quality Control representative
6. Other business

QUESTIONS/DISCUSSION**/**EVALUATION

Protocol Support Committee Workshop
Quality Control Working Group (CLOSED)

Date:	**Thursday, July 12, 2018**
Start and End Time:	**5:30pm – 7:00pm**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
Working Group Facilitator	**Joyce Neading, RHIT, CTR**
Working Group Co-Facilitator	**Michele Lacy RN, BSN**

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

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

WORKSHOP AGENDA

1. Review and approval of minutes from January 25, 2018 meeting
2. Introductions/Welcome
3. Quality Assurance /Audit Team Liaison report/discussion
4. Vacancy: Quality Control Working Group Liaison to Mentorship Working Group
5. Working Group Liaisons report
    a. Protocol Review Working Group – Donna White
    b. Education and Training Working Group – Robin Burgess
6. Suggestions for new projects for Quality Control Working Group
7. Old Business

QUESTIONS/DISCUSSION
EVALUATION

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

Date:	**Friday, July 13, 2018**
Start and End Time:	**7:00am – 9:00am**
PSC Chair:	**Susan Nolte, PhD, CRNP**
PSC Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
CTN Chair:	**Cindy Licavoli RN, BSN, MA,**
CTN Co Chairs:	**Nancy Fusco RN, BSN, Hee Sun Kim-Suh RN, BSN**

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

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

WORKSHOP AGENDA:

1. Working Group Reports
    a. Protocol Review
    b. Education and Training

c. Quality Control
d. Mentorship
2. Discuss and review goals, objectives and membership guidelines for CTN Sub Committee members
3. Discuss roles, responsibilities and reporting methods for appointments to NRG Oncology disease site and modality committees
4. Review Meeting Programs
5. Discuss meeting schedules and future educational needs
6. Other business

QUESTIONS/DISCUSSION
EVALUATION

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

Date:	**Friday, July 13, 2018**
Start and End Time:	**7:00am – 9:00am**
PSC Chair:	**Susan Nolte, PhD, CRNP**
PSC Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**
CRA Chair:	**Sharon Stockman BA, C-CRP**
CRA Co-Chairs:	**Sally Brown RN, BSN, MGA, Joyce Neading RHIT, CTR**

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

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

WORKSHOP AGENDA

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

QUESTIONS/DISCUSSION
EVALUATION

Radiation Development Therapeutics Workshop

Date: **Saturday July 14, 2018**
Start and End Time: **10:00 am - 12:00 pm**
Chairs: **David Raben, MD; Steven Lin, MD PhD**

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

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

I. Introduction
   A. General Business **David Raben, M.D**.
      a. Dealing with Pharma and FDA
II. Scientific Talk **Steven Leong, M.D.**
   A. Innovative statistical methods in phase I/II clinical trials
III. Disease Site Committee Updates
   a. Head & Neck **Julie Bauman, MD**
      i. NRG-HN003: Phase I study of post-op CRT + Pembro for post-operative locally advanced HNSCC
   b. Sarcoma **Meng Welliver, MD, PhD/Phil Wong, MD**
      i. NRG-DT001: Phase ib Trial of Neoadjuvant AMG-232 Concurrent with Preoperative Radiotherapy in Wild-Type P53 Soft Tissue Sarcoma
   c. Lung **Steven Lin MD, PhD**
      i. Status on LU004, Stage III lung proposal with ImmunoRT in PD-L1 high NSCLC - Lin
   d. GI-non colorectal **Terrence Williams, MD / Salma Jabbour, MD**
      i. Phase I concept proposal in pancreatic cancer with Wee-1 and RT - Kyle Cuneo, M.D.
      ii. GI1824: Phase 1b study of OBP-301 (ODB-301) and definitive chemradiation for patients with Locally advanced esophageal and gastroesophageal adenocarcinoma who are not candidates for Surgery – Geoffrey Ku, M.D.
      iii. GI1824: A randomized multi-arm phase II trial of gemcitabine and hypofractionated Radiotherapy with or without talazoparib or AZD1775 in patients with locally advanced pancreatic cancer – Richard Tuli, MD, PhD
   e. GI-colorectal **Thomas George, MD / Terrence Williams, MD**
      i. NRG-GI002: A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer
   f. GYN **Jyoti Mayadev, MD**
      i. LNRG-PI727: Revised Phase I concept for CRT+ Anti-PDL1 in locally advanced cervical cancer

QUESTIONS / DISCUSSION

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Rare Tumor Workshop

Date: **Friday, July 13, 2018**
Start and End Time: **2:00 pm - 4:00 pm**
Chair: **Allan Covens, MD**
Co-Chair: **Jubilee Brown, MD**

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

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

WORKSHOP AGENDA

Session I

A. Closed Studies

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

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

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

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

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

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

GY-001: A Phase II Trial of Cabozantinib in Women with Recurrent Clear Cell Carcinoma of the Ovary, Fallopian Tube, or Peritoneum (Farley)

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

GOG 281: A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (GSK1120212) in Patients with Recurrent or Progressive Low-grade Serous Ovarian Cancer or Primary Peritoneal Cancer (David M Gershenson), opened additional 20 US pts, biopsy requirement removed.

B. Presentation:

Novel hormonal therapy targets revealed by genomic analysis of recurrent adult type ovarian granulosa cell tumors- Dr. Tyler Hillman

C. Proposed Studies

DT1822/RT1531: A randomized phase II trial of Temozolomide and Cisplatin versus Nivolumab (BMS-936558) in patients with completely resected mucosal melanoma (Vicus)- submitted to *CTEP ad hoc SC.*

GY016: A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary (Gien)- *In development with CTEP, ? funding for translational from Incyte*

RT1507: A phase II trial of Cediranib in recurrent ovarian sex-cord stromal tumours (Vicus)- *rejected by CTEP*

GY019 RT1753: A randomized phase III, 3-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 (Fader/Gershenson)- *GCSC approved.*

CLEE011XUS5IT: GOG Partners. Phase II trial of letrozole + Ribociclib for women with recurrent low-grade serous carcinoma. Budget approved, protocol being developed.

RT1835 Ph II/III Trial of Adjuvant Combination Radiotherapy and Immunotherapy for Clear Cell Ovarian Carcinoma (CCOC) (Kosei Hasegawa

RT1841 A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien)

RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus)

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)

D. Discussion Topics:

a) tumour types for RTM
   - **1)** Clear Cell Tumors
   - **2)** Germ Cell Tumors
   - **3)** Ovarian - Low Grade Serous
   - **4)** Ovarian - Mucinous
   - **5)** Ovarian - Stromal Tumors
   - **6)** Vulvar/Vaginal Melanoma

b) RFA Recurrent Ovarian sex-cord Stromal tumours

c) improve accrual to AGCT 1531

QUESTIONS / DISCUSSION

Surgical Oncology Committee Agenda

Date:	Saturday, July 14, 2018
Start and End Time:	6:30 am – 8:00 am
Chair:	Thomas Julian, MD
Co-Chairs:	Drew Ridge, MD, Nick Spirtos, MD

Learning Objectives:

Following this activity, participant will be better able to:

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

Workshop Agenda

6:30 – 6:35	Welcome/Introduction -Minutes approval	Thomas Julian, M.D.
6:35 - 6:45	Medical Oncology Update	Corey Langer, M.D.
6:45 – 6:55	Radiation Oncology Committee Update	Jeff Michalski, M.D.
6:55 - 7:05	Update QA & QC Committee	Charles Whitney
7:05 – 7:10	NRG Oncology Update	Thomas Julian, M.D.
7:10 – 745	Disease Site Liaisons Reports (very brief update on developments)* a. Brain b. Breast c. GI d. GU e. Gynecology f. Head and Neck g. Lung *Liaison to provide a 5 minute update on latest surgical advancement	Minesh Mehta, M.D. or Michael Vogelbaum Irene Wapnir, M.D. Atif Iqbal, MD Lenny Gomella, M.D. Nick Spiritos, M.D. Quynh Le or Erich Sturgis Jeffrey Bradley, M.D. or Jessica Donington
7:45 – 8:00	Questions/Discussion	

Translational Science Workshop

Date:	**Thursday, July 12, 2018**
Start and End Time:	**6:30 pm – 8:00 pm**
Chair:	**Michael Birrer, MD, PhD**
Co-Chair:	**Adam Dicker, MD, PhD**
	Matthew Ellis, MB, BCHIR, PhD

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

1 To understand the emerging immunotherapy approaches to human cancers
2 To understand the value of CIMAC/-CIDC
3 To understand the state of the science for proteomics in nrg/oncology
4 To understanding the present state of biobanking in nrg/oncology
5 To recognize critical aspects of developing translational endpoints for legacy GOG clinical trials.

WORKSHOP AGENDA

6:30 – 6:45	Opening Remarks and Introduction	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD
6:45 – 7:00	Use of the biorepositories/Navigator	Heather Lankes MPH
7:00 – 7:30	Proteomic update/CPTAC	Matthew Ellis, MB, BCHIR, PhD Michael Birrer MD PhD
7:30 – 8:00	NRG Oncology Immunotherapy Trials/CIMAC-CIDC	Adam Dicker, MD, PhD Sacha Gnjatic, MD

Translational Science GYN Workshop Agenda

Date: **Friday, July 13, 2018**
Start and End Time: **10:30 am – 12:00 pm**
Chair: **Michael Birrer, MD, PhD**
Co-Chair: **Heather Lankes, PhD, MPH**

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

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

WORKSHOP AGENDA

10:30-10:40	Opening Remarks	Michael Birrer, MD, PhD
	NCTN Navigator Update	Heather Lankes, PhD, MPH
10:40-10:50	NRG TR U10/UG1 Update	David Mutch, MD
	CPTAC Update	Michael Birrer, MD, PhD
10:50-11:20	TS-GYN Disease Site Updates	
	Ovary	Rebecca Arend, MD
	Uterine Corpus	Elizabeth Swisher, MD
	210 Subcommittee	David Mutch, MD
	Cervix	Dmitriy Zamarin, MD
11:20-11:35	Cell-Free/Circulating Tumor DNA	Doug Levine, MD
	Biospecimen Collection and Testing	
	GYN Translational Science – Works in Progress	
11:35-11:50	GOG 0225	Tracy Crane, PhD

Concept Review

1. 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)
2. RT1835 Ph II/III Trial of Adjuvant Combination Radiotherapy and Immunotherapy for Clear Cell Ovarian Carcinoma (CCOC) (Kosei Hasegawa)
3. UC1837 Phase III Trial of Adjuvant doxorubicin plus olaratumab: pivotal trial for uterine leiomyosarcoma (ADOPT-FUL) (Elizabeth Loggers)
4. OV1838 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Non-Platinum Chemotherapy in Patients with Recurrent Platinum Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
5. OV1839 Randomized Phase II trial Comparing the Combination of the PI3-Kinase Inhibitor Copanlisib and the PARP-Inhibitor Olaparib to Standard Platinum-Based Chemotherapy in Patients with Recurrent Platinum Sensitive Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP-Inhibitor Therapy (P. Konstantinopoulos)
6. CV1840 Randomized Phase II Study of Stereotactic Body Radiotherapy + Anti-PD1 Antibody (Pembrolizumab) in Recurrent or Persistent Metastatic Cervical Cancer (L Gien)
7. RT1841 A Phase II Evaluation of bevacizumab and bortezomib for Recurrent sex-cord stromal ovarian tumors. (L Gien)
8. CV1842 A Phase II Study of Epacadostat plus Pembrolizumab in patients with recurrent cervical cancer (J Farley)

9. UC1843: Efficacy of first line immunotherapy with checkpoint inhibitors (CPI) vs. standard chemotherapy in patients with stage IV or recurrent endometrial carcinoma with deficient mismatch repair system: randomized phase II study (H Mahdi)
10. UC1844 Phase II study of efficacy of second line treatment with immunotherapy comparing combined regimen (PD1/PDL1 and CTLA-4 inhibitors) vs. PD1 /PDL1 monotherapy in patients with recurrent endometrial carcinoma with deficient mismatch repair system. (H Mahdi)
11. PI1845 Efficacy of mesothelin-directed antibody drug conjugate (anetumab ravtansine) in combinational therapy in patients with recurrent ovarian cancer with moderate-strong mesothelin expression: phase I/Ib study. (H Mahdi)
12. OV1847 A randomized controlled study of the effectiveness of neoadjuvant chemotherapy (carboplatin and paclitaxel) versus chemo-immunotherapy (carboplatin, paclitaxel and oregovomab) in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal carcinoma. (R Previs, A Secord)
13. CV1848 A Phase II trial of tumor directed Surgery or Radiotherapy followed by Cisplatin, Paclitaxel, and Bevacizumab, with or without Pembrolizumab for women with Oligometastatic Cervical Cancer. (Junzo Chino)
14. RT1849 A phase II trial of Durvalumab and Cediranib in recurrent ovarian sex-cord stromal tumors. (D Vicus)
15. OV1850 Randomized Phase II Study of Carboplatin and Paclitaxel and Bevacizumab followed by bevacizumab maintenance vs Carboplatin and Mirvetuximab Soravtansine and Bevacizumab and Bevacizumab + Mirvetuximab Soravtansine maintenance in First-Line Treatment of Patients with Advanced-Stage Ovarian, Fallopian Tube or Primary Peritoneal Cancer (M Birrer/ K Moore)
16. OV1851 **B**iomarker-directed Therapy for Platinum-Sensitive **R**ecurrent **O**varian **C**ancer (**BROC** protocol) (A Secord/D O'Malley)
17. OV1852 A phase III randomized trial of neoadjuvant paclitaxel, carboplatin, and bevacizumab with interval cytoreductive surgery versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation versus neoadjuvant paclitaxel, carboplatin, and bevacizumab followed by cytoreductive surgery with HIPEC consolidation and atezolizumab in newly diagnosed stage III and IV ovarian, primary peritoneal, and fallopian tube cancer in patients who are not candidates for primary cytoreductive surgery (M. Crispins)
18. UC1853 EmBATTLE: **EndoMetrial Cancer and Tumor Biopsy Assigned Targeted Therapy Based on MoLecular AltErations** (B Pothuri)
19. UC1644: Biomarker Driven Adjuvant Therapy for High-Risk Uterine Leiomyosarcoma (ALDO study) (E Loggers/B Slomovitz)

Other Business

Questions/Discussion

Translational Science Lung Cancer Workshop Agenda

Date: **Friday, July 13, 2018**
Start and End Time: **4:00 pm – 6:00 pm**
Chair: **Bo Lu, MD, PhD**

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

1. Novel biomarkers for cancer Immunotherapies and radiotherapy.
2. Combination of immunotherapy with radiotherapy.
3. Novel Therapeutic Targets for lung cancer

WORKSHOP AGENDA

Intro/Overview: Bo Lu, MD, PhD

Speaker: Sheralee Miller, BS (NRG Oncology)
Presentation Title: "NCI NCTN Navigator Introduction"

Speaker: Joanne Weidhaas, MD, PhD, MSM (UCLA)
Presentation Title: "The KRAS-Variant and MicroRNA Binding Site Mutations in 0617"

Speaker: Salma Jabbour, MD (Rutgers Cancer Institute of New Jersey)
Presentation Title: "Checkpoint Inhibition in Chemoradiation for NSCLC"

Speaker: Timothy Chan, MD, PhD (Memorial Sloan Kettering Cancer Center)
Presentation Title: "The Evolving Landscape of Immunotherapy Biomarkers and Mechanisms"

Speaker: Sam Williams, PhD (Abbvie Stemcentrx)
Presentation Title: "Patient Derived Tumor Xenografts as a Resource for Cancer Stem Cell and Therapeutic Discovery"

Speaker: George C. Prendergast, PhD (Lankenau Institute for Medical Research)
Presentation Title: "IDO Inhibitors from Bench to Bedside: Future Perspectives after ECHO-301"

QUESTIONS / DISCUSSION

Uterine Corpus Agenda

Date: **Friday, July 13, 2018**
Start and End time: **2:30 pm – 4:30 pm (Session I)**

Date: **Saturday, July 14, 2018**
Start and End time: **10:00 am – 11:00 am (Session II)**

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

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

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

NOTE:
GTN subcommittee: FRIDAY 10:00-11:30 (Lead Neil Horowitz, MD)
GOG 210 Subcommittee: FRIDAY 8:00-9:00 (Lead David Mutch, MD)

Workshop Agenda

A. Introduction (Powell)

B. Review of Closed Studies

1. **GOG0086P:** A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab(NSC #704865, IND #7921), paclitaxel/carboplatin/temsirolimus (NSC #683864, IND#61010), and ixabepilone (NSC#710428 IND # 59699)/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer **(Carol Aghajanian)**

2. **GOG0184:** Tumor Volume-Directed Pelvic Plus or Minus Para-Aortic Irradiation followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for advanced Endometrial Carcinoma (Spirtos) (Gynecol Oncol 112: 543-52, 2009; Gynecol Oncol 119: 538-42, 2010)**: Reviewed by Spirtos. Manuscript almost ready.**

3. **GOG0188:** Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [Gynecol Oncol 120(2): 185-8, 2011]**: Reviewed by Leslie. 1 patient still on trial, over 10 yrs. Consideration of supplying drug off study and then terminate.**

4. **GOG0209:** A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer **(David Scott Miller)** [Gynecol Oncol 125: 771-3, 2012] **Nearly ready for submission to NEJM**

5. **GOG0210:** A Molecular Staging study of Endometrial Carcinoma (William T Creasman) **: Reviewed by Mutch**

6. **GOG0229J:** A Phase II Evaluation of Cediranib (RECENTIN; AZD2171) in the Treatment of Recurrent or Persistent Endometrial Cancer **(David P Bender)**. Terminated January 25, 2016. doi:10.1016/j.ygyno.2015.04.018

1. **GOG0229O** A randomized phase II study with a phase I lead-in to assess the antitumor efficacy of the MEK inhibitor Trametinib alone or in combination with GSK2141795, an AKT inhibitor in patients with recurrent or persistent endometrial cancer (Shannon N Westin)**: Manuscript written.**

2. **GOG0233:** Utility Of Pre-Op Fdg-Pet/Ct Scanning Prior To Primary Chemoradiation Therapy. To Detect Retroperitoneal Lymph Node Metastasis In Patients W/Locoregionally Advanced Ca Of The Cervix (Ib2, IIa ¡Ý4 Cm, IIB-Iva), Or Endometrium (Gr 3 Endometrioid Endometrial Ca; Serous Papillary Ca, Clear Cell Ca, Or Ca (Any Grade); And Grade 1 Or 2 Endometrioid Endometrial Ca With Cervical Stromal Involvement Overt In Clinical Exam Or Confirmed By Endocervical Curettage) (Michael Gold). Terminated July 16, 2016. [J Clin Oncol 29(15s) (ASCO #5035): 340s, 2011; J Clin Oncol 29(15s) (ASCO #5042): 342s, 2011]**: Terminated 3 OCT 16: Manuscript published: Radiology 283:450 '17**

3. **GOG0249:** Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy **(Randall)** doi:10.1016/j.ygyno.2014.07.078: **Manuscript under internal review for submission to NEJM**

4. **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**)**

5. **GOG0261**: A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus **(Matthew A Powell) Events complete for analysis.**

6. **GOG0275** A Phase III Randomized Trial of Pulse Actinomcyin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia **(Julian C Schink)**

7. **GOG0277** A Phase III Randomized Trial of Gemcitabine (NSC# 613327) plus Docetaxel (NSC# 628503) followed by Doxorubicin (NSC# 123127) v. observation for uterus-limited, High Grade Uterine Leiomyosarcoma **(Martee L Hensley) 38 patients accrued, limited manuscript possible.**

8. **GOG0283** A Phase II Trial of DCTD-Sponsored Dasatinib (NSC #732517 IND #73969) In Recurrent/Persistent Ovary, Fallopian Tube, Primary Peritoneal, Endometrial, or Endometriosis-Associated Clear Cell Carcinoma Characterized for the Retention or Loss of BAF250a Expression. (David M Hyman) **Reviewed by Powell. Closed after 1st stage accrual. Data pending. Closed.**

9. **NRG-GY008:** A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA and PIK3R1/R2 mutations (A Santin) **Reviewed by Powell. 1st stage accrual completed. Awaiting data update.**

C. Review of Active Studies

1. **Endometrial Protocols:**

   a. **GOG0238:** A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus (Jonathan Feddock)**: Reviewed by Randall. Currently 129 enrolled out of target 154.**

   b. **GOG0286B** A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer **(Victoria L Bae-Jump) Accruing, interim analysis pending. Change upcoming, possible closure.**

   c. **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) Accrued 43/50 patients**

Action: Amendment: Reviewed by Darcy, Mutch: Define endpoints for frozen tissue analyses. Money in budget for shipping frozen tissue. Amendment approved

d. S1609, DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors **(Schink)**

D. Review of Approved Concepts/Protocols

1. **GOG-8038:** Epidemiologic Risk Factors and Endometrial Cancer Survival (Louise A Brinton**): Reviewed by Felix. Concepts being solicited.**

2. **UC0905:** Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 **(Mutch) In 210 report, paper largely written. Creasman paper has been published as a starting point.**

3. **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)**: Reviewed by Mutch Problematic, driven by Dr. Zaino. Dr. Soslow taking over, working with stats. Review at July '18 meeting to make sure plan is in place.**

4. **GOG-8040 (UC1107):** An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino)**: Reviewed by Mutch**
   Status update by July'18 meeting.

5. **UC1506** Translational Science for Uterine Carcinosarcoma Trials [Amendment to GOG0261] (Douglas Levine)**: Reviewed by Maxwell. Comments back from CTEP. Amendment based on those comments in progress. Will resubmit.**

6. **NRG TS008 (UC1601):** Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black Women with Endometrioid Endometrial and Uterine Serous Cancer **(L. Maxwell)**

7. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (Tanner) **Reviewed by Temkin. Approved by CPC Feb 2017. Not to DCP yet. Still developing endpoints for lymphedema or alternatives. Suggest update by Dr. Tanner.**

8. **GY013 (DT1620)**: A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma **(Temkin) Working with CTEP, withdrawn. Will resubmit.**

9. **GY012 (UC1633):** A Three Arm Randomized Phase II Study Comparing Single-Agent Olaparib, Single Agent Cediranib and the Combination of Cediranib/Olaparib in Women with Recurrent or Persistent Endometrioid Endometrial Cancer (**Mackay**/Bender/Rimmel) **to activate 7/9/18.**

10. **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) Negotiating for drug availability with Pharma**

11. **GY014** (DT1718)**:** A phase II study of tazemetostat (EPZ-64438) an EZH2 inhibitor in select gynecologic cancers **(Eskander)**

12. **NC1744:** A Randomized Phase II Trial of Conventional versus Hypofractionated Pelvic Radiotherapy for Adjuvant Treatment of Endometrial Cancer **(Gunderson/Bernard)**

E. Proposed studies:

1. UC1837 Phase III Trial of Adjuvant doxorubicin plus olaratumab: pivotal trial for uterine leiomyosarcoma (ADOPT-FUL) (Elizabeth Loggers)

2. UC1843 Efficacy of first line immunotherapy with checkpoint inhibitors (CPI) vs. standard chemotherapy in patients with stage IV or recurrent endometrial carcinoma with deficient mismatch repair system: randomized phase II study. (H Mahdi)

3. UC1844 Phase II study of efficacy of second line treatment with immunotherapy comparing combined regimen (PD1/PDL1 and CTLA-4 inhibitors) vs. PD1 /PDL1 monotherapy in patients with recurrent endometrial carcinoma with deficient mismatch repair system. (H Mahdi)

4. UC1853 EmBATTLE: **EndoMetrial Cancer and Tumor Biopsy Assigned Targeted Therapy Based on MoLecular AltErations** (B Pothuri)

F. Studies from Other Committees for Review:

1. DT1831: A Phase II study of combination pegylated liposomal doxorubicin (PLD) with durvalumab in women with microsatellite stable recurrent endometrial cancer. (B Corr)

2. 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)

G. New Business

1. Report from GOG Foundation

a. **GOG3007** A RANDOMIZED PHASE II TRIAL OF EVEROLIMUS AND LETROZOLE OR HORMONAL THERAPY (TAMOXIFEN/MEDROXYPROGESTERONE ACETATE) IN WOMEN WITH ADVANCED, PERSISTENT, OR RECURRENT ENDOMETRIAL CARCINOMA (**Brian M Slomovitz**) O**pened and closed 14 months. Plenary at SGO in 2018.**

b. **UCP1701**: A phase II trial of doxorubicin + olaratumab in the treatment of recurrent or persistent carcinosarcoma of the uterus or ovary **(Martee Hensley) No further updates.**

2. Report from Subcommittee on Gestational Trophoblastic Disease **(Schink)**
See Subcommittee Report from Dr. Horowitz below

3. Report from GOG0210 Scientific Advisory Board **(Mutch)**
See 210 Subcommittee Report below

4. Report from RTOG **(Klopp)**

Workshops Agendas (NON-CME)

Breast Cancer Workshop Agenda

Date: **Saturday, July 14, 2018**
Start and End Time: **9:00 am – 12:00 pm**
Chair: **Eleftherios Mamounas, MD**
Co-Chairs: **Julia White, MD**

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

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

WORKSHOP AGENDA

9:00 – 9:15	**Welcome/Update**	Norman Wolmark, MD
9:15 – 9:45	**Report from the Breast Working Group Meeting**	Eleftherios Mamounas, MD Julia White, MD
9:45 – 10:00	**NRG BR-003** A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Weekly Carboplatin in Women with Node-Positive or High-Risk Node-Negative Triple Negative Invasive Breast Cancer	Vicente Valero, MD
10:00 – 10:15	**NRG BR-005-**A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy	Mark Basik, MD Jennifer Delossantos, MD
10:15 – 10:45	**Immunotherapy Trials**	
	NRG BR-004 A Randomized Phase III Trial of Paclitaxel/ Trastuzumab/Pertuzumab/Placebo Compared to Paclitaxel/ Trastuzumab/Pertuzumab/Atezolizumab in First Line HER2-Positive Metastatic Breast Cancer	Charles Geyer, Jr., MD
	NSABP-59/GBG 96 A Randomized, Double-Blind, Phase III Clinical Trial of Neoadjuvant Chemotherapy with Atezolizumab or Placebo in Patients with Triple-Negative Breast Cancer Followed by Adjuvant Continuation of Atezolizumab or Placebo	
	NRG BR-006 Phase III Trial to Evaluate Adjuvant Therapy of Pembrolizumab for TNBC with Residual Invasive Cancer or Positive Lymph Nodes After Neoadjuvant Chemotherapy	Eleftherios Mamounas, MD
10:45 – 10:55	**FB-12**-Neoadjuvant Chemotherapy plus Anti-HER2 Therapy in HER2 Negative Patients with Increased HER2 Signaling Activity	Eleftherios Mamounas, MD

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

Cancer Care Delivery Research (CCDR) Workshop Agenda

Date:	**Friday, July 13, 2018**
Start and End Time:	**11:30 am – 1:00 pm ET**
Co-Chair:	**Debra Ritzwoller, PhD**
Co-Chair:	**Matthew F. Hudson, PhD, MPH**

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

WORKSHOP AGENDA		**SPEAKERS**
Session I		
A.	Welcome and information	Matt Hudson, PhD, MPH
B.	Brief introduction of new NRG CCDR committee members a. Call for new committee members following last meeting	Matt Hudson, PhD, MPH
C.	Update on CCDR Committee	Deb Ritzwoller, PhD
D.	NCI CCDR updates a. NCI approved protocol and operations updates b. CCDR concept submission guidelines	 Kate Castro, RN Elisabeth Kato, MD, MRP
E.	Update on CCDR Pilot Awards a. Breast Cancer Screening Decisions in Younger Women: A Hybrid Effectiveness-Implementation Study b. PROTECT: Patient Reported Outcomes to Enhance Care on Treatment	 Erin Hahn, MD Alexi Wright, MD
F.	NRG-CC007CD: "Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy" Protocol update	Ron Chen, MD, MPH
G.	NRG CCDR Concept updates a. Concepts in development b. NRG NCORP approved concept updates c. CCDR Committee approved concepts	Matt Hudson, PhD, MPH
H.	Deimplementation of RT In Older Women With Stage 1 Cancer	Jean Wright, MD
I.	Alliance A231601CD: "Improving Surgical Care and Outcomes in Older Cancer Patients Through Implementation of an Efficient Pre-Surgical Toolkit	George Chang, MD
J.	NCORP submission dates a. Priorities for CCDR activities	Matt Hudson, PhD, MPH
K.	New Business	

QUESTIONS / DISCUSSION

Health Disparities Committee
Friday, July 13, 2018
10am-12pm
Agenda

Tri-Chairs: *Carol Brown, MD; Elise Cook, MD, MS; Kate Yeager, PhD, RN, MS*

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

10:05-10:35 am **Kathleen Darcy –** *Cancer Health Disparities in Gynecologic Oncology: Current Evidence and Opportunities*

10:35-11:15 am **Disease Site and Other Committee Liaisons**

- **HDC Disease Site Liaisons-*Committee-****Tri Chairs*
  - HDC Disease Site Liaisons awareness presentations to disease site/other committees
  -Disease Site Committee Updates-Liaisons

Breast	Eleanor Walker	(Alternate: Kathie-Ann Joseph)
Brain	Na Tosha Gatson*	(Alternate: Marianne Matzo)
GI	Edith Mitchell	
GU	Mack Roach	(Alternate: Eleanor Walker)
Gyn-Ovarian	Melissa Simon	(Alternate: Dana Chase)
Gyn-Cervix	Wendy Brewster	
Gyn-Uterine	Anuja Jhingran	(Alternate: Marianne Matzo)
Head & Neck	Steven Chang*	
Rare Tumors	Mary Scroggins	
Lung (Thoracic)	Tom Simon	

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Older Adult Working Group	William Tew
Cancer Prevention & Control (CPC)	Rusty Robinson
Patient Centered Outcomes Research (PCOR)	Dana Chase
NCORP	Carol Brown

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

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

*Committee Liaison to HDC

11:15-11:45 am **Working Groups Updates-***Tri Chairs*
-2018 goals –review of and future plans
-Naming of Co Leaders

- **Clinical trial enrollment**- *William (Rusty) Robinson*
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- **Education/training/mentorship**-*Kathie Ann Joseph*
  -HDC Workshop - July 2018
  -HDC Mentor Program
  plans to collaborate with the Young Investigators Committee

- **Health disparities research**-*Electra Paskett*
  -NRG Recruitment Survey Manuscript – Elise Cook, Electra Paskett & Kate Yeager

  Published: *Recruitment practices for U.S. minority and underserved populations in NRG oncology: Results of an online survey*
  Contemporary Clinical Trials Communications
  Volume 10, June 2018, Pages 100-104
  Article link: https://doi.org/10.1016/j.conctc.2018.03.003

  Socioeconomic/demographic information collection on NRG Oncology trials
  - Alliance Pilot Study Update -Electra Paskett

- **Statistics/metrics**-*Reena Cecchini*
  -SDMC Reports

11:45- 11:55 am **Future Plans: NCTN and NCORP grant renewal -***Tri Chairs*

Other Business / Discussion

12:00 pm **Adjournment**

Future Meetings

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

February 7 - 9, 2019
Phoenix Convention Center
Phoenix, AZ

July 18 - 20, 2019
Philadelphia Marriott -Downtown
Philadelphia, PA*****HDC Workshop-TBA***

January 9 - 11, 2020
Marriott Marquis
Houston, TX

July 16 - 18, 2020
Marriott Marquis
Washington, DC *****HDC Workshop-TBA***

IMAGING COMMITTEE MEETING AGENDA

Date:	**Friday, July 13, 2018**
Start and End Time:	**10:00 am – 12:00 pm**
Chair	**Daniel Pryma, MD**
Members	**James Fink, MD, Amy Fowler, MD, PhD, Feng-Ming (Spring) Kong, PhD, MD, Mark Rosen, MD, Rathan Subramaniam, MD, PhD and Ying Xiao, PhD**

MEETING AGENDA

10:00-10:10	**Committee introduction and charge** (10 min)	Dan Pryma
10:10-10:20	**Committee workflow and resources** (10 min)	Panel
10:20-10:40	**Update on imaging in NRG trials** (20 min)	Mark Rosen/Delegate
10:40- 11:10	**QIN presentation** (30 min)	John Buatti
11:10-11:15	**Questions for Dr. Buatti**	
11:15- 11:45	**Trial concept/Protocol presentations** (30 min)	
11:15-11:30	***GU1827 Ph III Randomized trial of molecular imaging vs no molecular imaging in high-risk prostate cancer***	Ashesh Jani
11:30-11:45	***HN1707 Randomized Phase II/III Trial of Reduced-Field Radiation Therapy (RFRT for Patients with Early-Stage, p16-Positive, Non-Smoking-Associated Oropharyngeal Cancer***	Rathan Subramaniam
11:45-12:00	**Wrap up and Questions**	

Immunotherapy and Immune Modulation Workshop, Friday, July 13, 2018
11 am - 12:30 pm

"**Pancreas Cancer, Immunogenicity and checkpoint resistance**". **Robert H. Vonderheide, MD, DPhil.,** Director, Abramson Cancer Center; John H. Glick MD Abramson Cancer Center's Professor, University of Pennsylvania, Philadelphia, PA.

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

"**Immune Cytolytic Activity Stratifies Molecular Subsets of Human Pancreatic Cancer."** By David Balli, Andrew J. Rech, Ben Z. Stanger, and Robert H. Vonderheide. *Clin Cancer Res* **2017,** *23* (12), 3129-3138.

"**Lack of immunoediting in murine pancreatic cancer reversed with neoantigen."** Evans, R. A.; Diamond, M. S.; Rech, A. J.; Chao, T.; Richardson, M. W.; Lin, J. H.; Bajor, D. L.; Byrne, K. T.; Stanger, B. Z.; Riley, J. L.; Markosyan, N.; Winograd, R.; Vonderheide, R. H.

"**T-cell exhaustion and PD-1 targeted therapies". Alice Kamphorst, Ph.D.,** Assistant Professor of Oncological Sciences Precision Immunology Institute, Icahn School of Medicine at Mount Sinai, New York, New York.

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

"**Rescue of exhausted CD8 T cells by PD-1-targeted therapies is CD28-dependent."** Kamphorst, A. O.; Wieland, A.; Nasti, T.; Yang, S.; Zhang, R.; Barber, D. L.; Konieczny, B. T.; Daugherty, C. Z.; Koenig, L.; Yu, K.; Sica, G. L.; Sharpe, A. H.; Freeman, G. J.; Blazar, B. R.; Turka, L. A.; Owonikoko, T. K.; Pillai, R. N.; Ramalingam, S. S.; Araki, K.; Ahmed, R.

"**Reprogramming Tumor Microenvironment to Improve Responses to Immunotherapy**". **Vineet Gupta, PhD.,** Professor and Vice Chair for Research and Innovation, Department of Internal Medicine, Director, Drug Discovery Center, Rush University Medical Center, Chicago, IL.

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

Abstract 57: "Reprogramming Tumor Microenvironment to Improve Responses to Immunotherapy in Pancreatic Cancer". R.Z. Panni, B. Knolhoff, J. Herndon, G. Hogg, V. Gupta, W. Hawkins,1 R. Fields, D.G. David.
http://expo.jspargo.com/exhibitor/web/Abstracts18.pdf

Abstract B03: "Integrin agonists reduce infiltration of tumor associated macrophages to promote T-cell mediated antitumor immunity". Samia Q. Khan, Mohd. H. Faridi, Shehryar J. Khaliqdina, Antonio J. Barbosa, Judith A. Varner, and Vineet Gupta.
http://cancerimmunolres.aacrjournals.org/content/5/3_Supplement/B03

"Abstract A17: An integrin agonist suppresses breast cancer by reducing CD11b+ leukocytes, promoting antitumor immunity". Samia Q. Khan, Mohd H. Faridi, Brian Ruffell, Ana M. S. Lopez, Shehryar Jehangir, Antonio J. Barbosa, Marta TorroellaKouri, Lisa M. Coussens, Judith Varner, and Vineet Gupta.
http://cancerres.aacrjournals.org/content/76/15_Supplement/A17

"Unveiling New Molecular Biomarkers for Immunotherapy Using Immunosequencing". Catherine M. Sanders, MT, Ph.D., Senior Director, Scientific Liaisons, at Adaptive Biotechnologies, Seattle, Washington.

If you would like to read more about this research, please see https://www.adaptivebiotech.com

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

Date:	**Friday, July 13, 2018**
Start and End Time:	**4:00 pm – 6:00 pm**
Chair:	**Ying Xiao, PhD**
Co-Chairs	**Jason Sohn, PhD and Stanley Benedict, PhD**

Learning Objectives

Following this activity, participants will be better able to:

1. Determine the technical concerns arising from the protocol development
2. Develop strategies to address the technical concerns/issues identified from protocol development
3. Provide updates on developments related to technology from other NCTN groups
4. Provide a summary on latest developments in technology that impacts Patient Care to enhance knowledge, improve Systems-Based Practice, and to prepare for possible application in trials.

WORKSHOP AGENDA

4:00 – 4:05	**Introductions / Subcommittee Updates**	Ying Xiao/Jason Sohn
4:05 – 4:10	**NCI Communications/NCTN Medical Physics**	Ceferino Obcemea
4:10 – 4:20	**NRG QA Report**	
	• IROC Houston	David Followill
	• IROC Philadelphia RT (Contouring & Dosimetry)	Ying Xiao, PhD
	• IROC Philadelphia Imaging	Mark Rosen, MD
4:20 – 4:50	**Disease Site Reports**	
	• Brain	Fangfang Yin
	• Breast	Ying Xiao/ Jason Sohn
	• GI	Adam Yock
	• GU	Rajat Kudchadker / Robert Wallace
	• GYN	Cecilia Lee /Hayeon Kim
	• H&N	Nataliya Kovalchuk
	• Lung	Tim Solberg / Martha Matuszak
4:50 – 5:15	**Modality Technology Reports**	
	• Imaging	Kristy Brock
	○ Fluciclovine PET	
	○ MR guided GI boost for GI	
	• Notable technologies	Zoufeng Li
5:15 – 5:40	**Working Group and Other Updates**	
	• Adaptive QA	Carrie Glide-Hurst
	• Deformable QA	Stan Benedict
	• Mesothelioma IMRT	Ellen Yorke
	• SBRT Practice Survey	Jason Sohn
5:40 – 5:50	**Other Business**	
5:50 – 6:00	**Questions/Discussions**	

Proton Working Group Workshop Agenda
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Date: **Saturday, July 14, 2018**
Start and End Time: **6:45 am – 8:30 am**
Chair: **Tom DeLaney, MD**

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

1. Recognize critical aspects of developing and conducting a clinical trial in cancer therapy research using proton therapy in a cooperative group setting.
2. Identify and describe the design and status of new clinical trials using proton therapy being planned and launched by NRG Oncology, to enable potential contribution to protocol design vetting and/or effective patient enrollment in newly-launched studies.
3. Identify and describe new forms and techniques of proton delivery and its use in NRG Oncology trials.

WORKSHOP AGENDA

6:45 – 6:50	Welcome/Introduction/ Moderator	Tom DeLaney, MD
6:50 –7:00	Update on Proton Center Credentialing by IROC Houston	Paige Taylor, PhD
	Protocols/ Concepts	
7:00 – 7:15	Protons in liver studies	
	RTOG 1112 - Ph III Sorafenib +/- SBRT for hepatocellular ca (L. Dawson)	Laura Dawson MD
	NRG-GI001 - Ph III Cis/Gem +/- RT for unresectable cholangioCa	Ted Hong, MD
	NRG-GI003 - Ph III Protons vs Photons for Hepatocellular Carcinoma	Ted Hong, MD
7:15 – 7:25	Brain Studies	Minesh Mehta, MD
	NRG-BN001: Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation w/ Concomitant /Adjuvant Temozolomide in Glioblastoma	
	NRG BN003- Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma	
	NRG BN005 - A Phase II Randomized Trial of Proton vs. Photon Therapy (IMRT) for Cognitive Preservation in Patients with IDH Mutant, Low to Intermediate Grade Gliomas.	
7:25 – 7:35	**NRG-BN005 Brain:** Ph II Randomized Proton vs IMRT for Cognitive Preservation in Pts with IDH Mutant, Low to Intermediate Grade Gliomas	David Grosshans MD
7:35--7:45	**RTOG 1308**: Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable Stage II-IIIB NSCLC	ZhongXing Liao, MD Jeffrey Bradley, MD
7:45 – 7:55	**NRG-HN001**: Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA): Addition of Protons	Annie Chan, MD Tom DeLaney, MD
7:55 – 8:05	**GI 006:** Ph III Randomized Protons vs. IMRT for Esophageal CA	Tom DeLaney MD
8:05– 8:15	**PCORI** (Patient-Centered Outcomes Research Institute) RADCOMP Breast Randomized Trial of Photons versus Protons	Shannon Macdonald, MD
8:15– 8:25	**PCORI** (Patient-Centered Outcomes Research Institute) Prostate Ca Study	Brad Hoppe, MD
8:25 – 8:30	Other Business/Questions	Tom DeLaney, M.D.

Protocol Support Committee Workshop
PSC Business Meeting (Closed)

Date:	**Saturday, July 14, 2017**
Start and End Time:	**7:00 am – 9:30 am**
Chair:	**Susan Nolte, PhD, CRNP**
Co-Chairs:	**Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC**

WORKSHOP AGENDA

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

QUESTIONS/DISCUSSION
EVALUATION

Radiation Oncology Committee Workshop Agenda
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

Date:	Friday, July 13, 2018
Start and End Time:	2:00 pm – 4:00 pm
Chair:	Jeff Michalski, MD
Co-Chairs:	Ivy Petersen, MD and Evan Wuthrick, MD

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

1. Provide information on the latest developments related to the Imaging and Radiation Oncology Core (IROC) Group and NRG Oncology. Learn about mechanisms of quality assurance and protocol development as they relate to innovative technology in radiation oncology.
2. Describe different aspects of the field of medical physics such as credentialing for advanced technologies.
3. Discuss the most recent findings and technological advances in radiation oncology for multiple NRG clinical disease sites.

WORKSHOP AGENDA

2:00 – 2:05	**Welcome / Introduction**		Jeff Michalski
2:05 – 2:20	**Update on NCTN Cooperative Groups**		
	a. NRG Oncology Group Update		Jeff Michalskli
	b. Imaging and Radiation Oncology Core (IROC) RT Update		David Followill Denise Manfredi
	c. Imaging and Radiation Oncology Core (IROC) Imaging Update		Mark Rosen
2:20– 2:30	**Overview of Medical Physics**		Ying Xiao
2:30 – 3:40	**Disease Site Liaisons Reports**		
	a. H&N	Sue Yom, MD	
	b. Brain	Christina Tsien, MD	
	c. Breast	Steven Chmura, MD	
	d. Gyn	Sushil Beriwal, MD	
	e. GI	Evan Wuthrick, MD / Eugene Koay, MD	
	f. GU	Dan Krauss, MD / Hiram Gay, MD	
	g. Lung	Charles Simone, MD	
	h. Sarcoma	Philip Wong, MD	
3:40 – 3:50	**Other Business**		
3:50 –4:00	**Q & A Discussion**		

Save the Date Next Meeting: February 8, 2019 Phoenix Convention Center in Phoenix, AZ!

SARCOMA WORKING GROUP AGENDA

DIAN WANG, M.D, PH.D., CHAIR
Peter Houghton, Ph.D., TRP Liaison
Friday, July 13, 2018
10:00AM – 12:00PM

A. Active Studies

1. ARST1321 (COG-NRG study): Pazopanib Neoadjuvant Trial In non-rhabdomyosarcoma soft tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (Chen/Scharschmidt/Weiss)
2. MGH/NRG: Phase I/II Trial of Preoperative Intensity Modulated Radiation Therapy (IMRT) For Retroperitoneal Sarcoma using a Simultaneous Integrated Boost (DeLaney/Wang)
3. Phase Ib Study To evaluate Neoadjuvant p53/MDM2 inhibitor combined with IMRT for Soft Tissue Sarcomas (Welliver/Wang)

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

1. Phase IIR Trial of Radiotherapy versus Surgery and Radiotherapy for Soft Tissue Sarcomas of the Extremities and Chestwall Following an Unplanned Excision (Wolfson)
2. Phase II trial to investigate the role of peri-operative RT in desmoid tumors harboring CTNNB1 S45 mutation (Pollock/Welliver)
3. A Potential SARC/NRG Collaboration: Phase II/III Randomized Trial of PD-1 Immune Checkpoint Blockade + Radiotherapy for Localized Soft Tissue Sarcoma of the Extremity (Kirsch)
4. Phase IIR Trial of Immunotherapy and SBRT for Metastatic Soft Tissue Sarcoma (Wong): update only

C. Sarcoma TRP

1. Sarcoma Radiomics (Yong Fan)
2. Translational Research using Radiochemotherapy and Novel Targeted Agents in Adult and Pediatric sarcomas (John Kalapurakal)

D: New Business

Translational Science Brain Cancer Subcommittee / Low Grade Glioma Working Group

Philadelphia, PA
Philadelphia Marriott Downtown
Friday, July 13, 2018
8:00am – 10:30am
Dr. Arnab Chakravarti, Chair

8:00 – 8:05	Introduction (Dr. Arnab Chakravarti, MD.)
8:05 – 8:10	NCI NTCN Navigator Introduction Sheralee Miller, BS (NRG, Navigator Concierge)
8:10 – 8:25	"Genomic Evolution of Gliomas" (Rameen Baroukhim, MD, PhD, Dana Farber Cancer Institute)
8:25 – 8:40	"Advances in Molecular Classification of Gliomas" (Jill Barnholtz-Sloan, PhD, Case Western)
8:40 – 8:55	"Resistance Mechanisms of Gliomas" (Keith Ligon, MD, PhD, Dana Farber Cancer Institute)
8:55 – 9:10	"Updates on IkB in LGGs" (Markus Bredel, MD, PhD, University of Alabama, Birmingham)
9:10 – 9:25	"ATP-Based Resistance Mechanisms in Gliomas" (Prof. Dr. P.A.J.T. Pierre Robe, University Medical Center, Utrecht)
9:25 – 9:40	"EORTC-Based Updates on Clinical and Translational Research on Gliomas" (Michael Weller, MD, University Hospital, Zurich)
9:40 – 9:55	"Updates on Genomics-Based Prognostics & Predictive Biomarkers Based on RTOG 9802 9813 0424" (Erica Bell, PhD, Ohio State University)
9:55 – 10:10	"Updates on Expression-Based Prognostic & Predictive Biomarkers based on RTOG 9802 9813 0424" (Jessica Fleming, PhD, Ohio State University)
10:10 – 10:25	"Updates on MGMT Assessment in Gliomas" (Aline Becker, Ohio State University)
10:25 – 10:30	Round Table Discussion

Translational Science GI Cancer Subcommittee Agenda

Date: **Saturday, July 14, 2018**

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

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

7:00 – 7:15 **Introduction/Overview**
Chandan Guha, MD, PhD / Christopher Crane, MD

7:15 – 7:20 **"NCI NCTN Navigator Introduction"**
Sheralee Miller, BS (NRG, Navigator Concierge)

7:20 – 7:50 **"Opportunities of Circulating Tumor DNA in Colorectal Cancer"**
S. Kopetz, MD, PhD **(**MD Anderson Cancer Center)

7:50 – 8:20 **"The Evolving Landscape of Immunotherapy Biomarkers and Mechanisms"**
T. Chan, MD, PhD (Memorial Sloan Kettering Cancer Center)

8:20 – 8:50 **"Expression of DNA Repair Gene MLH1 Correlates with Survival in Resected Pancreatic Cancer receiving Adjuvant Chemoradiation: NRG Oncology RTOG 9704"**
Y. Lawrence, MD (Sheba Medical Center, Israel)

8:50 – 9:00 **Closing Remarks and Discussion**
Chandan Guha, MD, PhD / Christopher Crane, MD

Translational Science Head & Neck Cancer Subcommittee Agenda

Date: Friday, July 13, 2018

Time: 2:00 pm – 3:00 pm

Chair: Neil Hayes, MD, MPH

2:00 – 2:10	Introduction/Overview Neil Hayes, MD, MPH
2:10 – 2:20	"NCI NCTN Navigator Introduction" Sheralee Miller, BS (NRG, Navigator Concierge)
2:20 – 2:50	"Finding Value in Scarcity: How Genomics Can Drive New Molecular and Immunotherapies for Salivary Cancer" Luc Morris, MD MSc, FACS (Memorial Sloan Kettering Cancer Center)
2:50 – 3:00	Closing Remarks and Discussion Neil Hayes, MD, MPH

NRG ONCOLOGY SUMMER 2018 EXHIBITING COMPANIES

NRG Oncology wishes to acknowledge the following exhibitors:

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MITRA BIOTECH
NOVOCURE
SOCIETY OF GYNECOLOGIC ONCOLOGY/FOUNDATION FOR WOMEN'S CANCER
TESARO

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

Franklin Hall Foyer (4th Floor)

Exhibit hours are:

Friday, July 12, 2018 - 7:00 am - 5:00 pm
Saturday, July 13, 2018 - 7:00 am - 2:00 pm

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

AstraZeneca

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

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Clovis Oncology

Clovis Oncology is a biopharmaceutical company focused on acquiring, developing and commercializing cancer treatments in the United States, Europe and other international markets. Our development programs are targeted at specific subsets of cancer, combining precision medicine with companion diagnostics to direct therapeutics to those patients most likely to benefit from them.

Eli Lilly and Company

For more than fifty years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

Foundation Medicine, Inc.

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

Genentech, a Member of the Roche Group

Founded over 40 years, Genentech is a leading biotechnology company that discovers, manufactures, and commercializes medicines to treat patients with serious of the life threatening medical conditions. The company, a member of the Roche Group, is headquartered in South San Francisco, CA.

Genmab and Seattle Genetics

Genmab's objective:

Genmab is a publicly traded, international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer. Founded in 1999, the company has two approved antibodies, DARZALEX® (daratumumab) for the treatment of certain multiple myeloma indications, and Arzerra® (ofatumumab) for the treatment of certain chronic lymphocytic leukemia indications. Daratumumab is in clinical development for additional multiple myeloma indications and solid tumors. A subcutaneous formulation of ofatumumab is in development for relapsing multiple sclerosis. Genmab also has a broad clinical and pre-clinical product pipeline. Genmab's technology base consists of validated and proprietary next generation antibody technologies – the DuoBody® platform for generation of bispecific antibodies, and the Hexabody® platform which creates effector function enhanced antibodies. The company intends to leverage these technologies to create opportunities for full or co-ownership of future products. Genmab has alliances with top tier pharmaceutical and biotechnology companies.

Seattle Genetics's objective:

Seattle Genetics, Inc. is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) utilizes the company's industry-leading antibody-drug conjugate (ADC) technology and is currently approved for the treatment of multipleCD30-expressing lymphomas. Beyond ADCETRIS, the company has established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing or planned pivotal trials for solid tumors. Enfortumab vedotin for metastatic urothe-

lial cancer and tisotumab vedotin for metastatic cervical cancer utilize our proprietary ADC technology. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies to build a portfolio of proprietary immune-oncology agents in clinical trials targeting hematologic malignancies and solid tumors. The company is headquartered in Bothell, Washington, and has a European office in Switzerland. For more information on our robust pipeline, visit www.seattlegenetics.com and follow @SeattleGenetics on Twitter.

Mitra Biotech

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

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

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

Novocure Inc.

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

Society of Gynecology Oncology/Foundation for Women's Cancer

Learn about SGO's plans to celebrate its 50th anniversary at the 2019 Annual Meeting on Women's Cancer, March 16 – 19, in Honolulu, Hawaii. Pick up a copy of SGO's new Chemotherapy Handbook and clinical trials resources for you patients.

TESARO

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

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NRG ONCOLOGY SEMIANNUAL MEETING
FEBRUARY 7 - 9, 2019
PHOENIX CONVENTION CENTER
PHOENIX, ARIZONA

Notes

NRG Oncology Semiannual Meeting

Save the date for these upcoming NRG Oncology Semiannual Meetings

February 7 - 9, 2019
Phoenix Convention Center
Phoenix, AZ

July 18 - 20, 2019
Philadelphia Marriott Downtown
Philadelphia, PA

January 9 - 11, 2020
Marriott Marquis
Houston, TX

Visit the NRG Oncology website at www.nrgoncology.org

July 16 -18, 2020
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