



Final Program

Sheraton Dallas Hotel
Dallas, Texas

2016 NRG Oncology Semiannual Meeting

July 14 - 17



NRG
ONCOLOGY

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FACULTY DISCLOSURE INFORMATION
NRG Oncology Semiannual Meeting

July 14-16, 2016
Dallas, TX

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” is defined as any 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.

NAME	Nothing To Disclose	DISCLOSURE <company & role>
Planning Disclosures		
Aghajanian, Carol, MD		Steering Committee Meeting/Honorarium: Oxigene
Alberts, David, MD		Consultant: INSYS Therapeutics
Alvarez, Ronald, MD		Ad Board/Honorarium: Clovis; CTisus Consultant/Honorarium: Unleash
Arthur, Doug, MD	X	
Bahary, Jean-Paul, MD	X	
Bialy, Sally	X	
Birrer, Michael, MD, PhD		Advisory Board/Honorarium: AstraZeneca; Roche Laboratories; Sanofi; Acceleron Pharma, Inc.; Immunogen
Blessing, John, PhD	X	
Bodis, Stephan, MD	X	
Bookman, Michael, MD		Ad-hoc consultation for development of clinical trials using investigational agents/Travel, Meal, Time & Effort Reimbursement: AbbVie; Clovis; OxiGene; Endocyte; Immunogen; AstraZeneca; Genentech-Roche, Independent Data Monitoring Committee/Reimbursement for time and effort: Immunogen
Boyle, Elaine, RN	X	
Brown, Sally, RN, BSN, MGA	X	
Bruner Deborah, PhD	X	
Burger, Robert, MD		DSMB Service/Contractual Fee: Gradalis; Janssen; Morphotek Advisory Board/Honorarium: Invitae; NuCana; Clovis Oncology
Chakravarti, Arnab, MD	X	
Cohn, David, MD		Author/Honorarium: Up to Date Consultant/Salary: Oncology Analytics
Corn, Benjamin, MD	X	
Covens, Allan, MD		Speaker/Honorarium: AstraZeneca; Roche; Merck
Crane, Christopher, MD		Consultant/Honorarium: Vertex
Delaney, Tom, MD	X	
Dicker, Adam, MD, PhD		Consultant/Honorarium: RedHill; Glenview; Janssen
DiSilvestro, Paul, MD	X	
Ellis, Matthew, MB, BCHIR, PhD		Ad Hoc Consultant/Honorarium: Nanostrins; Novartis; AstraZeneca; Pfizer Patent Holder/Royalty: Bioclassifier
Fusco, Nancy, RN, BSN	X	
Ganz, Patricia, MD	X	
George, Thomas, MD, PhD		Consultant/Consultant Fees: New Links Genetics
Gershenson, David, MD		Ownership/Stock: Pfizer; Biogen; Celgene; Johnson & Johnson; Merck; Abbvie

FACULTY DISCLOSURE LIST

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Gilbert, Mark, MD	X	
Gomella, Leonard, MD		Advisory/Consulting Fee: Astellas; Janssen Advisory/Consulting: MDX; Bayer
Joseph, Kathie-Ann, MD, MPH	X	
Julian, Thomas, MD	X	
Kachnic, Lisa, MD	X	
Kim-Suh, HeeSun, RN	X	
Knudsen, Nancy, RN, BSN	X	
Koh, Wui-Jin, MD	X	
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Koss, Jerome, RN, BSN	X	
Langer, Corey, MD		Institutional Grant/Research Support: BMS; ImClone Systems Inc.; Pfizer; Eli Lilly; Genentech; OSI Pharmaceuticals, Inc.; GSK; Clovis; Merck; Nektar; Advantagene; Inovio; Ariad Scientific Advisor: BMS; ImClone Systems Inc.; Pfizer; Eli Lilly; AstraZeneca; Novartis; Genentech; Bayer Healthcare Pharmaceuticals/Onyx; Abraxis Oncology (Celgene); Abbott Laboratories; Biodesix; Clariant; CarisDx; ARIAD Pharmaceuticals, Inc.; Boehringer Ingelheim; Synta; Clovis DSMC Member: Amgen; Synta; Peregrine; SWOG; Incyte CME: PIK; PED; NOCR; CCO; RTP
Lankes, Heather, PhD, MPH	X	
Le, Quynh-Thu, MD, FACR, FASTRO	X	
Licavoli, Cindy, RN, BSN, MA	X	
Lipscomb, Joe, PhD	X	
Lu, Bo, MD, PhD	X	
Magliocco, Anthony, MD		Consultant/Travel/Honorarium: DiaCarta; Circulogene; Ventana Medical Systems; BioTheragnostics; Guardant Health; BNS; Sequenom, Inc.; Canadian Breast Cancer Foundation; Quality Star Advisory Board Member/Travel/Honorarium: Novartis Board Member/Travel/Honorarium: NRG Oncology Consultant/Speaker/Honorarium/Travel: Illumina Consultant/Honorarium: Genoptixs; BioNest; Janssen Diagnostics, LLC Speaker/Travel/Honorarium: Definiens' International; Association of Pathology Chairs
Mamounas, Eleftherios, MD		Speaker/Advisor/Honorarium: Genomic Health, Inc.; Genentech Advisor/Honorarium: Novartis; Celgene; Biotheranostics; Pfizer; Bayer
Mannel, Robert, MD		Ad Board/Honorarium: Endocyte; Clovis; GOG
Mayadev, Jyoti, MD	X	
McLaughlin, Tamara, MHA, MPH	X	
Mehra, Minesh, MD		Consultant/Consulting Fee: Varian DSMB/Board Fee: Monteris
Michalski, Jeff, MD	X	
Miller, David, MD		Advisory/Speaker/Honorarium: Genentech Consultant/Honorarium: Janssen Grants/Consultant/Honorarium: AstraZeneca Speaker/Consultant/Honorarium: Roche-Singapore Advisory/Honorarium: Insys Therapeutics, Inc.; Vermillion, Inc. Speaker/Honorarium: Clovis Oncology, Inc. PI/Grant Funding: Ergomed Clinical Research Inc.(Aeterna Zentaris)
Monk, Bradley, MD		Researcher/Grant to Institution: Amgen; Genentech; Lilly; Array; TESARO; Morphotek; Janssen/Johnson&Johnson Speaker/Honorarium: Roche/Genentech; AstraZeneca; Myriad; Janssen/Johnson&Johnson Consultant/Consulting Fee: Merck; TESARO; Gradalis; Advaxis; Cerulean; Amgen; Vermillion; ImmunoGen; Bayer; NuCana; Insys; Clovis; Oxigene; Roche/Genentech; AstraZeneca; Pfizer
Movsas, Benjamin, MD		Investigator/Research Support: Varian, Inc.; Philips Inc.
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Nolte, Susan, PhD, CRNP	X	
O'Cearbhaill, Roisin, MD	X	
Raben, David, MD		Paid Consultant: AstraZeneca
Randall, Marcus, MD	X	
Ridge, John (Drew), MD, PhD, FACS	X	
Robidoux, Andre, MD		Advisory Board/Honorarium: Genomic Health; Novartis Ad Hoc Consultant: Pfizer
Romond, Edward, MD	X	
Rodgers, William, MD, PhD	X	
Safran, Howard, MD	X	
Sandler, Howard, MD		Speaker/Honorarium: Sanofi Consultant for clinical Trial/Consulting Fee: Janssen Medical Advisory Board/Consulting Fee: Ferring; Eviiti Mock ODAC/Consulting Fee: Clovis Oncology
Sartor, Oliver, MD		Research/Support: Tulane
Schilder, Russell, MD		Ad Hoc/Ad Board/Honorarium: MedImmune; Merck Serano; Clovis Chair/IDMC/Honorarium: Merck Serano
Shipley, William, MD	X	
Small, William, MD	X	

FACULTY DISCLOSURE LIST

Sohn, Jason, PhD	X	
Spirtos, Nicola, MD	X	
Stehman, Fred, MD	X	
Stockman, Sharon, BA, C-CRP	X	
Thomas, Alexandra, MS	X	
Thomas, Terry, MS, CCRC	X	
Trotti, Andy, MD	X	
Vicini, Frank, MD	X	
Vogelbaum, Michael, MD, PhD		Officer/Honorarium (optional): Infusion Therapeutics, Inc. DSMB Member/Honorarium: Neuralstem
Wenzel, Lari, PhD	X	
Werner-Wasik, Maria, MD	X	
White, Julia, MD		Speaker/Honorarium: Qfix
Wong, Stuart, MD	X	
Xiao, Ying, PhD	X	
Speaker Disclosures		
Abrams, Ross, MD	X	
Adelstein, David, MD	X	
Aghajanian, Carol, MD		Steering Committee Meeting/Honorarium: Oxigene
Alberts, David, MD		Consultant: INSYS Therapeutics
Alvarez, Ronald, MD		Ad Board/Honorarium: Clovis; CTisus Consultant/Honorarium: Unleash
Antonelli, Mary Jo, MBA	X	
Arthur, Doug, MD	X	
Bae-Jump, Victoria, MD, PhD	X	
Bahary, Jean-Paul, MD	X	
Bar-Ad, Voichita, MD	X	
Barton, Deb, RN, PhD	X	
Bauman, Julie, MD, MPH		Consultant/Honorarium: Incyte; Merck; Kolltan; EMD – Serono/Merck
Bae-Jump, Victoria, MD, PhD	X	
Bear, Harry, MD, PhD		Surveys/Ad Hoc/Honorarium: Genomic Health PI/Research Support: Genomic Health
Beaverson, Lisa	X	
Benedict, Stanley, PhD		Speaker/Travel Expenses: Eletra; Accuray Speaker/Honorarium: Accuray Speaker/Organizer/Honorarium: Astro Speaker/Organizer/Travel Expenses: AAPM/RSS
Ben-Josef, Edgar, MD	X	
Bialy, Sally	X	
Birrer, Michael, MD, PhD		Advisory Board/Honorarium: AstraZeneca; Roche Laboratories; Sanofi; Acceleron Pharma, Inc.; Immunogen
Blessing, John, PhD	X	
Blum, Joanne, MD, PhD, FACP		Consultant/Steering Committee Member for Clinical Trial/Honorarium: Medivation
Bodis, Stephan, MD	X	
Bookman, Michael, MD		Ad-hoc consultation for development of clinical trials using investigational agents/Travel, Meal, Time & Effort Reimbursement: AbbVie; Clovis; OxiGene; Endocyte; Immunogen; AstraZeneca; Genentech-Roche Independent Data Monitoring Committee/Reimbursement for time and effort: Immunogen
Boyle, Elaine, RN	X	
Bradley, Teresa, PhD	X	
Brinton, Louise, PhD	X	
Brown, Carol, MD	X	
Brown, Paul, MD	X	
Brown, Sally, RN, BSN, MGA	X	
Burger, Robert, MD		DSMB Service/Contractual Fee: Gradalis; Janssen; Morphotek Advisory Board/Honorarium: Invitae; NuCana; Clovis Oncology
Buyyounouski, Mark, MD	X	
Cahill, Daniel, MD	X	
Capala, Jacek, MSc., PhD	X	
Carter, Jeanne, PhD	X	
Caudell, James, MD, PhD	X	
Chakravarti, Arnab, MD	X	
Chang, Albert, MD, PhD	X	
Chase, Dana, MD		Speaker/Honorarium: Roche Consultant/Consulting Fee: Oxigene
Chen, Allen, MD	X	
Chen, Ronald, MD, MPH		PI/Research Grant: Accuray, Inc. Consultant/Consulting Fee: Medivation/Astellas
Chetty, Indrin, PhD		Sponsored Research: Philips Health Care; Best, Netherlands
Chmura, Steven, MD, PhD	X	
Chung, Christine, MD		Scientific Advisory Board/Honorarium: Eli Lilly; Vigilant BioSciences; AstraZeneca
Cohn, David, MD		Author/Honorarium: Up to Date Consultant/Salary: Oncology Analytics
Coleman, Robert, MD		Consulting: AbbVie; AstraZeneca; CritiTech, Inc.; Debiopharma; Genmab; ImmuoGen, Merck

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Corn, Benjamin, MD	X	
Covens, Allan, MD	X	Speaker/Honorarium: AstraZeneca; Roche; Merck
Covington, Laura	X	
Crane, Christopher, MD		Consultant/Honorarium: Vertex
Crane, Tracy, MS, RD	X	
Creasman, Bill, MD	X	
Dawson, Laura, MD		Co-Investigator/Co-Inventor/Honorarium: Ray Search
Delaney, Tom, MD	X	
DeNero, Lisa	X	
Denicoff, Andrea, MS, RN, ANP	X	
DeVries, Sandy	X	
Dicker, Adam, MD, PhD		Consultant/Honorarium: RedHill; Glenview; Janssen
DiSilvestro, Paul, MD	X	
Donington, Jessica, MD	X	
Eapen, Libni, MD	X	
Eaton, Sue, MD	X	
Edwards, Robert, MD	X	
Efstathiou, Jason, MD, PhD		Joint Safety Review Committee/Honorarium: Bayer Healthcare
Elgie, William	X	
Ellis, Matthew, MB, BCHIR, PhD		Ad Hoc Consultant/Honorarium: Nanostrins; Novartis; AstraZeneca; Pfizer Patent Holder/Royalty: Bioclassifier
Ellis, Rodney, MD		Speaker/Honorarium: Bayer Healthcare Pharmaceuticals Consultant/Per Diem: Radiadyne; Augmedix
Fakih, Marwan, MD		Speaker/Consultant/Honorarium: SIRTEX Consultant/Honorarium: Amgen
Feng, Felix, MD		Ad Board Member/Honorarium: Astellas/Medivation Grant Recipient/Grant Funding: Varian Founder/President/Ownership: PFS Genomics
Field, Erica	X	
Finnigan, Melanie	X	
Fleming, Gini, MD		Co-Investigator/Drugs for IIT DSMB: AstraZeneca
Followill, David, PhD	X	
Ford, Marvella, PhD	X	
Frank, Steven, MD		Consultant/Grant: Varian Grant Recipient/Honorarium: NIH/NCI Grant: POI; UIG Employee/Salary: MD Anderson Cancer Center Honorarium: IBA; Hitachi Ownership Interest/Stock: C4 Imaging
Fu, Yang-Xin, MD, PhD	X	
Fusco, Nancy, RN	X	
Ganz, Patricia, MD	X	
George, Thomas, MD, PhD		Consultant/Consultant Fees: New Links Genetics
Gershenson, David, MD		Ownership/Stock: Pfizer; Biogen; Celgene; Johnson & Johnson; Merck; Abbvie Author/Editor/Royalty: Up to Date; Elsevier AdHoc Advisory Board/Honorarium: Clovis Oncology Speaker/Honorarium: MDACC Medical Conference; Gyn Onc Canadian Specialty Meeting; Chemotherapy Foundation Symposium
Geyer, Charles, Jr., MD, FACP	X	
Gilbert, Mark, MD	X	
Gillison, Maura, MD		Consultant/Fee: Merck; BMS; Amgen
Goldstein, Desiree, RN, MSN, CCRC	X	
Golden, Encouse, MD	X	
Gomella, Leonard, MD		Advisory/Consulting Fee: Astellas; Janssen Advisory/Consulting: MDX; Bayer
Gondi, Viani, MD	X	
Grosshans, David, MD	X	
Hayes, Neil, MD, MPH		Founder/Board Member: GeneCentric Diagnostic
Hensley, Martee, MD		Spouse is employee/Salary: Sanofi Advisory Board/Honorarium: Janssen Author/Royalties: UpToDate
Hering, Martha	X	
Hodge, James, PhD	X	
Hong, Theodore, MD	X	
Hooper, D. Craig, PhD	X	
Horton, Janet, MD		PI/Research Funding: Varian Medical Systems
Hurwitz, Mark, MD	X	
Jeraj, Robert, PhD	X	
Joseph, Kathie-Ann, MD, MPH	X	
Julian, Thomas, MD	X	

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Kachnic, Lisa, MD	X	
Kauff, Noah, MD	X	
Khan, Shaka	X	
Kim-Suh, HeeSun, RN	X	
Klopp, Ann, MD, PhD	X	
Knudsen, Nancy, RN, BSN	X	
Koh, Wui-Jin, MD	X	
Konstantinopoulos, Panagiotis, MD, PhD		Scientific Engagement/Consultant/Honorarium: Merck
Kopetz, Scott, MD, PhD		Consultant/Honorarium: Amgen; Array Biopharma; Bayer Healthcare; Genentech; Merrimack
Kotsko, Kristen, RN, BSN	X	
Koss, Jerome, RN, BSN	X	
Kudchadker, Rajat, PhD, DABR	X	
Kuerer, Henry, MD, PhD		Research Funding: Genomic Health, Inc.
Lacy, Michele, RN, BSN	X	
Land, Stephanie, PhD	X	
Langer, Corey, MD		Institutional Grant/Research Support: BMS; ImClone Systems Inc.; Pfizer; Eli Lilly; Genentech; OSI Pharmaceuticals, Inc.; GSK; Clovis; Merck; Nektar; Advantagene; Inovio; Ariad Scientific Advisor: BMS; ImClone Systems Inc.; Pfizer; Eli Lilly; AstraZeneca; Novartis; Genentech; Bayer Healthcare Pharmaceuticals/Onyx; Abraxis Oncology (Celgene); Abbott Laboratories; Biodesix; Clariant; CarisDx; ARIAD Pharmaceuticals, Inc.; Boehringer Ingelheim; Synta; Clovis DSMC Member: Amgen; Synta; Peregrine; SWOG; Incyte CME: PIK; PED; NOCR; CCO; RTP
Lankes, Heather, PhD, MPH	X	
Le, Quynh-Thu, MD, FACR, FASTRO	X	
Leal, Debra	X	
Lee, James, MD, PhD		Advisory Committee/Honorarium: Genentech
Liao, ZhongXing, MD	X	
Licavoli, Cindy, RN, BSN, MA	X	
Lichtman, Stuart, MD	X	
Lin, Steven, MD		Honorarium: AstraZeneca Grant/Research: Peregrine Pharmaceuticals
Lipscomb, Joe, PhD	X	
Liu, Joyce, MD, MPH		Speaker/Consultant/Honorarium/Fee: AstraZeneca Consultant/Fee: Genentech
Liu, Tian, PhD	X	
Lu, Bo, MD, PhD	X	
Macdonald, Shannon, MD	X	
Machtay, Mitchell, MD		Research Funding: Abbvie; Stemnion
Magliocco, Anthony, MD		Consultant/Travel/Honorarium: DiaCarta; Circulogene; Ventana Medical Systems; BioTheragnostics; Guardant Health; BNS; Sequenom, Inc.; Canadian Breast Cancer Foundation; Quality Star Advisory Board Member/Travel/Honorarium: Novartis Board Member/Travel/Honorarium: NRG Oncology Consultant/Speaker/Honorarium/Travel : Illumina Consultant/Honorarium: Genoptix; BioNest; Janssen Diagnostics, LLC Speaker/Travel/Honorarium: Definiens' International; Association of Pathology Chairs
Maitly, Amit, MD, PhD		PI of Trial: Merck
Mamounas, Eleftherios "Terry", MD		Speaker/Advisor/Honorarium: Genomic Health, Inc.; Genentech Advisor/Honorarium: Novartis; Celgene; Biotheranostics; Pfizer; Bayer
Mannel, Robert, MD		Ad Board/Honorarium: Endocyte; Clovis; GOG
Matuszak, Martha, PhD		PI/Research Grant: Varian
Maxwell, Larry, MD, FACOG, COL(ret)	X	
Mayadev, Jyoti, MD	X	
Mehta, Minesh, MB, ChB, FASTRO		Consultant/Consulting Fee: Varian DSMB/Board Fee: Monteris
Michaelson, Dror, MD, PhD		Advisory Board/Honorarium: Medivation; Pfizer; Novartis; Exelixis
Michalski, Jeff, MD	X	
Miller, David, MD		Advisory/Speaker/Honorarium: Genentech Consultant/Honorarium: Janssen Grants/Consultant/Honorarium: AstraZeneca Speaker/Consultant/Honorarium: Roche-Singapore Advisory/Honorarium: Insys Therapeutics, Inc.; Vermillion, Inc. Speaker/Honorarium: Clovis Oncology, Inc. PI/Grant Funding: Ergomed Clinical Research Inc.(Aeterna Zentaris)
Monk, Bradley, MD		Researcher/Grant to Institution: Amgen; Genentech; Lilly; Array; TESARO; Morphotek; Janssen/Johnson&Johnson Speaker/Honorarium: Roche/Genentech; AstraZeneca; Myriad; Janssen/Johnson&Johnson Consultant/Consulting Fee: Merck; TESARO; Gradalis; Advaxis; Cerulean; Amgen; Vermillion; ImmunoGen; Bayer; NuCana; Insys; Clovis; Oxigene; Roche/Genentech; AstraZeneca; Pfizer
Moore, Kathleen, MD		Ad Board/Honorarium: AstraZeneca; Clovis; Immunogen; Genentech/Roche; Merrimack
Movsas, Benjamin, MD		Investigator/Research Support: Varian, Inc.; Philips Inc.
Mutch, David, MD		Honorarium: AstraZeneca
Neading, Joyce, MS, CCRC	X	

FACULTY DISCLOSURE LIST

Nichols, Elizabeth, MD	X	
Nolte, Susan, PhD, CRNP	X	
Norquist, Barbara, MD	X	
O'Cearbhaill, Roisin, MD	X	
Ohri, Nitin, MD	X	
Oleszewski, Karen, RN, MSN, AOCN		Employer/Salary: Genentech
Parker, William, PhD	X	
Plaxe, Steven, MD		Equity Holder: Abbot Labs
Powell, Matthew, MD		Speaker/Consultant/Honorarium: Genentech/Roche Speaker/Honorarium: AstraZeneca
Raben, David, MD		Paid Consultant: AstraZeneca
Ramirez, Ezequiel, LPC	X	
Ramirez, Nilsa, MD	X	
Randall, Marcus, MD	X	
Rastogi, Priya, MD	X	
Ridge, John (Drew), MD, PhD, FACS	X	
Ritzwoller, Debra, PhD	X	
Roach, Mack, III, MD		Consultant/Honorarium: Accuray; Janssen (Johnson & Johnson); Bayer Consultant/Honorarium/Consulting Fees: Ferring Pharma
Robidoux, Andre, MD		Advisory Board/Honorarium: Genomic Health; Novartis Ad Hoc Consultant: Pfizer
Rodgers, William, MD, PhD	X	
Romond, Edward, MD	X	
Rosen, Mark, MD	X	
Rosenthal, David, MD		Ad Board/Research/Honorarium/Support: Merck Serano
Safran, Howard, MD	X	
Salama, Joseph, MD		PI – Clinical Trial/Research Support: AbbVie; BMS; Merck; Genentech; Celldex; Immunocore; Reata Pharmaceuticals
Sandler, Howard, MD		Speaker/Honorarium: Sanofi Consultant for clinical Trial/Consulting Fee: Janssen Medical Advisory Board/Consulting Fee: Ferring; Eviti Mock ODAC/Consulting Fee: Clovis Oncology
Sartor, Oliver, MD		Grant/Research Support: Tulane
Schilder, Russell, MD		Ad Hoc/Ad Board/Honorarium: MedImmune; Merck Serano; Clovis Chair/IDMC/Honorarium: Merck Serano
Schmitz, Katheryn, PhD, MPH	X	
Schink, Julian, MD	X	
Shaitelman, Simona, MD		Grant: Elekta Consultant: MD Anderson Physician's Network
Sherman, Eric, MD		Consultant/Consulting Fee: Eisai; BMS; Loxo Oncology
Shiple, William, MD		Stock Ownership: Pfizer; Genomics Dx
Sikov, William, MD, FACP		Speaker/Honorarium: Eisai Advisory Board Member/Honorarium: Abbvie
Simone, Charles, MD	X	
Small, William, MD	X	
Smith, Judith, PharmD	X	
Snyder, Alexandra, MD		Speaker/Honorarium: Merck; BMS; Syndax
Sohn, Jason, PhD	X	
Sood, Anil, MD	X	
Spirtos, Nicola, MD	X	
Stehman, Fred, MD	X	
Stockman, Sharon, BA, C-CRP	X	
Suhayda, Lynne, RN, MSEd	X	
Taylor, Paige, MS	X	
Tewari, Krishansu, MD		Speaker/Consultant/Honorarium: Genentech/Roche Consultant/Honorarium: Clovis Speaker/Honorarium: AstraZeneca
Thomas, Alexandra, MS	X	
Thomas, Terry, MS, CCRC	X	
Timmerman, Robert, MD		PI of Clinical Trial/Grant Research: Varian Medical Systems; Accuray, Inc.; Elekta Oncology
Torres, Mylin, MD	X	
Tremaine, Troy		Director/Salary/Stock/Health: MyRIAD - RBM
Trotti, Andy, MD	X	
Tsien, Christina, MD		Speaker/Honorarium: Merck
Ulin, Ken, PhD	X	
Vicini, Frank, MD	X	
Vicus, Danielle, MD	X	
Videtic, Greg, MD	X	
Vogelbaum, Michael, MD, PhD		Officer/Honorarium (optional): Infusion Therapeutics, Inc. DSMB Member/Honorarium: Neuralstem
Wapnir, Irene, MD	X	
Wenzel, Lari, PhD	X	
Werner-Wasik, Maria, MD	X	
White, Julia, MD		Speaker/Honorarium: Qfix
Whitney, Charles, MD	X	
Wolmark, Norman, MD	X	

FACULTY DISCLOSURE LIST

Wong, Phil, MD	X	
Wong, Stuart, MD	X	
Woodward, Wendy, MD, PhD	X	
Xia, Ping, PhD		Speaker/Honorarium: Philips PI/Research Grant: Philips
Xiao, Ying, PhD	X	
Yang, Eddie, MD, PhD		Principal Investigator/Research Support: Eli Lilly & Co. Advisory Board/Honorarium: Bayer Advisory Board/Consultant/Honorarium: Nanostring Technologies
Ybarra, Cathi, RN	X	
Yom, Sue, MD, PhD		PI/Clinical Trail Funding: Genentech PI/Drug for preclinical: Clinigen Author/UpToDate: Royalties
Yuan, Jianda, MD, PhD		Employee: Merck & Co., Inc.
Educational Planning Committee		
Alvarez, Ronald D., MD (Chair)		Ad Board/Honorarium: Clovis; CTisus Consultant/Honorarium: Unleash
Farley, John, MD (Member)		Speaker Bureau/Honorarium: Genentech
Horowitz, Neil, MD (Member)	X	
Mackey, Denise (Staff)	X	
Reese, Jill (Staff)	X	
Sharp, Mary (Staff)	X	
Shumaker, Lauren (Staff)	X	
Small, Michelle (Staff)	X	
Stehman, Frederick, MD (Vice Chair)	X	
Tew, William, MD (Member)	X	

LAS – 06/23/16

Welcome!

It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Dallas, Texas, July 14 - 17, 2016.

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, "**Endometrial Cancer: The Future of Targeted Therapy**," with noted oncologists and scientists serving as speakers and moderators. The speakers will focus their presentations on the mechanism by which cancer escapes the immune system. Presentations will also be focused on current and future strategies developing immunotherapies that address such mechanisms for good clinical outcomes.
- An educational session designed for clinical trial nurses and clinical research associates will take place on Thursday.
- NRG Oncology research achievements will be featured during Friday's Scientific Session, "**NRG Oncology Research Review**," which will highlight the results of recently reported results in breast, head and neck, prostate and gynecologic cancers.
- A workshop entitled "**Cultural Competency in Clinical Trials**" sponsored by the Health Disparities Committee will be held on Friday.

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 NRG Oncology's research potential and invite your input about how we can make future meetings as meaningful and productive as possible. Welcome to Dallas!

Sincerely,



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

A handwritten signature in black ink that reads "Walter J. Curran, Jr., MD".



Philip J. DiSaia, MD
NRG Oncology Group Chair

A handwritten signature in black ink that reads "Philip J. DiSaia, M.D.".



Norman Wolmark, MD
NRG Oncology Group Chair

A handwritten signature in black ink that reads "Norman Wolmark".

NRG ONCOLOGY MISSION STATEMENT

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

FOR THE EDUCATIONAL OBJECTIVES, WE LIST THE FOLLOWING:

1. Inform the participants of the current state of clinical and basic oncologic research, particularly, but not exclusively as it relates to clinical trials.
2. Provide participants with peer review critiques of progress (or lack of it) with the objective of self-improvement.
3. Provide an opportunity to learn research administration and financial management in a cooperative group setting.
4. 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 included in this program.



ACCREDITATION /CME 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.



Continuing Medical Education Program

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

THE GOG FOUNDATION, INC. CONTINUING MEDICAL EDUCATION (CME) PROGRAM MISSION

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

Sign-in sheets are located outside each session that receives CME credit and must be signed as you enter the workshop session. Sign-in sheets will be collected 30 minutes after the start of the session.

EVALUATIONS/CME CERTIFICATES

Overall evaluations are included in 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. (GYN symposium will not be included in the total) Correct email must be included on registration form.

NO EVALUATIONS WILL BE ACCEPTED AFTER: August 28, 2016

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.

For questions or comments about this CME activity, please contact :

Michelle N. Small, Director, Education Programs and 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 Dallas, TX July 14-16, 2016 - AMA PRA Category 1 credits™

GYN Symposium -

Workshop/Session Agendas

Audit Training Workshop

Brain Tumor Workshop

Breast Cancer Workshop

Breast Cancer Rare and Genetically Linked Subcommittee workshop

Canadian Members Workshop

Cancer Care Delivery Research Session

Cancer Prevention and Control Workshop

Cervix Cancer Workshop

Cultural Competency Workshop

Gastrointestinal Cancer Workshop

GOG 0225 Information Session (CPC)

Genitourinary Cancer Workshop

GYN Developmental Therapeutics Workshop

GYN Dev. Therapeutics/Phase I/Translational Science

GYN Protocol Development Workshop

Head and Neck Cancer Workshop

International Members Workshop

Medical Oncology Workshop

Medical Physics Workshop

Local Regional Breast Cancer

NRG Scientific Session-----TICKETED

Ovarian Workshop

Pathology Workshop

Patient Centered Outcomes Research (PCOR)

Proton Working Group Workshop

Radiation-Developmental Therapeutics Workshop

Radiation Oncology Workshop

Rare Tumor Workshop

NRG Surgical Oncology Workshop

Translational Science Workshop

Translational Science GYN Workshop

Translational Science Lung Cancer Subcommittee Workshop

Uterine Corpus Workshop

PROTOCOL SUPPORT WORKSHOPS – Certificate of Attendance to all non-MD's

CTN/CRA Breakout Sessions

Clinical Trial Nurse Subcommittee (Closed)

Clinical Research Assoc Subcommittee (Closed)

Clinical Trial Nurse / Clinical Research Assoc Ed Workshop

Education & Training (Closed)

Mentorship Working Group (Closed)

Quality Control Working Group (Closed)

Protocol Review Working Group (Closed)



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NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA
 Sheraton Dallas Hotel
 Dallas, Texas
 July 14 – 16, 2016

Thursday, July 14, 2016		
6:30 am – 8:30 am	Symposium Breakfast	Dallas D/Conference Center – 1 st Fl.
7:00 am – 6:00 pm	Registration/CME/Information Desk	Grand Hall/Conference Center – 1 st Fl.
9:45 am – 10:00 am	Symposium Coffee Break	Dallas D/Conference Center – 1 st Fl.
11:45 am – 1:00 pm	Symposium Lunch	Dallas D/Conference Center – 1 st Fl.
2:00 pm – 6:00 pm	IT Resource Room/Internet Café	Press Club/Main Building – 2 nd Fl.
4:00 pm – 6:00 pm	Exhibit Setup	Grand Hall/Conference Center – 1 st Fl.
8:00 am – 12:00 pm	Imaging and Radiation Oncology Core (IROC) RT Focused Staff Meeting *	State Room 1/Conference Center – 3 rd Fl.
8:00 am – 2:30 pm	Summer Symposium - "Endometrial Cancer: The Future of Targeted Therapy"	Dallas A/Conference Center - 1 st Fl.
8:00 am – 5:00 pm	GYN Chart Review *	Pearl 2/Main Building – 2 nd Fl.
9:00 am – 12:00 pm	NRG DMC Panel A *	State Room 2/Conference Center - 3 rd Fl.
9:00 am – 1:00 pm	SOCRA Certification Exam	Majestic 1/Main Building – 37 th Fl.
1:00 pm – 2:00 pm	VisionTree Workshop	Majestic 1/Main Building – 37 th Fl.
1:00 pm – 4:00 pm	NRG DMC Panel B *	State Room 2/Conference Center - 3 rd Fl.
1:00 pm – 5:00 pm	Clinical Trial Nurse/Clinical Research Associate Workshop - Educational Session	Dallas BC/Conference Center – 1 st Fl.
2:00 pm – 4:00 pm	Immunotherapy and Immune Modulation Workshop	San Antonio AB/Conference Center – 3 rd Fl.
2:30 pm – 4:00 pm	Cost Effectiveness Research (CER) Committee *	State Room 4/Conference Center – 3 rd Fl.
3:00 pm – 5:00 pm	NRG-Harvard-Ohio State-Case Western R01 Grant Meeting *	State Room 1/Conference Center – 3 rd Fl.
4:00 pm – 6:00 pm	GYN Developmental Therapeutics/Phase 1/Translational Science Workshops	Dallas A2-A3/Conference Center - 1 st Fl.
4:00 pm – 6:00 pm	Patient Centered Outcomes Research (PCOR) Workshop	San Antonio AB/Conference Center – 3 rd Fl.
5:00 pm – 6:30 pm	Clinical Trial Nurse Subcommittee *	State Room 2/Conference Center – 3 rd Fl.
5:00 pm – 6:30 pm	Clinical Research Associate Subcommittee *	State Room 4/Conference Center – 3 rd Fl.
6:00 pm – 8:00 pm	NCORP Concept Review (<i>Invitation Only</i>)	Dallas A1/Conference Center - 1 st Fl.
7:00 pm – 9:00 pm	Ancillary Projects Committee *	Houston C/Conference Center – 3 rd Fl.

Revised 6/23/16

*Sessions for Committee Member



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**NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA**
Sheraton Dallas Hotel
Dallas, Texas
July 14 – 16, 2016

Friday, July 15, 2016		
6:30 am – 8:30 am	Continental Breakfast	Grand Hall/Conference Center – 1 st Fl.
7:00 am – 5:00 pm	Exhibits	Grand Hall/Conference Center – 1 st Fl.
7:00 am – 6:00 pm	Registration/CME/Information Desk	Grand Hall/Conference Center – 1 st Fl.
7:00 am – 6:00 pm	IT Resource Room/Internet Café	Press Club/Main Building – 2 nd Fl.
10:00 am – 10:30 am	General Coffee Break	Grand Hall/Conference Center – 1 st Fl.
2:00 pm – 3:30 pm	General Coffee Break	Grand Hall/Conference Center – 1 st Fl.
7:00 am – 8:00 am	NRG Radiomics Bioinformatics Working Group	Lone Star C3/Conference Center – 2 nd Fl.
7:00 am – 8:00 am	GYN GTD Subcommittee	Houston C/Conference Center – 3 rd Fl.
7:00 am – 8:00 am	GYN PDC Executive Session *	State Room 1/Conference Center – 3 rd Fl.
7:00 am – 9:00 am	Protocol 210 Subcommittee	Majestic 5/Main Building – 37 th Fl.
7:00 am – 9:00 am	PSC Working Groups *	State Rooms 2,3,4/Conference Center – 3 rd Fl. & Trinity 1/Main Building – 3 rd Fl.
7:00 am – 12:00 pm	GYN/RT Case Review	Press Club/Main Building – 2 nd Fl.
8:00 am – 9:00 am	NRG SDMC Executive Committee *	State Room 1/Conference Center – 3 rd Fl.
8:00 am – 10:00 am	Ovarian Cancer Workshop	Lone Star A1-A3/Conference Center – 2 nd Fl.
8:00 am – 10:00 am	Scientific Session – <i>NRG Oncology Research Review</i>	Lone Star B/Conference Center – 2 nd Fl.
8:00 am – 10:00 am	Sarcoma Working Group	San Antonio B/Conference Center – 3 rd Fl.
8:00 am – 5:00 pm	GYN Chart Review *	Pearl 2/Main Building – 2 nd Fl.
8:00 am – 5:00 pm	Pathology Workshop & Review	Houston A/Conference Center – 3 rd Fl.
9:00 am – 10:00 am	Low-Grade Glioma Working Group *	Dallas A3/Conference Center – 1 st Fl.
10:00 am – 11:00 am	International Members Meeting	Lone Star C3/Conference Center – 2 nd Fl.
10:00 am – 11:30 am	Translational Science Brain Cancer Subcommittee *	Dallas A3/Conference Center – 1 st Fl.
10:00 am – 11:30 am	Publications Committee *	Trinity 1/Main Building – 3 rd Fl.
10:00 am – 12:00 pm	NRG-GY004 and NRG-GY005 Investigators Meeting	Dallas D3/Conference Center – 1 st Fl.
10:00 am – 12:00 pm	Functional Imaging Working Group	Lone Star C4/Conference Center – 2 nd Fl.
10:00 am – 12:00 pm	Cervix Cancer Workshop	Lone Star A1-A3/Conference Center – 2 nd Fl.
10:00 am – 12:00 pm	Audit Training Workshop	Lone Star A4/Conference Center – 2 nd Fl.
11:00 am – 12:00 pm	Protocol 225 Information Session	Houston B/Conference Center – 3 rd Fl.
11:00 am – 12:00 pm	Local Regional Breast Cancer Subcommittee *	State Room 3/Conference Center - 3 rd Fl.
11:00 am – 12:00 pm	Rare Breast Cancer Subcommittee *	San Antonio B/Conference Center – 3 rd Fl.
11:00 am – 12:30 pm	Immunotherapy and Immune Modulation Workshop	Lone Star C1/Conference Center – 2 nd Fl.
11:00 am – 1:00 pm	Neurosurgical Subcommittee	Majestic 2/Main Building – 37 th Fl.
11:00 am – 1:00 pm	Elderly Working Group	Lone Star C3/Conference Center – 2 nd Fl.

Revised 6/23/16

*Sessions for Committee Member



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NRG ONCOLOGY SEMIANNUAL MEETING

FINAL AGENDA

Sheraton Dallas Hotel

Dallas, Texas

July 14 – 16, 2016

Friday, July 15, 2016		
11:00 am – 1:00 pm	Cultural Competence Workshop	Dallas B/Conference Center – 1 st Fl.
11:00 am – 1:00 pm	NRG Oncology Foundation Board of Directors *	Majestic 5/Main Building – 37 th Fl.
11:30 am – 1:00 pm	Cancer Care Delivery Research Session Workshop	Dallas A1-A2/Conference Center – 1 st Fl.
12:00 pm – 1:00 pm	Pathology Committee *	Houston A/Conference Center – 3 rd Fl.
1:00 pm – 2:00 pm	NRG Oncology General Session	Lone Star B/Conference Center – 2 nd Fl.
2:00 pm – 3:00 pm	Communications Committee *	Trinity 1/Main Building – 3 rd Fl.
2:00 pm – 3:00 pm	New Investigators Committee	Houston B/Conference Center – 3 rd Fl.
2:00 pm – 3:00 pm	Translational Science Head & Neck Cancer Subcommittee	Dallas A3/Conference Center – 1 st Fl.
2:00 pm – 3:30 pm	Translational Science Breast Cancer Subcommittee	Dallas A1-A2/Conference Center – 1 st Fl.
2:00 pm – 4:00 pm	Translational Science GYN Subcommittee	Houston C/Conference Center – 3 rd Fl.
2:00 pm – 4:00 pm	Translational Science GU Cancer Subcommittee	Lone Star C3/Conference Center – 2 nd Fl.
2:00 pm – 4:00 pm	Rare Tumor Workshop	Lone Star C2/Conference Center – 2 nd Fl.
2:00 pm – 4:00 pm	Radiation Oncology Workshop	Lone Star A4/Conference Center – 2 nd Fl.
2:00 pm – 5:00 pm	Brain Tumor Core Committee *	Dallas B/Conference Center – 1 st Fl.
2:00 pm – 6:00 pm	CTN/CRA Breakout Session	Majestic 2,3,4,8/Main Building – 37 th Fl.
2:30 pm – 4:30 pm	Uterine Corpus Cancer Workshop	Lone Star A1-A3/Conference Center – 2 nd Fl.
2:30 pm – 5:30 pm	Cancer Prevention and Control Workshop	Lone Star C1/Conference Center – 2 nd Fl.
3:00 pm – 5:00 pm	Health Disparities Committee	Lone Star C4/Conference Center – 2 nd Fl.
3:00 pm – 6:00 pm	Head & Neck Cancer Core Committee *	San Antonio A/Conference Center – 3 rd Fl.
4:00 pm – 5:00 pm	NRG Oncology Human Research Committee *	State Room 4/Conference Center – 3 rd Fl.
4:00 pm – 6:00 pm	Medical Physics Workshop	San Antonio B/Conference Center – 3 rd Fl.
4:00 pm – 6:00 pm	Translational Science Lung Cancer Subcommittee	Houston B/Conference Center – 3 rd Fl.
4:00 pm – 6:00 pm	Genitourinary Cancer Core Committee *	Lone Star C3/Conference Center – 2 nd Fl.
4:00 pm – 7:00 pm	Breast Cancer Working Group *	Dallas A1-A2/Conference Center – 1 st Fl.
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group Meeting	Majestic 5/Main Building – 37 th Fl.
5:00 pm – 7:00 pm	Brain Tumor Workshop	Dallas B/Conference Center – 1 st Fl.
6:00 pm – 8:00 pm	NRG Oncology Welcome Reception	Lone Star B/Conference Center – 2 nd Fl.
7:00 pm – 8:30 pm	NRG Oncology Japan Meeting	State Room 1/Conference Center – 3 rd Fl.

Revised 6/23/16

*Sessions for Committee Member



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NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA
 Sheraton Dallas Hotel
 Dallas, Texas
 July 14 – 16, 2016

Saturday, July 16, 2016		
6:30 am – 8:30 am	Continental Breakfast	Grand Hall/Conference Center – 1 st Fl.
7:00 am – 1:00 pm	IT Resource Room/Internet Café	Press Club/Main Building – 2 nd Fl.
7:00 am – 4:00 pm	Exhibits	Grand Hall/Conference Center – 1 st Fl.
7:00 am – 5:00 pm	Registration/CME/Information Desk	Grand Hall/Conference Center – 1 st Fl.
10:00 am – 11:00 am	General Coffee Break	Grand Hall/Conference Center – 1 st Fl.
2:00 pm – 3:30 pm	General Coffee Break	Grand Hall/Conference Center – 1 st Fl.
6:30 am – 8:00 am	Surgical Oncology Workshop	Lone Star A4/Conference Center – 2 nd Fl.
6:45 am – 8:30 am	Proton Working Group Workshop	Lone Star A1/Conference Center – 2 nd Fl.
7:00 am – 8:00 am	NRG SDMC Data Management Working Group *	Cityview 8/Main Building – 4 th Fl.
7:00 am – 8:00 am	NRG SDMC IT Working Group *	State Room 3/Conference Center - 3 rd Fl.
7:00 am – 8:00 am	NRG SDMC Statistical Working Group *	State Room 4/Conference Center – 3 rd Fl.
7:00 am – 8:00 am	Medical Oncology Workshop	San Antonio A/Conference Center – 3 rd Fl.
7:00 am – 9:00 am	GI Colorectal Cancer Subcommittee *	Lone Star C3-C4/Conference Center – 2 nd Fl.
8:00 am – 9:30 am	Safety Review Committee *	State Room 2/Conference Center – 3 rd Fl.
8:00 am – 10:00 am	NCORP PI & Administrators Meeting	San Antonio A/Conference Center – 3 rd Fl.
8:00 am – 10:00 am	Developmental Therapeutics/Phase I Workshops	Lone Star A2-A3/Conference Center – 2 nd Fl.
8:00 am – 10:00 am	Genitourinary Cancer Workshop	Dallas A3/Conference Center – 1 st Fl.
8:00 am – 10:00 am	Lung Cancer Core Committee *	San Antonio B/Conference Center – 3 rd Fl.
8:00 am – 5:00 pm	GYN Chart Review *	Pearl 2/Main Building – 2 nd Fl.
9:00 am – 10:00 am	Quality Assurance Audit Meeting *	State Room 3/Conference Center - 3 rd Fl.
9:00 am – 11:00 am	GI Non-Colorectal Cancer Subcommittee *	Lone Star C3-C4/Conference Center – 2 nd Fl.
9:00 am – 1:00 pm	Breast Cancer Workshop	Lone Star C1-C2/Conference Center – 2 nd Fl.
10:00 am – 11:00 am	Ovarian Cancer Workshop	Lone Star A2-A3/Conference Center – 2 nd Fl.
10:00 am – 11:00 am	Cervix Cancer Workshop	Dallas B/Conference Center – 1 st Fl.
10:00 am - 11:00 am	Uterine Corpus Cancer Workshop	Dallas C/Conference Center – 1 st Fl.
10:00 am – 11:30 am	Membership Committee *	State Room 4/Conference Center – 3 rd Fl.
10:00 am – 12:00 pm	Radiation-Developmental Therapeutics Workshop	Lone Star A4/Conference Center – 2 nd Fl.
10:00 am – 12:00 pm	Protocol Support Committee Business Meeting *	Cityview 8/Main Building – 4 th Fl.

Revised 6/23/16

*Sessions for Committee Member



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**NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA**
Sheraton Dallas Hotel
Dallas, Texas
July 14 – 16, 2016

Saturday, July 16, 2016		
10:00 am – 12:00 pm	Protocol 225 Workshop	Majestic 1/Main Building – 37 th Fl.
10:00 am – 12:00 pm	Protocol 0199 Subcommittee Meeting *	San Antonio B/Conference Center – 3 rd Fl.
10:00 am – 12:00 pm	Translational Science Workshop	Lone Star A1/Conference Center – 2 nd Fl.
10:00 am – 12:00 pm	Head & Neck Cancer Workshop	Dallas A3/Conference Center – 1 st Fl.
11:00 am – 12:00 pm	GYN Operations Committee	Dallas B/Conference Center – 1 st Fl.
11:00 am – 1:00 pm	Translational Science GI Cancer Subcommittee	Lone Star C3-C4/Conference Center – 2 nd Fl.
12:00 pm – 1:00 pm	Patient Advocates Meeting *	State Room 3/Conference Center - 3 rd Fl.
12:00 pm – 1:00 pm	Voting Members PI Meeting *	Houston A/Conference Center – 3 rd Fl.
1:30 pm – 3:00 pm	GYN Protocol Development Workshop	Dallas C/Conference Center – 1 st Fl.
1:30 pm – 3:30 pm	Gastrointestinal Cancer Workshop	Lone Star C1-C2/Conference Center – 2 nd Fl.
1:30 pm – 3:30 pm	Lung Cancer Workshop	Dallas A3/Conference Center – 1 st Fl.
2:00 pm – 3:00 pm	Canadian Members Meeting	Majestic 1/Main Building – 37 th Fl.
2:00 pm – 3:00 pm	VA/MTF Meeting	San Antonio B/Conference Center – 3 rd Fl.
3:30 pm – 6:00 pm	Research Strategy Meeting *	Dallas B/Conference Center – 1 st Fl.

Revised 6/23/16

**Sessions for Committee Member*

Information Technology Resource Center

**NRG Semi-Annual
Meeting
Dallas, TX
July 14-16, 2016**

**Sheraton Dallas Hotel
The Press Club
2nd Floor – Main Building**

**Open
Thur. Jul 14: 2PM -6PM
Fri. Jul 15: 7AM-6PM
Sat. Jul 16: 7AM-1PM**

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<http://www.nrgoncology.org>



The Resource Center will feature:

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

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

Available services include:

- ❑ Internet Access
- ❑ Email
- ❑ Printing

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

NRG Scientific Session - NRG Oncology Research Review

Date: Friday, July 15, 2016
Start and End Time: 8:00 am – 10:00 am
Co-Chairs: Deborah Bruner, PhD; Fred Stehman, MD; Maria Werner Wasik, MD
Moderator: Maria Werner Wasik, MD

Learning Objectives:

Following this activity, participants will be better able to:

- Describe the NCI's National Clinical Trial Network (NCTN) Study Champion Program and its implementation.
1. Describe the findings of the recent interim analysis conducted on the multi-arm phase II NCI-MATCH precision medicine cancer trial that defines patient eligibility by molecular characteristics of the tumor rather than tumor type, and explain the changes made to the trial as a result of the analysis
 2. Discuss the interim joint analysis of the ABC (anthracyclines in early breast cancer) phase III trials comparing docetaxel + cyclophosphamide (TC) v anthracycline/taxane-based chemotherapy regimens (TaxAC) in women with high-risk, HER2-negative breast cancer.
 3. Discuss the role of anti-androgen therapy (AAT) with bicalutamide during and after salvage radiation therapy (RT) following radical prostatectomy (RP) and an elevated PSA for prostate cancer patients.
 4. Describe mutations in homologous recombination genes and response to treatment as found in GOG 218.
 5. Identify the correlation between the severity of cetuximab-induced skin rash and clinical outcome for head and neck cancer patients

WORKSHOP AGENDA

8:00 – 8:05 am	Welcome	Maria Werner-Wasik, MD
8:05 – 8:20 am	NCI's National Clinical Trial Network (NCTN) Study Champion Program and Implementation	Andrea Denicoff, MS, RN, ANP
8:20 – 8:39 am	Interim analysis results of the NCI's Molecular Analysis for Therapy Choice (NCI-MATCH) Trial	Eddy S. Yang, MD, PhD
8:39-8:44 am	Questions	
8:44 – 8:59 am	Interim joint analysis of the ABC (anthracyclines in early breast cancer) phase III trials (USOR 06-090, NSABP B-46I/USOR 07132, NSABP B-49 [NRG Oncology]) comparing docetaxel + cyclophosphamide (TC) v anthracycline/taxane-based chemotherapy regimens (TaxAC) in women with high-risk, HER2-negative breast cancer.	Joanne L Blum, MD
8:59 – 9:07 am	Discussant & Questions	William Sikov, MD
9:07 – 9:22 am	NRG Oncology/RTOG 9601, a phase III trial in prostate cancer patients: Anti-androgen therapy (AAT) with bicalutamide during and after salvage radiation therapy (RT) following radical prostatectomy (RP) and an elevated PSA.	William Shipley
9:22 – 9:30 am	Discussant-Questions	Mark Buyyounouski, MD
9:30 – 9:45 am	Mutations in homologous recombination genes and response to treatment in GOG 218: An NRG Oncology study.	Barbara Norquist
	Questions	
9:45 – 10:00 am	Correlation between the severity of cetuximab-induced skin rash and clinical outcome for head and neck cancer patients: The NRG Oncology RTOG experience.	Voichita Bar-Ad, MD
	Questions	



WELCOME TO DALLAS!

Please join us at the

NRG Oncology Welcome Reception

Friday, July 15, 2016 - 6 pm - 8 pm

Lone Star B



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Advancing Research. Improving Lives.

NRG Oncology General Session
Friday, July 15, 2016
1:00 pm–2:00 pm
Lone Star B, Conference Center 2nd Floor

Opening

Philip J. DiSaia, MD
NRG Oncology Presiding Group Chair

Welcome to Dallas
University of Texas Southwestern
Medical Center: Drs. Choy and Miller

Hak Choy, MD
Nancy B. & Jake L. Hamon Distinguished
Chair in Therapeutic Oncology Research
Professor & Chairman of Radiation Oncology

David Scott Miller, MD, FACOG, FACS
Director & Dallas Foundation Chair in
Gynecologic Oncology
Amy and Vernon E. Faulconer Distinguished Chair in
Medical Science
Professor of Obstetrics & Gynecology
University of Texas Southwestern Medical Center

Q & A Session for the NCTN Recompetition:
Drs. Abrams, Mooney, Jaffe

Jeffrey S. Abrams, MD
Acting Director, Clinical Research, DCTD
Associate Director, NIH NCI CTEP

Margaret Mooney, MD, MBA
Branch Chief, CIB, NIH NCI CTEP DCTD

Deborah Jaffe, PhD
Program Director, Coordinating Center for
Clinical Trials, NIH NCI OD

NCI NCTN Core Correlative Sciences
Committee (CCSC)

Elise C. Kohn, MD
CIB, NIH NCI CTEP DCTD

Joan K. Mauer Memorial Quality Assurance
Award Presentation

Margaret Mooney, MD, MBA
Branch Chief
CIB, NIH NCI CTEP DCTD

**2016 Top Accruing Institutions/
Membership Update**

D. Lawrence Wickerham, MD
NRG Oncology
Deputy Group Chair for Membership

Closing Remarks

Philip J. DiSaia, MD
NRG Oncology Presiding Group Chair

CME WORKSHOPS

.....All workshops are in alphabetical order.

NRG
ONCOLOGY

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Audit Training Workshop Agenda

Date: Friday, July 15, 2016
Start and End Time: 10:00 am – 12:00 pm
Chairs: John A. Blessing, Elaine Boyle, Tamara Mc Laughlin, Sally Bialy, Jerry Koss

Learning Objectives:

Following this activity, participants will be better able to:

1. Identify NRG philosophy regarding the educational aspects of NRG Oncology Quality Assurance Audits;
2. Prepare for a successful audit;
3. Become familiarized with Quality Assurance Audit conduct;
4. Discuss evaluation of audits and be able to prepare a comprehensive Corrective Action Plan (where indicated);
5. Identify frequently encountered deficiencies and how to avoid them.

WORKSHOP AGENDA

Session I

- A. Introduction to NRG Quality Assurance Audits;
- B. NRG Audit Philosophy;
- C. Preparation for audits;
- D. Audit conduct;
- E. Avoiding frequently encountered deficiencies;
- F. Evaluation of results;
- G. Submission of Corrective Action Plans.

QUESTIONS / DISCUSSION

Brain Tumor Workshop

Date: Friday, July 15, 2016
Start and End Time: 5:00 pm - 7:00 pm
Chair: Minesh P. Mehta, MD
Co-Chairs: Mark Gilbert, MD; Michael Vogelbaum, MD, PhD; Arnab Chakravarti, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA:

1. Ongoing Studies:

	STUDY	NAME	DX	START	N	COMMENTS
1	1071	NCCTG N0577/Endorsed Study: Phase III CODEL PFS endpoint. RT/PCV vs RT/TMZ, NI P3 study	G2/3 Glios	9/09	68/360 26 NRG	Vogelbaum
2*	1205	Phase IIR Trial of Bev + Re-RT (35/10) vs. Bev Alone	rGBM	12/12	182/178	Accrued and closed
3*	1114	Phase IIR Rituximab, Methotrexate, Procarbazine, Vincristine, & Cytarabine +/- Low-Dose WBRT for PCNSL	PCNSL	9/11	91/89	Accrued and closed

	STUDY	NAME	DX	START	N	COMMENTS
4	1119	Phase IIR WBRT +Concurrent Lapatinib in Pts With Brain Mets from HER2+ Breast Ca: RTOG/KROG	Brain Mets	7/12	85/143	Protocol amendment to permit SRS alone underway Kim/Peereboom
5	0631	Phase II/III Image-Guided Radiosurgery/SBRT for Localized Spine Mets---RTOG CCOP Study	Spine Mets	8/09	269/352	SBRT vs 8 Gy single fx; protocol revised Ryu
6	1470 A071101	Randomized Phase II Trial of Bevacizumab +/- HSP vaccine in Patients with rGBM	rGBM	5/13	69/222 9 NRG	Raizer
7	BN 001	Hypofractionated Dose escalated Photon IMRT or PBT vs Conventional Photon Irradiation with Concomittant and Adjuvant Temozolomide	nGBM	10/14	257/576 Photon: 209/288 Proton: 48/288	IIR: Mehta/Gondi
8	BN 002	Phase I Study of Ipilimumab, Nivolumab, and the Combination in nGBM	nGBM	4/15	12/42	Gilbert
9	A071102	Phase II/III GBM w MGMT promoter hypermethylation	nGBM	12/14	169/440 25 NRG	Sarkaria
10	CC 001	Phase III WBRT+Memantine +/- HA	BM	7/15	116/510	Brown/Gondi
11	CC 003	Phase II/III PCI WBRT +/- HA	SCLC PCI	12/15	13/172 and 304	Gondi
12	Alliance A071401	Meningioma targeted agents, 3 arms (SMO, AKT, NF2)	Menin	8/15	15/24, 24, 24 4 screened	Cahill, Brastianos Temporarily suspended
13	RTOGf 3508	IIR/III RT/TMZ +/- ABT 414 for nGBM	nGBM	9/15	17??/720	Lassman
14	RTOGf 3503	Bev-refractory rec GBM PIIR	rGBM	5/16	0/85	Ahluwalia

Breast Cancer Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 9:00 am – 12:00 m
Chair: Eleftherios Mamounas, MD, MPH
Co-Chairs: Julia White, MD; Paul DiSilvestro, 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 – 10:15	Immunotherapy Trials	Eleftherios Mamounas, MD
	– Phase III Trial to Evaluate Adjuvant Therapy of Pembrolizumab for TNBC with Residual Invasive Cancer or Positive Lymph Nodes After Neoadjuvant Chemotherapy	
	– Trials in Development	Charles Geyer, Jr., MD
10:15 - 10:25	NRG BR-001 A Phase 1 Study of Stereotactic Body Radiotherapy (SBRT) for the Treatment of Multiple Metastases	Joseph Salama, MD
10:25 – 10:35	NRG BR-002 A Phase IIR/III Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer	Steve Chmura, MD, PhD
10:35 – 10:45	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	Priya Rastogi, MD
10:45 – 11:00	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
11:00 – 11:15	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

11:15 – 11:25	ECOG 2112: A Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Men and Postmenopausal Women with Hormone Receptor-Positive Advanced Breast Cancer	Alexandra Thomas, MD
11:25 – 11:35	ALTERNATE Trial: Alternate Approaches for Clinical Stage II and III Estrogen Receptor Positive Breast Cancer Neoadjuvant Treatment in Postmenopausal Women: A Phase III Study	Matthew Ellis, MD
11:35 – 11:45	Penelope (NSABP B-54-I): Phase III Study Evaluating Palbociclib, in Patients with Hormone-Receptor +, HER2-Normal Breast Cancer with High Relapse Risk After Neoadjuvant Chemotherapy	Harry Bear, MD, PhD
11:45 – 11:55	S1207/B-53- Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2-Negative Breast Cancer	Priya Rastogi, MD

Breast Cancer Rare and Genetically-Linked Subcommittee Workshop

Date: Friday, July 15, 2106
Start and End Time: 11:00 am- 12:00 pm
Chair: Ed Romond, MD
Co-Chair: Alexandra Thomas, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Identify and describe trials of rare tumors that have been conducted in gynecology
2. Identify and describe successes and missteps of other groups studying rare malignancy
3. Identify and describe mechanisms by which to request trial proposals on rare and genetically-linked breast cancers
4. Identify and describe topics which match clinical questions for which to request concept proposals

WORKSHOP AGENDA

- 11:00- 11:10 Committee Updates
- 11:10- 11:20 Discussions with GOG Rare Tumors Subcommittee
- GOG experience in this area
 - Possible synergies
- 11: 20- 11:45 Discussion of mechanisms for bringing forward trial proposals
- Request for proposals mechanism
 - Topics for which to develop RFP
- 11:45- 11:50 Registry - concepts
- 11:50- 11:55 Secondary analyses
- Concepts which mine existing legacy or NRG data to build new knowledge on rare or genetically linked tumors
 - Funding sources (possibility outside NCI?)
- 11:55- – 12:00 Discussion
- Committee goals, focus and prioritization

Canadian Members Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 2:00 pm – 3:00 pm CST
Chair: Jean-Paul Bahary, MD
Co-Chairs: Andre Robidoux, MD; Al Covens, MD
NRG Operations: Erica Field (back-up representative: Katie Campbell)

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 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 of Interest
- II. Status of NRG trials open to accrual – *discussion lead NRG Regulatory* Erica Field
 - a. Accrual Update (January 2016 – June 2016)
- III. Optimizing accrual in Canada - Discuss best practices for optimizing accrual among Canadian sites.
Discussion lead Jean-Paul Bahary, MD,
Andre Robidoux, MD
Al Covens, MD
 - I. Disease Sites of interest
 - II. Review previously collected site data to support enrollment in these specific disease sites
- IV. New concepts and protocols
 - a. NRG-GY004: *A Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer* (Joyce Liu, MD)
 - b. NRG-GY005: *A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib 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, MD)
- V. Canadian Review Board – *discussion lead* Jean-Paul Bahary, MD,
Andre Robidoux, MD
Al Covens, MD
 - a. Discuss concepts/protocols in development
- VI. Next meeting – January 2017, Houston, TX
 - a. Please review current NRG Oncology agenda to propose alternate times. Please submit suggestions to Erica Field (fielde@nrgoncology.org) Based on responses a survey will be sent to determine a time for the meeting in January.
- VII. New Business, General Questions, Discussion - *discussion lead* Jean-Paul Bahary, MD
Andre Robidoux, MD
Al Covens, MD
- VIII. Evaluation

Cancer Care Delivery Research Session Workshop Agenda

Date: Friday, July 15, 2016
Start and End Time: 11:30 m – 1:00 pm
Chair: Joe Lipscomb, PhD
Co-Chair: David Cohn, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Demonstrate an understanding of the definition of CCDR
2. Apply knowledge regarding to CCDR to the review and development of concepts

WORKSHOP AGENDA

SPEAKERS

- | | |
|---|---------------------------|
| A. Update on CCDR Committees | |
| a. NCI CCDR Steering Committee | |
| b. NCI CCDR Coordinating Committee | |
| c. NRG Oncology CCDR Committee | |
| B. Concept Update | |
| a. Submitted to NCI | |
| i. "Choosing Wisely" | Debra Ritzwoller, PhD |
| b. In development | |
| i. Continuous activity monitoring | Nitin Ohri, MD |
| ii. Dose of palliative care (Andrew Barnes) | |
| iii. Exercise and breast cancer | Kathryn Schmitz, PhD. MPH |
| iv. Ovarian cancer chemotherapy | |
| C. New Concepts | |
| D. New Business | |

QUESTIONS / DISCUSSION

Cancer Prevention and Control Workshop Agenda

Co-Chair: David S. Alberts, MD
Co-Chair: Lisa Kachnic, MD

Session I: Friday, July 15, 2016 11:00 am – 12:00 pm GOG-225 Informational Session
Session II: Friday, July 15, 2016 2:30 pm – 5:30 pm CPC Workshop
Session III: Saturday, July 16, 2016 10:00 am – 12:00 pm GOG-225 Workshop
Session IV: Saturday, July 16, 2016 10:00 am – 12:00 pm GOG-199 Subcommittee (closed)

SESSION I – GOG-0225, Information Session

Friday, July 15, 2016 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

David S. Alberts, MD, Regents Professor of Medicine, Pharmacology, Public Health and Nutritional Science, and Director Emeritus, University of Arizona Cancer Center

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 15, 2016 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)
- **RTOG-0631**- Phase II/III Study of Image-Guided Radiosurgery/SBRT for Localized Spine Metastasis (S. Ryu)
- **NRG-CC001**: Phase III Memantine and Whole Brain RT +/- Hippocampal Avoidance (P. Brown, V. Gondi)
- **NRG-CC002**: Pre-Operative Assessment and Post-Operative Outcomes of Elderly Women with Gynecologic Cancers (A. Ahmed)
- **NRG-CC003**: Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC (V. Gondi)

C. Review of Concepts & Protocols in Development:

- NRG-CC1609: Phase II Dose Finding Trial of Bupropion for Sexual Motivation/Entergy (D. Barton)
- NRG-CC1608: National Trial of Surveillance Colonoscopy (R. Schoen)
- Pilot Study of Salpingectomy to Reduce Risk of High-Grade Serous Carcinoma among Premenopausal *BRACA1/2* Carriers (D. Levine)
- NEXT Steps: An RCT of a Tailored Weight Loss Intervention for Endometrial Cancer Survivors (K. Basen-Engquist)

D. Breakout Session for Working Groups

- **Symptom Management /Survivorship** – Co-Chairs: Mylin Torres, MD; Steve Plaxe, MD, Jeanne Carter, PhD; Deb Barton, PhD, MD
- **Epidemiology/Behavioral Health** – Co-Chairs: Louise Brinton, PhD; Kathryn Schmitz, PhD, MPH; Tracy Crane, MS, RD; Noah Kauff, MD

E. Working Group Reports

SESSION III – CPC Training GOG-0225

Saturday, July 16, 2016 10:00 –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:

David S. Alberts, MD, Regents Professor of Medicine, Pharmacology, Public Health and Nutritional Science, and Director Emeritus, University of Arizona Cancer Center

Tracy Crane, MS, RD, Research Specialist, Sr., LIVES Study Coordinator

QUESTIONS/DISCUSSION

EVALUATION

SESSION IV – GOG-199 Subcommittee (closed)

Saturday, July 16, 2016 10:00 am-12:00 pm

- **Status of the GOG-0199 (Greene)**
- **Status of the GOG-0199 Data**

Cervix Cancer Workshop Agenda

Date: Friday, July 15, 2016
Start and End time: 10:00 am – 12:00 pm (Session I)

Date: Saturday, July 16, 2016
Start and End time: 10:00 am – 11:00 am (Session II)

Chair: Bradley J. Monk, MD
Co-Chair: Wui-Jin Koh, MD

Learning Objectives:

Following this activity, participants will be better able to:

- Discuss national and international priorities and initiatives in the management of cervical cancer
- Discuss active and developing NRG clinical trials on the prevention, diagnosis, and treatment of cervical and vulvar cancers
- Discuss promising developmental therapeutics and translational research objectives and strategies for future clinical trials
- Apply standards and procedures required to design, submit, and conduct a research protocol by the NRG
- Outline barriers and potential solutions to improve enrollment to NRG clinical trials in cervical and vulvar cancer, including International cooperation

WORKSHOP AGENDA

SESSION I: Friday, July 15, 2016 (Scientific development focus) 10:00 am – 12:00 pm

A: Introduction (10:00 – 10:05)

1. Welcome and review of workshop minutes from Jan 2016

B: Scientific updates/discussion (10:05 – 10:45)

1. Update on Developmental Therapeutics and Committee on Experimental Medicine initiatives in cervical and vulvar cancer. 10:05 – 10:15 (John Farley)
2. GCSC-Cervical Task Force update – strategic directions and priorities for clinical trials in cervical cancer. 10:15 – 10:30 (Al Covens)
3. Update from ASCO 2016 – 10:30 – 10:50 (Brad Monk)

C: Previously committee-approved concepts – current and future directions (10:50 – 11:10)

1. NRG DT1433 A Randomized Phase II Trial of Cisplatin, Paclitaxel, Bevacizumab plus Veliparib or Placebo in the Treatment of Advanced (Stage IVB), Recurrent or Persistent Carcinoma of the Cervix (Ritu Salani) renumbered **DT1622**

Disapproved by CTF, Oct 2015.

New concept (single agent Veliparib):

A phase II evaluation of Veliparib in the treatment of persistent or recurrent carcinoma of the cervix (Ritu Salani)

D: Other ongoing trials/approved concepts

1. GOG 9929: Ipilimumab as maintenance following definitive chemo RT (J Mayadev)
2. NRG-GY002: Nivolumab in recurrent/metastatic cervical cancer (A Santin)
3. GOG-0265: ADXS11-001 (HPV-E7 vaccine) for recurrent/metastatic cervical cancer (W Huh)
4. PI1607: Atezolizumab (Anti PDL-1) concurrently/sequentially with definitive cis-RT for LACC (Mayadev) CRDL LOI

E: New directions/proposed concepts (primary review by cervical cancer committee) 11:10 – 11:30

F: New Concepts from other committees (secondary review by cervical cancer committee) 11:30 – 11:45

1. **DT1622** (Resubmission DT1433) (Ritu Salani, MD) – A phase II evaluation of veliparib in the treatment of persistent or recurrent carcinoma of the cervix
2. **DT1628**: A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)

SESSION II: Sat, July 16, 2016 (Operational management of on-going trials) 10:00 am – 11:00 am

G: Closed Studies

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

H: Active/Ongoing Studies (10:00 - 10:30)

1. GOG-0724/RTOG0724: Phase III 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)
 - a) Opened April 2009; New Accrual Goal 285; enrolled XX
2. GOG-0263: Randomized Clinical Trial for Adjuvant Chemoradiation in Post-operative Cervical Cancer Patients with Intermediate Risk Factors. (Sang Young Ryu, Wui-Jin Koh)
 - a) Opened April 2010; Accrual Goal 534; enrolled XX
3. GOG-0270: Groningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-VII), An observational study (Brian Slomovitz)
 - a) NRG Opened January 3rd, 2012; Accrual Goal total international ~1500; enrolled >1400
NRG target accrual 140, enrolled XX
 - b) Amendment for treatment of SLN macro-metastatic disease
 - c) Amendment for IMRT approved July 2015 by GROINSS, but NOT by CTEP

- d) Expected closure Q3 2016
 - e) GROINSS-V3? – macroscopic LN+ cohort
4. 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)
 - a) Activated January 9, 2012, Accrual Goal 780 total international; enrolled >XX
NRG target accrual 500, enrolled XX
 - b) Anticipated initial accrual target to be reached Q4 2016
 - c) Expanded accrual target to 900 total patients
 5. GOG 0278: “Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgical Therapy for Stage IA1-IB1 (≤ 2 cm) Cervical Cancer.” (Al Covens)
 - a) Activated October 1, 2012, Accrual Goal 220; enrolled XX
 - b) PET imaging amendment approved July 2015
 6. GOG 0279: A Phase II trial evaluating Cisplatin and Gemcitabine concurrent with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva. (Neil S. Horowitz)
 - a) Activated July 2, 2012, Accrual Goal 52;
 - b) Temporarily closed 6/15/2015, after enrolling 28 in 1st stage
 - b) 2nd stage re-opening pending analysis of first stage accrual
 7. 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. (Charles Leath, Loren Mell)
 - a) Activated Jan 15, 2016
 - b) Accrual goal 188 ; enrolled XX
 8. RTOG 1203: Phase III 3D vs IMRT in post-op Endo or Cervix (TIME-C) (Ann Klopp)
 - a) Activated Oct 4, 2012, Accrual Goal 281 – completed accrual Aug 2015

I: Reports from Other Committees and Groups (10:30 - 10:45)

- 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

J: Wrap up and questions 10:45 - 11:00

Cultural Competency Workshop Agenda

Date: Friday, July 15, 2016
Start and End Time: 11:00 am-1:00 pm
Chair: Kathie-Ann Joseph, MD, MPH

Learning Objectives:

Following this activity, participants will be better able to:

1. Define Culture
2. Discuss skills and strategies to increase cultural competency
3. Identify approaches to improve communication with minority populations
4. List potential cultural barriers to recruiting minority populations to clinical trials

WORKSHOP AGENDA

A. The aim of this workshop is to help NRG Oncology research investigators, nurses, CRAs, and support staff to understand the role cultural competency plays in clinical trials. With recruitment of patients from underrepresented minority groups in clinical trials at less than 1%, there is an opportunity to reduce this gap in health disparity.

Participants will learn what the term cultural competency means and the importance of cultural competency in clinical trial recruitment. The meaning of culture will be discussed as well as understanding how we communicate with our patients, use of interpreters, being respectful of your patient's cultural beliefs and being aware of one's own biases.

By understanding the role cultural competency plays in clinical trials recruitment, investigators and staff can help to increase recruitment and retention of racial/ethnic minorities into therapeutic clinical trials with the ultimate goal of reducing cancer-related health disparities.

Introduction	Kathie-Ann Joseph, MD, MPH
Pre-Workshop Assessment	Kathie-Ann Joseph, MD, MPH
Lecture	Marvella Ford, PhD, Professor, Public Health Sciences. MUSC Assoc. Director of Cancer Disparities at Hollings Cancer Center
Interactive Session	Marvella Ford, PhD
Q&A-moderated by	Kathie-Ann Joseph, MD, MPH
Post Assessment	Kathie-Ann Joseph, MD, MPH

Gastrointestinal Cancer Committee Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 2:30 pm – 4:30 pm
Colorectal Chair: Thomas George, MD
Colorectal Co-Chair: Scott Kopetz, MD, PhD
Non-colorectal Chair: Christopher Crane, MD
Non-colorectal Co-Chair: Howard Safran, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

2:30 – 2:35	Introduction and Opening Remarks	Christopher Crane, MD Thomas George, MD
2:35 – 3:00	CRC SUBCOMMITTEE N1048: Intergroup PROSPECT Trial TNT: Platform Update ARGO FC-13: Randomized colon adjuvant trial with regorafenib	Thomas George, MD Thomas George, MD Thomas George, MD
3:00 – 3:25	Review of Developing Trials 1613: A Randomized Phase II Study of Pertuzumab and Trastuzumab compared to Cetuximab and Irinotecan in Advanced/mCRC with HER2 Amplification FC-MSS: A Phase II Study of the Dual Immune Checkpoint Blockade with Durvalumab plus Tremelimumab Following Palliative Hypofractionated Radiation in Patients with Microsatellite Stable (MSS) mCRC FR-MEDI: A Phase II Study to Assess the Activity of PD-L1 Inhibition with Durvalumab (MEDI4736) after Chemo-Radiotherapy in Patients with Stage II-IV Microsatellite Stable (MSS) Rectal Cancer	Marwan Fakih, MD James Lee, MD, PhD Thomas George, MD
3:25 – 4:20	NON-CRC SUBCOMMITTEE 0848: A Phase III Trial Evaluation both Erolotinib and Chemoradiation As Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma 1112: Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma 1201: Ph IIR SMAD-4 directed IMRT pancreas NRG GI- 001: Ph II/III Chemo +/- Hypofractionated XRT intrahepatic cholangioma	Ross Abrams, MD Laura Dawson, MD Edgar Ben Josef, MD Theodore Hong, MD
4:20 – 4:30	Review of Developing Trials NRG GI-1525: Concurrent (ADXS11-001) with 5FU/MMC and radiation for locally advanced anal cancer NRG GI-XXXX: Adjuvant PD1 Inhibition Following Trimodality Therapy For High Risk, Node +, Esophagogastric Cancer Proton vs photon Trials NRG XXXX Phase III Randomized Trial of Proton Beam Therapy (PBT) versus Intensity Modulated Radiation Therapy (IMRT) for the treatment of Esophageal Cancer NRG XXXX Phase III Randomized Trial of Protons vs. Photons for Hepatocellular Carcinoma	Lisa Kachnic, MD Howard Safran, MD Steven Lin, MD Ted Hong, MD

Genitourinary Cancer Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 8:00 am – 10:00 am
Chair: Howard Sandler, MD
Co-Chairs: Leonard Gomella, MD; Oliver Sartor, MD; William Shipley, MD

Learning Objectives

Following this activity, participants will be better able to:

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

WORKSHOP AGENDA

8:00 – 8:05 **Opening Remarks and Update**

8:05 – 9:05 **Review of Active Trials**

NRG GU001 Randomized Phase II Trial of Postoperative Adjuvant IMRT Following Cystectomy for pT3/T4 Transitional Bladder Cancer Libni Eapen, MD

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

RTOG 0926 A Phase II Protocol for Patients with Stage T1 Bladder Cancer to Evaluate Selective Bladder Preserving Treatment by Radiation Therapy Concurrent with Radiosensitizing Chemotherapy Following a Thorough Transurethral Surgical Re-Staging William Shipley, MD

9:05 – 9:35 **Review of Pending Studies**

NRG GUXX Update of high-risk localized strategies, clinical trial development Dror Michaelson, MD, PhD
Oliver Sartor, MD

RTOG 1548	A Randomized Phase III Trial of Hypofractionated Post-prostatectomy Radiation Therapy (HYPORT) Versus Conventional Post-prostatectomy Radiation Therapy (COPORT)	Mark Buyyounouski, MD
NRG GUXX	Phase IIR biomarker stratified trial with a lead in to phase III testing the benefit of salvage RT +/- ARN-509 in patients with a low PSA <1 pre-treatment.	Felix Feng, MD
NRG/Alliance	Phase III Study: Radium-223 + Androgen Deprivation vs. Androgen Deprivation Therapy Alone in Patients Ineligible or Refusing Docetaxel	Albert Chang, MD, PhD Oliver Sartor, MD
NRG GUXX	Androgen Deprivation Therapy With or Without Radiation Therapy in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial	Ronald Chen, MD, MPH
NRG GU002	Phase II-III Trial Of Adjuvant Radiotherapy Following Radical Prostatectomy ± Adjuvant Docetaxel	Mark Hurwitz, MD
NRG GUXX	Hypofractionation prostate	Rod Ellis, MD
NRG GUXX	Renal met SBRT	Dror Michaelson, MD, PhD

9:35 – 9:55 Other issues

Bladder Cancer	William Shipley, MD
Translational Research	Felix Feng, MD
Medical Oncology Update	Oliver Sartor, MD
Urology Update	Leonard G. Gomella, MD
New Business	Group

9:55 – 10:00 Review of Closed Studies

RTOG 0815	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer
RTOG 0534	A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only Radiotherapy (SPPORT) in Prostate Cancer Patients with a Rising PSA After Radical Prostatectomy
RTOG 0232	A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone for Selected Patients with Intermediate Risk Prostatic Carcinoma
RTOG 0621	Adjuvant 3DCRT/IMRT in Combination with Androgen Suppression and Docetaxel for High Risk Prostate Cancer Patients Post-Prostatectomy: A Phase II Trial
RTOG 9601	A Phase III Trial of Radiation Therapy With or Without Casodex in Patients with PSA Elevation Following Radical Prostatectomy for pT3N0 Carcinoma of the Prostate
RTOG 0126	A Phase III Randomized Study of High Dose 3D-CRT/IMRT versus Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer
RTOG 0521	A Phase III Protocol of Androgen Suppression (AS) And 3DCRT/IMRT vs. AS and 3DCRT/IMRT Followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk Prostate Cancer

- RTOG 0415 A Phase III Randomized Study of Hypofractionated 3DCRT/IMRT versus Conventionally Fractionated 3DCRT/IMRT in Patients with Favorable-Risk Prostate Cancer
- Other
Closed
Studies
- RTOG 0526: A Prospective Phase II Trial of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent Prostate Adenocarcinoma Following External Beam Radiotherapy
- RTOG 0622: A Phase II Trial of Samarium 153 Followed By Salvage Prostatic Fossa 3D-CRT or IMRT Irradiation In High-Risk, Clinically Non-Metastatic Prostate Cancer after Radical Prostatectomy
- RTOG 0712: A Phase II Randomized Study for Patients with Muscle-Invasive Bladder Cancer Evaluating Transurethral Surgery and Concomitant Chemoradiation by Either BID Irradiation plus 5-Fluorouracil and Cisplatin or QD Irradiation plus Gemcitabine Followed by Selective Bladder Preservation and Gemcitabine/Cisplatin Adjuvant Chemotherapy (Closed to Step 1 Registration; Step 2 Registration Open)
- RTOG 0938: A Randomized Phase II Trial Of Hypofractionated Radiotherapy For Favorable Risk Prostate Cancer- RTOG CCOP Study

GYN Protocol Development Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 1:30 pm – 3:00 pm
Chair: Robert S. Mannel, MD
Co-chairs: Ronald Alvarez, MD
William Small, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing Gyn clinical trials on the prevention, diagnosis, and treatment of all 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.
4. Assure strict quality control of Gyn clinical trials.

WORKSHOP AGENDA

I. General Business

- A. Call to order (Mannel)
- B. Approval of minutes from January 2016 (Mannel)
- C. Future Meeting dates and deadlines (Mannel)
- D. Symposia (Alvarez)
- E. Report from Special Advisor on Health Disparities Committee (Brown)
- F. Report from HRC (Creasman)
- G. Report from Cancer Prevention and Control (Alberts)
- H. Other

BOLDED concept numbers are new at this meeting.

II. Committee on Cancer of the Uterine Corpus (Miller)

1. UC1306: A randomized phase II study evaluating the role of maintenance therapy with cabozantinib in High Grade Uterine Sarcoma (HGUS) after stabilization or response to chemotherapy following surgery or in metastatic first line treatment (Martee L. Hensley)
2. UC1406 : A randomized Pilot investigation of the relationship of short term depo-provera (Medroxyprogesterone Acetate) (NSC #27408) Compared to depo-provera plus entinostat on the Morphologic, Biochemical and Molecular Changes in Primary Endometrioid adenocarcinoma of the Uterine Corpus. (Duska)
3. UC1506 Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine)
4. UC1601: Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black verses White Women with Endometrioid Endometrial Cancer and Uterine Serous Cancer. (L. Maxwell) CCSC
5. **UC1621: (UC1534)** A Phase II Study of pembrolizumab (MK-3475) in patients with Microsatellite Unstable (MSI), Persistent or Recurrent Endometrial Cancer (Nickles-Fader/Armstrong)
6. **UC1630:** Randomized Two Arm Phase II Cross-Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma Patients who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)

7. **UC1631:** Phase II Trial of the ATR inhibitor (ATRI), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens(Maxwell/Powell/Rimel)

DT Corpus

- a. NRG-GY008 (DT1419): A Phase II evaluation of BAY80-6946, a selective PI3K inhibitor in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA and PIK3R1/R2 mutations. (A Santin)
- b. DT1527: A Phase II Evaluation of Weekly Paclitaxel in the Treatment of Recurrent or Persistent Endometrial Carcinoma. (C. Gunderson)

CEM Corpus

- a. NRG GY-TS001 (GOG-8041/CEM1304): The Relationship of Racial Genetic Admixture and its Associated Protein Biomarkers with Endometrial Cancer Outcomes (Rodney P Rocconi) CCSC
- b. GOG-8040: An investigation of the heterogeneity of gene expression, epidemiology and behavior of endometrial carcinoma (Rodgers)
- c. UC1506 Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine) CCSC
- d. UC1601: Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black versus White Women with Endometrioid Endometrial Cancer and Uterine Serous Cancer. (L.Maxwell) CCSC

PCOR corpus : N/A

III. Committee on Cancer of the Ovary (Bookman)

1. NRG-GY007 (OV1310): A randomized phase II study with a safety lead-in to assess the anti-tumor efficacy of ruxolitinib combined with and maintained following front-line neoadjuvant therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Burger/Landen)
2. OV1505: 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 Moore)
3. OV1509: A Randomized Phase II Trial of Neoadjuvant Carboplatin/Paclitaxel +/- the PD-1 inhibitor, Nivolumab, for the Treatment of Primary Bulky, Advanced Stage Epithelial Ovarian, Peritoneal, or Fallopian Tube Cancer. (Stephanie Gaillard)
4. **OV1629** (OV1611): 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)
5. NRG-GY009 (OV1550) A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Bevacizumab with and without Atezolizumab in Platinum Resistant Ovarian Cancer (Aghajanian/ Snyder)
6. OV1602: A phase I/II study of birinapant with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Christina Annunziata)

DT Ovary:

N/A

PCOR Ovary:

a.

RTM Ovarian studies

- a. RT1205 MaGIC 3-cohort trials for low-, intermediate, and high-risk patients with malignant germ cell tumors (COG) (David M Gershenson)
- b. RT1313: A randomized phase II trial of paclitaxel/carboplatin versus Trametinib monotherapy in patients with stage III and IV low-grade serous carcinoma of the ovary or peritoneum (A Nickles-Fader)
- c. RT1507: A phase II trial of Cediranib in recurrent ovarian sex-cord stromal tumors. (Danielle Vicus) 3rd priority after RT1510
- d. RT1531: A randomized phase II trial of Temozolomide and cisplatin versus nivolumab (BMS-936558) in patients with completely resected mucosal sarcoma. (D. Vicus)
- e. RT1532: A Randomized Trial of Adjuvant Pembrolizumab, Adjuvant Chemotherapy, or Expectant Observation following Neoadjuvant Pembrolizumab and Surgical Resection of High-Risk Localized or Locoregionally Advanced Mucosal Melanoma. (Shoushtari/Carvajal) 2nd priority after RT1531.
- f. **RT1625**: A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)
- g. **RT1626**: A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SAbR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)
- h. **RT1627**: A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
- i. **RT1632**: Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Cell Carcinoma of the Ovary, Peritoneum or Fallopian Tube. (John Farley)

Translational Science

- a. TS1514 : Immuno Score Determination as Predictive Biomarkers for Clinical Outcome in GOG-0262 Population (Samir Khleif) CCSC
- b. OV1602: A phase I/II study of birinapant with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Christina Annunziata)

IV. Committee on Cancer of the Cervix and Vulva (Monk)

1. N/A

DT Cervix

- a. PI1607: A Phase I trial using anti-PDL1 (MPDL320A) as an Immune Primer and adjuvantly with standard chemoradiotherapy for locally advanced cervical cancer. (Mayadev/Schilder)
- b. **DT1628**: A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)

VI. Health Outcomes Research Committee (Wenzel)

A. Proposed studies

1. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (Ed Tanner)
2. **DT1620:** A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Sara Temkin)
3. **UC1621: (UC1534)** A Phase II Study of pembrolizumab (MK-3475) in patients with Microsatellite Unstable (MSI), Persistent or Recurrent Endometrial Cancer (Nickles-Fader/Armstrong)
4. **DT1622:** A Phase II Evaluation of Veliparib in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (Salani Ritu)
5. **RT1625:** A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)
6. **RT1626:** A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SAbR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)
7. **RT1627:** A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
8. **DT1628:** A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)
9. **UC1630:** Randomized Two Arm Phase II Cross-Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma Patients who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)
10. **UC1631:** Phase II Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)

VII. Treatment of Elderly Patients Working Group (Part of Health Disparities) (Fleming)

A. Proposed Studies

1. **NC1519 to NCORP ELD1303:** Use of Risk Models and Geriatric Assessment for Comprehensive Treatment Planning in Elderly Patients with Stage III-IV Epithelial Ovarian/Fallopian Tube/Peritoneal Cancer A Phase 2 randomized trial with observational cohorts. (Kathleen N Moore)

Developmental Therapeutics Workshop Agenda

GYN Developmental Therapeutics/Phase I/Translational Science Workshop

Date: Thursday, July 14, 2016

Start and End Time: 4:00 PM – 6:00 PM

Chairs: Carol Aghajanian, MD (Developmental Therapeutics) and Michael Birrer, MD, PhD (Translational Science)

Co-Chairs: Robert Burger, MD (Phase II), Russell Schilder, MD (Phase I); Jyoti Mayadev, MD (Phase I, RT), Heather Lankes, PhD (Translational Science)

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 14, 2016

Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

4:00 PM – 4:05 PM	Introduction, Drs. Aghajanian and Birrer
4:05 PM – 4:15 PM	NCI Division of Cancer Treatment and Diagnosis (DCTD), Biomarker Review Committee (BRC), Dr. Birrer
4:15 PM – 4:25 PM	Clinical Proteomic Tumor Analysis Consortium (CPTAC) Grant Applications, Dr. Birrer
4:25 PM – 4:45 PM	Evaluating novel combinations for synthetic lethality (Panagiotis Konstantinopoulos, MD, PhD)
4:45 PM – 5:05 PM	Immune therapy in ovarian cancer, how to improve on results to date and an update on NRG GY009 (Alex Snyder, MD)
5:05 PM – 6:00 PM	Review of new concepts <ul style="list-style-type: none">• 5-10 minute presentation of concept (by proposing investigator)• Review of concept

New Concepts:

- **DT1620** A window of opportunity pharmacodynamic trial of Triapine in uterine corpus serous adenocarcinoma (Sarah Temkin, MD)
- **DT1621** (Resubmission DT1534) (Dr. Amanda Nickles Fader, Dr. Deb Armstrong) – A phase II study of pembrolizumab in patients with mismatch repair deficient persistent or recurrent endometrial cancer
- **DT1622** (Resubmission DT1433) (Ritu Salani, MD) – A phase II evaluation of veliparib in the treatment of persistent or recurrent carcinoma of the cervix
- **DT1628:** A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)

GYN Developmental Therapeutics/Phase I Workshop

Date: Saturday, July 16, 2016

Start and End Time: 8:00 AM – 10:00 AM

Chair: Carol Aghajanian, MD (Developmental Therapeutics)

Co-Chairs: Robert Burger, MD (Phase II), Russell Schilder, MD (Phase I); Jyoti Mayadev, MD (Phase I, RT)

Learning Objectives:

Following this activity, participants will be better able to:

1. Discuss the current status of phase I, phase II studies that are under development and activated for accrual.
 - Immune Therapy and Immune Modulation workshop will present an update from Thursday, July 14, 2016 (2:00 – 4:00 PM) and plan for integration and prioritization.
 - Integration and prioritization of studies will be reviewed and reference to Cervical Cancer, Ovarian Cancer and Uterine Corpus Cancer workshops and the Translational Science workshop.
 - Recommendations for action by the GYN Protocol Development committee will be summarized.

Saturday, July 16, 2016

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

- 8:00 AM - 9:00 AM** **Russell Schilder, MD**
- Active
 - Studies under development
 - Closed studies
 - New Phase I concepts

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

- 9:00 AM – 9:15 AM** **Cervical Cancer (Kathleen Moore, MD)**
- Active
 - Studies under development
 - Closed studies
 - New Phase II concepts

- 9:15 AM - 9:30 AM** **Endometrial Cancer (Matthew Powell, MD)**
- Active
 - Studies under development
 - Closed studies
 - New Phase II concepts

- 9:30 AM - 9:45 AM** **Ovarian Cancer (Robert Coleman, MD)**
- Active
 - Studies under development
 - Closed studies
 - New Phase II concepts

- 9:45 AM - 10:00 AM** **Sarcoma (Martee Hensley, MD)**
- Active
 - Studies under development
 - Closed studies
 - New Phase II concepts

List of Studies

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

Cervical Cancer Studies:

- **9929** A phase I trial of sequential ipilimumab after chemoradiation for the primary treatment of patients with locally advanced cervical cancer stages IB2/IIA with positive para-aortic lymph nodes only and stage IIB/IIIB/IVA with positive lymph nodes (J Mayadev/R Schilder)
- **PI1607** A phase I trial using anti-PDL1 (atezolizumab) as an immune primer and as adjuvant with chemoradiotherapy for locally advanced cervical cancer (J Mayadev/R Schilder)

Ovarian Cancer Studies:

- **9923** A phase I study of intravenous carboplatin/paclitaxel or intravenous and intraperitoneal paclitaxel/cisplatin in combination with continuous or intermittent, CTEP supplied agent ABT-888 and CTEP supplied agent bevacizumab, in newly diagnosed patients with previously untreated epithelial ovarian, fallopian tube or primary peritoneal cancer (K Bell-McGuinn)

- **NRG-GY007** A phase I/II study of ruxolitinib with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (R Burger) **Safety lead in**
- **NRG-GY009** A randomized, phase II/III study of pegylated liposomal doxorubicin and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab in platinum resistant ovarian cancer (A Snyder Charen) **Safety lead in**

Closed studies:

Cervical Cancer

- 9926 A phase I evaluation of extended field radiation therapy with concomitant cisplatin chemotherapy followed by paclitaxel and carboplatin chemotherapy in women with cervical carcinoma metastatic to the para-aortic lymph nodes (C Boardman) **No TR specimens collected. Manuscript in preparation.**
- 76HH A limited access phase I/II trial of paclitaxel, cisplatin and CTEP supplied agent ABT-888 (veliparib) in the treatment of advanced, persistent, or recurrent carcinoma of the cervix (P Thaker/R Salani) **Completed accrual (phase I portion). CTEP disallowed phase II portion. TR completed. ASCO 2015. Manuscript submitted to publications committee.**

Endometrial Cancer Studies:

- **2290** A randomized phase II study with a safety lead-in to assess the antitumor efficacy of the MEK inhibitor trametinib alone or in combination with GSK2141795, an AKT inhibitor, in patients with recurrent or persistent endometrial cancer (S Westin) **Closed after safety lead in. SGO 2016. Protocol amendment needed to distribute specimens.**

Ovarian Cancer

- 9924 A phase I pharmacokinetic study of intraperitoneal CTEP supplied agent bortezomib and carboplatin in patients with persistent or recurrent ovarian, fallopian tube, or primary peritoneal cancer (D Dizon) **Bortezomib and carboplatin PK/PD – plasma and peritoneal fluid (completed). ASCO 2015. Manuscript submitted to publications committee.**
- 9925 A phase I study of VTX-2337 in combination with pegylated liposomal doxorubicin or in combination with weekly paclitaxel in patients with recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (B Monk) **ASCO 2013. PK, immune monitoring and pharmacogenomics specimens collected (plasma and whole blood) – completed. Manuscript in review.**
- 9928 A phase I study of intraperitoneal EGEN-001 (IL-12 plasmid formulated with PEG-PEI-Cholesterol Lipopolymer) administered in combination with pegylated liposomal doxorubicin in patients with recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (P Thaker) **Pre- and post-treatment peripheral blood and peritoneal specimens – analysis of cytokines and cell specific RNA transcripts. ASCO 2015. Manuscript in preparation.**

Cervical Cancer Phase II:

Recurrent/metastatic disease

- **265** A phase II evaluation of ADXS11-001 in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix (W Huh) **Safety lead in performed by Phase I subcommittee completed. ASCO 2016 (Stage I)**
- **GY-002** A phase II evaluation of nivolumab, a fully human antibody against PD-1, in the treatment of persistent or recurrent cervical cancer (A Santin) **Second stage accrual in progress**

Closed Studies

- **227G** A phase II evaluation of brivanib in the treatment of persistent or recurrent carcinoma of the cervix (J Chan) **TR specimens collected (serum). Manuscript in preparation.**

Endometrial Cancer Phase II:

Chemotherapy naïve

- **286B** A randomized phase II/III study of paclitaxel/carboplatin/metformin versus paclitaxel/carboplatin/placebo as initial therapy for measurable stage III or IVA, IVB, or recurrent endometrial cancer (V Bae-Jump) **Suspended after completion of randomized phase II portion.**

Recurrent/metastatic disease

- **NRG GY008** A phase II evaluation of BAY 80-6946, a selective inhibitor of PI3KCA, in patients with persistent or recurrent endometrial carcinoma harboring PIK3CA mutations (A Santin) **CTEP LOI submitted 4/17/15**
- **DT1527 (CRDL)** A phase II evaluation of weekly paclitaxel in the treatment of recurrent or persistent endometrial carcinoma. (C Gunderson, K Moore) **Under development CTEP LOI submitted 12/1/15. On Hold (1/4/16, 4/20/16).**

Closed Studies

- 86P A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab, paclitaxel/carboplatin/temsirolimus and ixabepilone/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, stage IVB, or recurrent endometrial cancer (C Aghajanian). **TR complete. ASCO 2015. Manuscript in preparation.**

Ovarian Cancer Phase II:

Recurrent disease

- **GY-003** Phase II randomized trial of nivolumab with or without ipilimumab in patients with persistent or recurrent ovarian, primary peritoneal or fallopian tube cancer (B Burger) **Suspended after completion of first stage accrual**

Closed studies:

- 170R A phase II evaluation of dalantercept, a novel soluble recombinant activin receptor-like kinase 1 (ALK-1) inhibitor receptor-fusion protein, in the treatment of persistent or recurrent epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (R Burger). **TR completed. Manuscript in preparation.**
- 186G A phase II randomized, double-blinded evaluation of oral everolimus (RAD001) plus bevacizumab vs. oral placebo plus bevacizumab in the treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (W Tew). **No TR specimens collected. ASCO 2014. Manuscript in preparation.**
- 186-H A randomized phase II evaluation of weekly paclitaxel versus weekly paclitaxel with oncolytic reovirus (Reolysin) in the treatment of recurrent or persistent ovarian, fallopian tube or primary peritoneal cancer (D Cohn). **No TR specimens collected. SGO 2016. Manuscript in preparation**
- 186J A randomized phase IIB evaluation of weekly paclitaxel plus pazopanib versus weekly paclitaxel plus placebo in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal carcinoma (D Richardson). **IGCS 2014. TR completed. Manuscript in preparation.**
- 186K A randomized phase II study of cabozantinib versus weekly paclitaxel in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (U Matulonis). **TR: BIQSFP, MET IHC – Center for Molecular Oncologic Pathology (CMOP) DFCI. SGO 2016. Manuscript in preparation.**
- 255 A phase II randomized, double-blind trial of a polyvalent vaccine-KLH conjugate + OPT-821 versus OPT-821 in patients with epithelial ovarian, fallopian tube, or peritoneal cancer who are in second or third complete remission (P Sabbatini). **TR completed. ASCO 2016. Manuscript in preparation.**
- 260 A phase II evaluation of elesclomol sodium and weekly paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (B Monk). **No TR specimens collected. In follow-up.**

Sarcoma Phase II:

Closed Studies

LEIOMYOSARCOMA

- 231-D A phase II evaluation of MLN8237 in the treatment of recurrent or persistent leiomyosarcoma of the uterus (D Hyman). **Closed after first stage. Manuscript submitted to publications committee.**

CARCINOSARCOMA

- 130-F A phase II evaluation of ixabepilone in the treatment of recurrent or persistent carcinosarcoma of the uterus (C McCourt). **Completed both stages of accrual. TR (FFPE for immunohistochemical analysis of pre-treatment class III beta-tubulin). ASCO 2016. Manuscript submitted to publications committee.**

QUESTIONS/DISCUSSION/EVALUATION

Head and Neck Cancer Workshop Agenda

Date: Saturday, July 16, 2016
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 (E. Zhang, PhD)
10:10 – 10:30	Review of Active Studies	
RTOG 0912	Concurrent radiation + chemotherapy + pazopanib for Anaplastic Thyroid Cancer (Phase II-R)	Eric Sherman, MD
RTOG 0920	IMRT/IGRT + cetuximab for “intermediate risk” resected head and neck cancer (Phase III)	Mitchell Machtay, MD
RTOG 1008	Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-III)	David Adelstein, 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)	Quyn-Thu Le, MD
NRG HN0002	Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good-Prognosis Advanced-Stage Oropharyngeal Cancer (RTOG 1333)	James Caudell, MD, PhD
HN003 (HN1541)	Phase I of Adjuvant Chemoradiotherapy +/- anti-PD1 (or PD-L1) mAb in High Risk, HPV(-) HNSCC	Julie Bauman, MD, MPH
RTOG 3501	Phase II R study of CRT +/- Lapatinib in high risk HNSCC	Stu Wong, MD
10:35 – 11:00	Review of developing studies	

RTOG 3504	Phase I/IIIR of CRT +/- Nivolumab in intermediate/high risk HNSCC	Maura Gillison, MD, PhD
RTOG 3507	Phase IIR - ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong, MD (Shlomo Koyfman, MD)
NRG HN1438	Phase IIR - PD1 inhibition +/- SBRT in patients with oligometastasis	Allen Chen, MD (Nooshin Hashemi, MD)
NRG/HN 1552	RT +/- EGFR inhibition for high risk cutaneous SCC (Phase IIR)	Quynh-Thu Le, MD (Randal Weber, MD)
NRG HN1539	Phase IIR RT+ Cetuximab vs. RT + Pembro in patients age \geq 70 with locally advanced HNSCC	Stuart Wong, MD
NRG HN ?	Concurrent radiation + chemotherapy + PD1 inhibition for Anaplastic Thyroid Cancer (Phase II-R)	Eric Sherman, MD
11:10 – 11:15	Discussion	
11:15 – 11:50	Presentations & Updates	
	Translational Research Program update	Christine Chung, MD/Neil Hayes
	Committee membership	Stu Wong, MD
11:50 – 12:00	New Business	

International Members Workshop Agenda

Date: Friday, July 15, 2016
Start and End Time: 10:00 am – 11:00 am CST
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

WORKSHOP AGENDA

- I. General
 - Overview of Workshop Agenda and Disclosures and Potential Conflict of Interest
- II. Status of NRG trials open to accrual Erica Field
- III. Optimizing accrual - Discuss best practices for optimizing accrual among International sites Ben Corn, MD
Stephan Bodis, MD
 - I. Disease Sites of interest
- IV. Regulatory Erica Field
 - a. Translation of informed consent forms and IRB approval letters
- V. New concepts and protocols Mark Hurwitz, MD
 - a. GU002 "Phase II-III Trial Of Adjuvant Radiotherapy Following Radical Prostatectomy With or without Adjuvant Docetaxel."
- VI. Site PI responsibility to review developing NRG trials – Erica Field
- VII. New Business, General Questions, Discussion - *discussion lead* Ben Corn, MD
Stephan Bodis, MD
 - a. Goals and milestones for January 2017
- VIII. Evaluation

Local Regional Breast Cancer Subcommittee Agenda

Date: Friday, July 15, 2016
Start and End Time: 11:00 am – 12:00 pm
Chair: Thomas Julian, MD
Co-Chair: Doug Arthur, MD

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.

Workshop Agenda:

11:00 – 11:05	Welcome/Introduction	Thomas Julian, M.D Doug Arthur, M.D.
11:05 – 11:20	DCIS Discussion Alliance Trial Window Study	Henry Kuerer, MD Irene Wapnir, MD
11:20 - 11:35	Pre-OP RT	Simona Shaitelman, MD Janet Horton, MD Elizabeth Nichols, MD
11:35 – 11:50	RT & Radiosensitization	Wendy Woodward, MD
11:50 – 12:00	Questions/Discussion	

Medical Oncology Workshop Agenda

Date: Saturday, July 16 2016
Start and End Time: 7:00 am - 8:00 am
Chair: Corey Langer, MD
Co-Chair: Roisin O’Cearbhaill, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Recognize the need for treatment adjustments in the setting of organ dysfunction
2. Understand the current recommendations for treatment in the setting of organ dysfunction
3. Discuss variance in determination of carboplatin dose among legacy groups
4. Provide updates on NRG clinical trial developments

WORKSHOP AGENDA

QUESTIONS / DISCUSSION

7:00-7:02 Introductions	Corey Langer, MD
7:02-7:17 Recommendations for Organ Dysfunction	Stuart Lichtman, MD
7:17-7:25 Open discussion of Organ Dysfunction Recommendations	
7:25-7:35 Harmonization of Carboplatin Dosing Recommendations	Roisin O’Cearbhaill, MD Judith Smith Pharm, MD Stuart Wong, MD
7:35-7:50 ASCO Highlights – Game Changers	Corey Langer, MD
a. GI:	
i. Upper (Legacy RTOG)	
ii. Lower (Legacy NSABP and RTOG)	
b. CNS (Legacy RTOG)	
c. HNC (Legacy RTOG)	
d. Thoracic (Legacy RTOG)	
e. GU (Legacy RTOG)	
f. Breast (Legacy NSABP and RTOG)	
g. GYN (Legacy GOG and RTOG)	
7:50-8:00 Other business	

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

Date: Friday, July 15, 2016
Start and End Time: 4:00 pm – 6:00 pm
Chair: Ying Xiao, PhD
Co-Chair: Jason Sohn, 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 (5 min)	Ying Xiao, PhD
4:05 – 4:15	NCI Communications (10 min)	Jacek Capala, MSc., PhD
4:15 – 4:30	NRG QA Report (15 min)	David Followill, PhD Ying Xiao, PhD Mark Rosen, MD
	<ul style="list-style-type: none"> • IROC Houston • IROC Philadelphia RT (Contouring & Dosimetry) • IROC Philadelphia Imaging 	
4:30 – 5:00	Disease Site Reports (30 min)	William Parker, PhD Rajat Kudchadker, PhD., DABR Stanley Benedict, PhD Ping Xia, PhD Martha M. Matuszak, PhD Tian Liu, PhD
	<ul style="list-style-type: none"> • GI • GU • GYN • H&N • Lung • Other (NCORP) 	
5:00 – 5:25	Modality Technology Reports (25 min)	Indrin Chetty, PhD Martha M. Matuszak, PhD Stanley Benedict, PhD Robert Jeraj, PhD Jason Sohn, PhD
	<ul style="list-style-type: none"> • SBRT • IMRT • IGBT • Imaging • Emerging technologies 	
5:25 – 5:40	NCTN Collaborations (15 min)	Ken Ulin, PhD
	<ul style="list-style-type: none"> • Alliance • ECOG-ACRIN • SWOG • COG 	
5:40 – 5:50	Other Business	
5:50 – 6:00	Questions/Discussions	

Ovarian Workshop Agenda

Date:	Friday, July 15, 2016	Saturday, July 16, 2016
Start and End Time:	8:00 am - 10:00 am	10:00 am - 11:00 am
Chair:	Michael A Bookman, MD	Michael A Bookman, MD
Co-Chair:	Paul DiSilvestro, MD	Paul DiSilvestro, 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

Session I

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

B. Reports from External Groups (as time permits)

- Institute of Medicine report "Ovarian Cancers: Evolving Paradigms in Research and Care" (Ronnie Alvarez)
<http://www.nationalacademies.org/hmd/Reports/2016/state-of-ovarian-cancer.aspx>

C. Reports (Task Forces, Working Groups, Committees)

- Overview of the NRG concept submission and review process, including disease-site committees, NRG-RSC, OTF-GCSC, CTEP, BIQSFP, industry, and translational research (Michael Bookman and Committee)
- Task force to update guidelines for interval cytoreductive surgery on protocols that include neoadjuvant chemotherapy (Paul DiSilvestro, Robert L Coleman, Thomas Herzog)
- Discussion of GOG0252 and IP Chemotherapy (Joan Walker and Committee)
- Training and Regulatory Compliance for NRG-GY004 and NRG-GY005 (Katie Campbell and study chairs)
- Elderly Patient Working Group (Gini Fleming)
- Developmental Therapeutics and Phase-I (Robert Burger)
- NRG Ancillary Data Projects

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)
- 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).
 - HRD Oral Presentation: BM Norquist, MF Brady, et al. Mutations in homologous recombination genes and response to treatment in GOG 218: An NRG Oncology study. 2016 SGO

- GOG0252 Phase III clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma (Joan L Walker)
 - Primary Oral Presentation: Walker JL, Brady MF, et al. A phase III Clinical trial of bevacizumab with IV versus IP chemotherapy in ovarian, fallopian tube and primary peritoneal carcinoma: An NRG study. 2016 SGO
- 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)
 - Primary Publication: Chan JK, Brady MF, et al. Weekly vs. Every-3-Week Paclitaxel and Carboplatin for Ovarian Cancer. *N Engl J Med.* 2016 Feb 25; 374(8):738-48. doi: 10.1056/NEJMoa1505067. PubMed PMID: 26933849.
 - Genomics Publication (with GOG0218): Norquist BM, Harrell MI, et al. Inherited Mutations in Women with Ovarian Carcinoma. *JAMA Oncol.* 2015 Dec 30:1-9. doi: 10.1001/jamaoncol.2015.5495. [Epub ahead of print] PubMed PMID: 26720728.
- GOG0273 Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen)
- 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 #2010129) (Bradley J Monk)
- GOG3004 A phase III, randomized, 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)

D. Review of Active Studies

- 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)
 - Ancillary Poster: Coleman RL, Brady MF, et al. Bevacizumab after bevacizumab in platinum-sensitive recurrent ovarian cancer: a subgroup analysis of GOG-0213. 2016 ASCO
- 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 (IND 121894) (Katherine M Bell-McGuinn)
 - Overview of Amendment 1 and discussion about intent-to-treat analysis on-study
- NRG-GY007 A Phase I/II Study of Ruxolitinib with Front-line Neoadjuvant and Post-surgical Therapy in Patients with Advanced Epithelial Ovarian, Fallopian Tube or Primary peritoneal Cancer (Robert A Burger)
- 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).
- 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)

E. Review of Approved Concepts under Development

- NRG-GY009 A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Alexander Snyder Charen, Carol Aghajanian). Protocol document to be submitted.
- 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). Awaiting phase I data.
- OVM1509 A Randomized Phase II Trial of Neoadjuvant Carboplatin/Paclitaxel +/- immune checkpoint inhibitor for the Treatment of Primary Bulky, Advanced Stage Epithelial Ovarian, Peritoneal, or Fallopian Tube Cancer. (Stephanie L Gaillard). Reviewed by OTF, approved by NRG-RSC, preparing for GCSC.

- OVM1611 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. (Seiko Diane Yamada). Withdrawn from GCSC due to lower sample size. Protocol being prepared for NCI PRC.
- OVM1602 A phase I/II study of birinapant with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Christina M Annunziata). Withdrawn by sponsor.

F. Review of New Concepts and Future Request for Proposals

- **RT1625:** A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)
- **RT1626:** A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SAbR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)
- **RT1627:** A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
- **RT1632:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Cell Carcinoma of the Ovary, Peritoneum or Fallopian Tube (John Farley)

QUESTIONS / DISCUSSION

Pathology Workshop Agenda

Date: Friday July 15, 2016
Start and End Time: 8:00 am-5:00 pm
Chair: William H Rodgers, PhD, MD
Co-Chair: Anthony Magliocco, MD

Learning Objectives:

Following this activity, participants will be better able to:

1. Apply standardized criteria for pathological classification of neoplasms
2. Discuss current diagnostic criteria for neoplasms as cited in the Pathology Manual
3. Utilize staging criteria as cited in the Pathology Manual
4. Utilize current quality assurance methods to review cases submitted for protocols
5. Discuss active and proposed protocols
6. Become familiar with Digital slide review technology

WORKSHOP AGENDA

Discussion Topics:

- Orientation for new members
- Review slides from cases for eligibility
- Concurrent discussion of eligibility criteria for proposed protocols

Noon: luncheon – business meeting

- Pathology Committee member involvement in protocol development
- Continuing review of cases

QUESTIONS / DISCUSSION

New GYN Concepts

1. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (Ed Tanner)
2. **DT1620:** A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Sara Temkin)
3. **UC1621: (UC1534)** A Phase II Study of pembrolizumab (MK-3475) in patients with Microsatellite Unstable (MSI), Persistent or Recurrent Endometrial Cancer (Nickles-Fader/Armstrong)
4. **DT1622:** A Phase II Evaluation of Veliparib in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (Salani Ritu)
5. **RT1625:** A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)
6. **RT1626:** A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SABR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)
7. **RT1627:** A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
8. **DT1628:** A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)
9. **UC1630:** Randomized Two Arm Phase II Cross-Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma Patients who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)

10. **UC1631:** Phase II Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens(Maxwell/Powell/Rimel)
11. **RT1632:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Cell Carcinoma of the Ovary, Peritoneum or Fallopian Tube. (John Farley)

Active Phase II and III Protocols

1. GOG-0213
2. GOG-0225
3. GOG-0237
4. GOG-0238
5. GOG-0263
6. GOG-0264
7. GOG-0265
8. GOG-0270
9. GOG-0274
10. GOG-0275
11. GOG-0277
12. GOG-0278
13. GOG-0279
14. GOG-0281
15. GOG-0283
16. GOG-9923
17. GOG-9929
18. NRG-GY001
19. NRG-GY002 temp closed
20. NRG-GY003 temp closed
21. NRG-GY004
22. NRG-GY005
23. NRG-GY006

Patient Centered Outcomes Research (PCOR) Workshop Agenda

Date: Thursday, July 14, 2016
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. Analyze appropriate PRO and CER endpoints and instruments for developing NRG PCOR studies
2. Apply criteria for inclusion of PROs and CER in NCTN Phase II and III clinical trials

WORKSHOP AGENDA

		PI/Person Reporting
4:00 – 4:40	<p>I. Incorporation of the Cancer Patient Tobacco Use Questionnaire (C-TUQ) in Clinical Trials to Assess Tobacco Use</p> <p>Comments/Audience Q & A</p>	Stephanie Land, PhD Program Director and Statistician, Tobacco Control Research Branch, Behavioral Research Program Chair, DCCPS Clinical Trials Coordination Group (NCI)
4:40 – 5:45	<p>II. Developing Concepts: Comments on PRO, QOL, and CER endpoints</p> <p>Concept: A Phase II Open-Label Trial of Pegylated Liposomal Doxorubicin plus Bevacizumab in Elderly Platinum-Resistant Ovarian Cancer Patients</p> <p>BN1536: Phase IIR double blind placebo controlled trial comparing adjuvant temozolomide and ipilimumab or nivolumab or nivolumab plus ipilimumab with adjuvant temozolomide in patients with newly diagnosed glioblastoma after successful completion of concurrent radiation and temozolomide</p> <p>BN1605: Pre-operative radiosurgery reduces leptomeningeal recurrence in comparison to post-operative radiosurgery in resected brain metastases</p> <p>GI1612: Phase IIR Pembrolizumab after trimodality therapy for high-risk node-positive esophagogastric cancer</p> <p>GU1604: Phase II Trial of Radiation Therapy Combined with Immunotherapy in Metastatic Renal Cell Carcinoma</p>	<p>Dana Chase, MD</p> <p>Ben Movsas, MD</p>
	<p>III. Developed Concepts/Protocols: Update on PRO, QOL, and CER endpoints</p> <p>BN003: Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma</p> <p>GI1525: A Phase II/III Trial Evaluating ADXS11-001 with Mitomycin, 5-Fluorouracil (5-FU) and IMRT for Locally Advanced Anal Cancer</p> <p>BR004: Randomized Phase III Trial of Nab-paclitaxel/Trastuzumab/Pertuzumab Compared to Nab-paclitaxel/Trastuzumab/Pertuzumab/MEDI4736 in First Line HER2-Positive Metastatic Breast Cancer</p> <p>GY009: A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab Versus Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer</p>	<p>Ben Movsas, MD</p> <p>Patricia Ganz, MD</p> <p>Lari Wenzel, PhD</p>

5:45 – 6:00	IV. NRG PCOR and Comparative Effectiveness Subcommittee Liaisons Updates V. Compliance Task Force Report: Discuss Enrollment and Longitudinal Missing Data VII. Other Business	Patricia Ganz, MD Ben Movsas, MD Lari Wenzel, PhD
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Note: PCOR studies activated

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-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-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 Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent/Persistent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (COCOS) (activated 2/16)

NRG-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)

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-III NSCLC (activated 2/14)

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

Date: Thursday, July 14, 2016
Start and End Time: 1:00 pm – 5:00 pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Program Facilitator: Sally Brown RN, BSN, MGA

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss importance of continued follow up in studies that have closed for accrual several years ago
2. Identify different biologic pathways that cause cancer
3. Explain best practices for patient education and for oral targeted therapies
4. Describe rationale for use of stereotactic radiation therapy
5. Explain the process to obtain an NRG Oncology PSC mentor
6. Recognize coverage analysis on CTSU web site

AGENDA

<u>Time</u>	<u>Topic</u>	<u>Speakers</u>
1:00pm – 1:15pm	Introduction	Sally Brown RN, MSN, MGA
	Update about delinquencies	Mary Jo Antonelli MBA, MHA
1:15pm – 3:00pm	The Immune Portrait of a Tumor New Therapeutics in our clinics	Karen Oleszewski RN, MSN, AOCN
3:00pm-4:00pm	Stereotactic Radiation Therapy	Robert Timmerman MD
4:00pm – 4:30pm	PSC Mentorship Program	Nancy Fusco RN, BSN
4:30 – 5:00pm	CTSU Coverage Analysis Project	Martha Hering

QUESTIONS/DISCUSSION
EVALUATION

**Protocol Support Committee Workshop
Clinical Trial Nurse Subcommittee (CLOSED)**

Date: Thursday, July 14, 2016
Start and End Time: 5:00 pm – 6:30 pm
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 and discuss educational needs of both new and experienced CRAs/Nurses
4. 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 roles, responsibilities and reporting methods for appointments to NRG Oncology disease site and modality committees
3. Committee Reports
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 (CLOSED)**

Date: Thursday, July 14, 2016
Start and End Time: 5:00 pm – 6:30 pm
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. Identify the responsibilities of CRAs appointed to Site and Modality Committees
3. Identify educational needs of both new and experienced CRAs
4. Discuss the role of the CRA Subcommittee and identify opportunities for member participation

WORKSHOP AGENDA

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

QUESTIONS/DISCUSSION
EVALUATION

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

Date: Friday, July 15, 2016
Start and End Time: 7:00 am – 9:00 am
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Working Group Facilitator Sally Brown RN, BSN, MGA

Learning Objectives

Following this activity, participants will be better able to:

1. Name a co-facilitator
2. Discuss alternative methods of education
3. Provide the PSC with potential topics and speakers for Jan 2017 meeting

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 2017 meeting
 - a. Sub working group
5. Suggestions for summer 2017 meeting
 - a. Sub working group

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop Mentorship Working Group (CLOSED)

Date: Friday, July 15, 2016
Start and End Time: 7:00 am – 9:00 am
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. Announcements:
3. Approval of minutes from most recent conference call
4. Review committee member numbers and the need to add members
5. Review top priorities for the working group: Outline tentative plan:
 - a. Welcome packet:
 - i. Outstanding work items
 - ii. Distribution: broadcasts, newsletters
 - iii. Evaluation process: How often, survey
 - iv. Annual review process
 - v. Identify potential new topics/areas to develop
 - vi. Identification process of new members update
 - b. Develop Mentor Program:
 - i. Continue to prioritize needs using sample mentor program flow chart
 - ii. Review temporary mentor plan and effectiveness
 - iii. Program Outline: Review current outline and update program sections
 1. Program Name
 2. Program Goal
 3. Define program standards for Mentorship Program in general
 4. Define program standards for Mentors
 5. Develop program SOP's
6. Meeting Plan: Conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting
7. Other business

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop Protocol Review Working Group (CLOSED)

Date: Friday, July 15, 2016
Start and End Time: 7:00 am – 9:00 am
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 new tracking form for the protocol working group reviewer responses
3. Discuss Medicare analysis/additional funding for NCTN studies, receive updates on other NCTN group and incorporate tools presented at this meeting by guest speakers
4. Discuss current method for updates and corrections of existing protocols
5. Discuss additional ways the working group can assist the protocol development teams.

WORKSHOP AGENDA

1. Review current Protocol review process
2. Update from the Protocol Development team. Any upcoming studies?
3. CIRB update if member can attend
4. Review progress to date (Reviewed B51, GY002, GY004, GY006, GY007, HN003, GOG238 and GOG225, RTOG848)
5. Protocol review assignments continue to send all or specific
6. Update on Funding sheets and Medicare analysis?
7. Replacement members – review current roster
8. Other business

QUESTIONS/DISCUSSION
EVALUATION

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

Date: Friday, July 15, 2016
Start and End Time: 7:00 am – 9:00 am
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) Define the role of the Quality Control Working Group
- 2) Describe how the Quality Control Working Group will interact with the Audit/Quality Control Committee of NRG Oncology
- 3) Describe how the Quality Control Working Group will interact with the other Working Groups of the Protocol Support Committee
- 4) Identify liaisons to the other Working Groups

WORKSHOP AGENDA

1. Review and approval of minutes from last meeting
2. Introductions
3. Discussion with Dr. Blessing about the role of the Quality Control Working Group as it relates to the Audit/Quality Control Committee of NRG Oncology
4. Develop SOP for Quality Control Working Group interaction(s) with other Working Groups of the Protocol Support Committee
5. Assign liaisons to other Working Groups

QUESTIONS/DISCUSSION
EVALUATION

Protocol Support Committee Workshop CTN/CRA Breakout Sessions

Date: Friday, July 15, 2016
Start and End Time: 2:00 pm – 6:00 pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Program Facilitator: Sally Brown RN, BSN

All sessions run concurrently (50 minutes/session)

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss the clinical logistics of the NRG GY-003 trial
2. Discuss the treatment of the NRG GY-003 trial
3. Discuss methods for successful accrual to the B-51 trial
4. Describe the treatment arms of the B-51 study
5. Discuss critical aspects of the correlative science of the B-55 and BR-003 trials
6. Discuss the study design and key inclusion criteria of the B-55 and BR-003 trials
7. Discuss the clinical logistics of the B-55 and BR-003 trials
8. Discuss the study design and key inclusion criteria for the NRG CC-001 trial
9. Discuss the clinical logistics of the NRG CC-001 trial
10. Describe the treatment arms of the NRG CC-003 trial
11. Discuss the study design and key inclusion criteria for the NRG CC-003 trial
12. Describe navigation in Medidata RAVE
13. Explain how to enter a participant utilizing OPEN
14. Define when use of the NCI CIRB is applicable
15. Access the site registration portal on CTSU web site
16. Describe process for submission of translational research specimens
17. Recall purpose of IROC
18. Explain reason for conducting site audits
19. Describe the therapy utilized in the NRG GY-004 trial
20. Discuss the study design and key inclusion criteria of the NRG GY-004 trial

AGENDA

Topic	Speaker	# of Sessions
Protocol NRG-GY-003	Robert Burger, MD & Cathi Ybarra, RN	1
Protocol B-51	Thomas Julian, MD, Simona F Shaitelman, MD Eleftherios Mamounas, MD, Julia White, MD Kristen Kotsko, RN, BSN	1
Protocols B-55 & NRG BR-003	Kristen Kotsko, RN, BSN & Lynne Suhayda, RN, MSED	1
Protocol NRG CC-001	Paul Brown, MD	1
Protocol NRG CC-003	Vinai Gondi, MD	1

Data Management Medidata RAVE	Bill Elgie, MBA	2
CIRB	Laura Covington, Desiree Goldstein RN, MSN, CCRC Debra Leal	2
CTSU	Martha Herring	2
Translational Research Specimens	Heather Lankes, PhD, MPH, Sandy DeVries, Teresa Bradley, Melanie Finnigan, Lisa Denero, Lisa Beaverson, BA	1
Dosimetry	Ezequiel Ramirez	1
Audit	John Blessing, PhD	2
Protocol NRG GY-004	Joyce Liu, MD	1

QUESTIONS/DISCUSSION
EVALUATION

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

Date: Saturday, July 16, 2016
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, describe, and discuss aspects of ongoing RTOG clinical trials using proton therapy which are in need of special support and improvement (including QA & credentialing problems), 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 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	Ted Hong, MD
6:50 – 6:55	Update on Proton Center Credentialing by IROC Houston	Paige Taylor, MS
6:55 – 8:10	Protocols/ Concepts	
6:55 – 7:15	Protons in liver studies	
6:55 – 7:05	<u>RTOG 1112</u> - Ph III Sorafenib +/- SBRT for hepatocellular ca (L. Dawson)	Laura Dawson MD
7:05 – 7:15	<u>NRG-GI001</u> - Ph III Cis/Gem +/- RT for unresectable cholangioCa	Ted Hong, MD
7:15 – 7:20	RTOG 1205–Ph IIR bevacizumab +/- IMRT recurrent GBM	Christina Tsien, MD
7:20 – 7:30	NRG-BN001 Brain: Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation with Concomitant /Adjuvant Temozolomide in Glioblastoma	Minesh Mehta, MD
7:30 – 7:40	RTOG 1308 Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable Stage II-IIIB NSCLC	Jeffrey Bradley, MD ZhongXing Liao, MD
7:40--7:50	PCORI (Patient-Centered Outcomes Research Institute) RADCOMP Breast Randomized Trail of Photons versus Protons	S. Macdonald, MD
7:50 – 8:15	Phase II/III Randomized Studies of IMRT vs. IMPT for Oropharyngeal Ca, Low Grade Brain Tumors, Hepatocellular and Esophageal CA	Drs. Steven Frank, David Grosshans, & Steven Lin
8:15 – 8:25	Other Business	Ted Hong, MD
8:25 – 8:30	Questions	

Radiation – Developmental Therapeutics Workshop

Date: Saturday, July 16, 2016
Start and End Time: 10:00 am -12:00 pm
Chair: David Raben, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Review and develop strategies to integrate immune modulators, targeted drugs and radiation across locally advanced diseases based on SITC-Radiotherapy workshop 2016
2. Apply current pre-clinical and clinical knowledge to better integrate immunotherapy (IO) and radiation
3. Detail current approaches with targeted drugs and immunotherapy to develop strategies to integrate
4. Review current approved/activated IO trials with radiation in locally advanced disease

WORKSHOP AGENDA

Session I

- A. Current Priorities:** The current priority of this committee is to assist in design and implementation of novel radiation trials with emerging biologics and immunologics. Significant projects in development include combination IT trials with radiation in disease sites such as but not limited to gastrointestinal malignancies, gynecological malignancies, head and neck cancer and lung cancer.
- B. Background:** This RT-DT committee was formed with the merging of the GOG, NASBP and RTOG in an effort to build towards clinical Phase I trials with correlative biomarker development combining novel agents and radiation.
- C. Advanced Topic:** Immunotherapy Guidelines and Recommendations for Radiotherapy Combinations in Patients with Locally Advanced or Oligometastatic Cancer- SITC-Radiotherapy Workshop Consensus Report.

QUESTIONS / DISCUSSION

- Workshop will include a review of disease site related RT-DT trial development and concepts
- Workshop will discuss current recommendations for combination IT and RT

List of Concepts:

- Role of Immunotherapy in locally advanced and metastatic cancer
- Recommendations for integrating IT (and/or targeted drugs) with radiotherapy
- Discussion of SITC consensus statements on RT sequencing, dosing with IT

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

Date: Friday, July 15, 2016
Start and End Time: 2:00 pm – 4:00 pm
Chair: Jeff Michalski, MD
Co-Chairs: Frank Vicini, MD; Ivy Petersen, 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, MD
2:05 – 2:40	Update on NCTN Cooperative Groups	
	a) NRG Oncology Group Update	Jeff Michalski, MD Frank Vicini, MD
	b) Imaging and Radiation Oncology Core (IROC) RT Update	David Followill, PhD Ying Xiao, PhD
	c) Imaging and Radiation Oncology Core (IROC) Imaging Update	Mark Rosen, MD, PhD
	d) RT Case Reviews at the NRG February Meeting	Jeff Michalski, MD Frank Vicini, MD
2:40 – 2:45	NCI Imaging Research Priorities/Opportunities	Ying Xiao, MD
2:45 – 2:50	Overview of Medical Physics	Ying Xiao, MD
2:50 – 2:55	Review RTOG/NRG Studies with Imaging and Oncology Trial	Jeff Michalski, MD
2:55 – 3:40	Disease Site Liaisons Reports	
	a. Brain	Christina Tsien, MD
	b. Breast	Steven Chmura, MD
	c. Gyn	Ann Klopp, MD, PhD
	d. GI	Laura Dawson, MD
	e. GU	Jeff Michalski, MD
	f. Head and Neck	Sue S. Yom, MD, PhD
	g. Lung	Greg Videtic, MD
	h. Sarcoma	Charles Simone, MD
	i. Outcomes	Dian Wang, MD Jason Efstathiou, MD
3:40 – 3:50	Other Business	
3:50 – 4:00	Questions/Discussion	

Rare Tumor Workshop Agenda

Date: Friday, July 15, 2016
Start and End Time: 2:00 pm - 4:00 pm
Chair: David M. Gershenson, MD
Co-Chair: Al Covens, 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)

B. Proposed Studies

AGCT1531: MaGIC 3-cohort trials for low-, intermediate, and high-risk patients with malignant germ cell tumors (COG) (Gershenson, Covens, Hurteau, etc.)

RTM1313: A randomized phase II trial of paclitaxel/carboplatin versus Trametinib monotherapy in patients with stage III and IV low-grade serous carcinoma of the ovary or peritoneum (Nickles Fader)

RT1504: A Phase II Study of Topotecan, Paclitaxel, and Bevacizumab for Advanced, Recurrent, or Persistent Small Cell Cervical cancer (Frumovitz) **Disapproved**

RT1508: A phase II evaluation of enzalutamide for recurrent sex cord-stromal ovarian tumors (Gien) **Pending further discussion of budgetary issues**

RT1530: A randomized phase II study of ICE alternating with VDC vs. VPCBAE as first-line therapy in women with small cell carcinoma of the ovary hypercalcemic type (SCCOHT) (Schmeler) **Withdrawn**

RT1547: A phase II multicenter open-label study of romidepsin (Istodax) in patients with recurrent small cell carcinoma of the ovary hypercalcemic type (SCCOHT) (Farley) **Disapproved**

RT1531: A randomized phase II trial of Temozolomide and Cisplatin versus Nivolumab (BMS-936558) in patients with completely resected mucosal melanoma (Vicus) **For discussion (see below)**

C. Review of New Recurrent Clear Cell Carcinoma of Ovary/Peritoneum Concepts

RT1625: A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)

RT1626: A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SAbR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)

RT1627: A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)

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

D. Discussion Topics

1. Follow-up Discussion of RT1531: Dr. Danielle Vicus
2. Follow-up Discussion of Trials for Endometrioid Carcinoma: Drs. Gershenson and Covens

QUESTIONS / DISCUSSION

..... Surgical Oncology Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 6:30 am – 8:00 am
Chair: Thomas Julian, MD
Co-Chairs: Drew Ridge, MD; Nick Spiritos, 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	Thomas Julian, M.D.
6:35 - 6:45	Medical Oncology Committee Update Radiation Oncology Committee Update	Jeff Michalski, M.D. Corey Langer, M.D.
6:45 – 7:00	NRG Oncology Update	Thomas Julian, M.D. and Nick Spiritos M.D
7:00– 7:10	Surgical QA/QC Protocol Development Plan	Charles Whitney, M.D.
7:10 – 7:45	Disease Site Liaisons Reports (very brief update on developments)* <ol style="list-style-type: none">a. Breastb. Gynecologyc. GUd. Lunge. Brain	Irene Wapnir, M.D. Nick Spiritos, M.D. Lenny Gomella, M.D. Jessica Donington, M.D. Dan Cahill, MD
	<i>*Liaison to provide a 5 minute update on latest surgical advancement</i>	
7:45 – 7: 55	Questions/Discussion	

Translational Science Workshop Agenda

Date: Saturday, July 16, 2016
Start and End Time: 10:00 am – 12:00 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 immunotherapy trials being designed
- 3 To identify, describe, and discuss the design and status of the new tumor banking reorganization.
- 4 To understanding the present translational research being conducted by the NRG U10.
- 5 To recognize critical aspects of developing translational endpoints for legacy GOG clinical trials.
- 6 To identify and describe new technologies for genomics and protein quantification and their use in legacy RTOG clinical trials

WORKSHOP AGENDA

10:00 – 10:15	Opening Remarks and Introduction	Michael Birrer, MD, PhD Adam Dicker, MD, PhD Matthew Ellis, MB, BCHIR, PhD
10:15 – 10:30	Use of the biorepositories/CSCC update	Michael Birrer MD PhD
10:30 – 11:00	Proteomic update/CPTAC	Matthew Ellis, MB, BCHIR, PhD
11:00 – 11:30	Novel Immunotherapy Trials	Jim Hodge PhD Adam Dicker, MD, PhD
11:30 – 12:00	Novel PARPi combinations	Joyce Liu MD

Active Breast Trials:

1. **NSABP B-51/RTOG 1304:** A Randomized Phase III Clinical Trial Evaluating 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.
2. **NSABP B-55/BIG 6-13 (OLYMPIA):** A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre 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.
3. **RTOG 1119:** Phase IIR WBRT + Concurrent Lapatinib for Brain Metastasis from HER2-Positive Breast Cancer.
4. **BR001:** Dose escalation Hypofractionated SBRT in Breast, Lung and Prostate Oligometastasis.
5. **BR002:** Ph IIR/III SBRT+Surgical ablation, Breast Oligometastasis;
6. **BR003:** A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Carboplatin for Node-Positive or High-Risk Node-Negative Triple-Negative Invasive Breast Cancer.

Breast trials in the OEWG Pipeline:

1. NRG-BR004 (BR1546): A Randomized Phase III Trial of Nab-paclitaxel/Trastuzumab/Pertuzumab Compared to Nab-paclitaxel/Trastuzumab/Pertuzumab/MEDI4736 in First Line HER2-Positive Metastatic Breast Cancer (submitted to BCSC)
2. BR1553: 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

Active Brain trials

1. **BN001:** Ph IIR Hypofx Dose-Escalated Photon IMRT or Proton RT vs. Conventional Photon RT with Concomitant/Adjuvant Temozolomide in Newly Diagnosed GBM
2. **BN002:** Ph I Ipilimumab, Nivolumab, and the Combination in Newly Diagnosed GBM (Limited Center; Temporarily closed to accrual 5-10-16 for protocol specified analysis)

Brain Trials in development:

1. BN1536: ND GBM Ph IIR TMZ/ipi vs TMZ/placebo; TMZ/nivolumab vs TMZ/placebo. (Development timeline is contingent on results from pilot safety trial BN002)
2. BN003 (concept#BN1540): Phase III Meningioma. **CTEP Approved; protocol is in development.**
3. BN1526: Phase II Randomized Trial of Pembrolizumab (MK-3475) with and without Stereotactic Radiosurgery (SRS) in Melanoma Patients with ≤ 5 Brain Metastases and Extracranial Metastases (**concept submitted to BMSC on 5-25-16**)

Active GI Trials (as of January 5, 2016)

1. **RTOG 1201** A Phase II Randomized Trial of High versus Standard Intensity Local or Systemic Therapy for Unresectable Pancreatic Cancer.
2. **RTOG 0848** A Phase IIR and A Phase III Trial Evaluating Both Erlotinib (Ph IIR) And Chemoradiation (Phase III) As Adjuvant Treatment For Patients With Resected Head Of Pancreas Adenocarcinoma.
3. **RTOG 1112** Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma.
4. **GI001:** Randomized Phase III Study of Focal Radiation Therapy for Unresectable Localized Intrahepatic Cholangiocarcinoma (**Temp Closed; pending redesign; amendment redesign approved by CTEP, study is being amended**)

GI Trials in the OEWG Pipeline:

1. **GI002:** A Phase II Clinical Trial Platform of Novel Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer(**Protocol submitted to CTEP**)
2. **GI1525:** A Phase III Trial Evaluating ADXS11-001 w/ Mitomycin 5-FU+ IMRT for Locally Advanced Anal Cancer (concept submitted to GISC on 6-1-16)
3. **GI003:** Ph IIR Protons vs. Photons for Hepatocellular Carcinoma; **Concept Approved 6-6-16; protocol is in development.**

GI Trials under development by GI committee

1. **GI1612:** Ph III Pembro after Trimodality therapy for high risk node+ esophagogastric CA (concept submitted to GI task force on 6/3/16)
2. **CR1556:** A Randomized Phase III Study of FOLFOX/Bevacizumab Combination Chemotherapy with or without Atezolizumab in the First-Line Treatment of Patients with Microsatellite Instability-High (MSI-H) Metastatic Colorectal Cancer. (Concept pending review by GI Task Force)

Active GU Trials (as of January 5, 2016)

1. **RTOG 0924:** Phase III intermediate to high risk prostate cancer + or - Pelvic RT.
2. **RTOG 0926** Phase II T1 Bladder cancer RT and Cisplatin.
3. **GU001:** Phase IIR/III postoperative adjuvant IMRT following cystectomy for pT3-T4 urothelial bladder cancer (CTEP Approved; protocol is in development)

GU Trials under development:

1. GU002: PhII-III Adjuvant RT Following Radical Prostatectomy \pm Adjuvant Docetaxel; CTEP approved, protocol in development
2. GU003 (GU1548) Phase IIR/III conventional vs. hypofrax RT (IGRT/IMRT) post-prostatectomy CTEP approved, protocol in development

Active Head & Neck Trials:

1. **RTOG 0912:** Concurrent radiation + chemotherapy+ pazopanib for Anaplastic Thyroid Cancer (Phase II-R) –First trial to address the role of targeted therapy + chemoradiotherapy in aggressive anaplastic thyroid cancer.
2. **RTOG 0920:** IMRT/IGRT + cetuximab for “intermediate risk” resected head and neck cancer (Phase III) - First trial to address the role of targeted therapy + RT in in the adjuvant setting in patients with intermediate risk pathologic features.

3. **RTOG 1008:** A Randomized Phase II/Phase III Study of Adjuvant Concurrent Radiation and Chemotherapy versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors (Reopened to Phase III 1-25-16)
4. **RTOG 1216:** RT-cisplatin vs. RT-Docetaxel vs. RT-Docetaxel + Cetuximab for “high risk” resected HNSCC (Phase IIR-III) – study the role of docetaxel vs. cisplatin based chemotherapy concurrent with radiation in the adjuvant setting in patients with high risk pathologic features, primarily HPV negative tumor. **(Phase II met accrual; temp closed for analysis)**
5. **HN001 :** Individualized nasopharyngeal cancer treatment based on post-RT EBV DNA (Phase III) – first study using EBV DNA as a biomarker to determine which NPC patient would need adjuvant chemotherapy and the type of adjuvant chemotherapy that they would need
6. **HN002:** A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer

H&N trials in the OEWG pipeline

1. **HN003:** Ph IIR (with phase I run-in) Adj. Cis-RT +/- Pembro in high-risk, HPV-neg. H&N (protocol under development)**HN1539:** Phase IIR, with single arm safety run in, RT with durvalumab vs. RT with cetuximab for stage III-IVB H&N for medically unfit for high-dose cisplatin (concept submitted to HNSC 6-20-16 review)
2. **DT1624 PTMA#100300(no NRG # assigned yet):** AMG232 in Sarcoma

Active Lung Trials

1. **RTOG 1306:** Randomized Phase II Study of Individualized Combined Modality Therapy for NSCLC.
2. **RTOG 1308:** Phase III Randomized Trial Comparing Overall Survival After Photon vs. Proton Chemoradiotherapy for Inoperable Stage II-III NSCLC.
3. **RTOG 1106/ACRON 6697:** Randomized Phase II Trial of Individualized Adaptive Radiotherapy Using During-Treatment FDG-PET/CT in Locally Advanced NSCLC.
- 4.
5. **LU001:** Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin in NSCLC.

Lung trials in the OEWG Pipeline:

1. **LU002 (LU1524):** Randomized Phase IIR with maintenance chemo +/- SBRT for patients with Stage IV NSCLC (Iyengar); CTEP approved, protocol is in development
2. **LU1613: ARCHON-1:** Phase I/II Randomized Trial of Accelerated Hypofractionated Radiotherapy Combined with Immunotherapy in chemotherapy ineligible Non-Small Cell Lung Cancer (targeting TMS 7-21-16)

Active Gyn Trials

1. **GOG-0213** A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab (NSC #704865, IND #7921) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer **Activated: 12-06-07. Closure projected 02/18**
2. **GOG-9923** A Phase I Study of Carboplatin/Paclitaxel/CTEP-Supplied Agent Bevacizumab (NSC #704865, IND #7921) and CTEP Supplied Agent ABT-888 (NSC #737664, IND #77840) in Newly Diagnosed Patients with Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer **Activated: 10-28-09. Closure projected 2015**
3. **GOG-0263** Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA, Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy. **Activated: 04-12-10. Closure projected 12/22**
4. **GOG-0265** A Phase II Evaluation of ADXS11-001 (NSC 752718, BB-IND#13,712) in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the cervix. **Activated: 05-23-11. Closure projected 10/15**
5. **GOG-0270** Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) II: An Observational Study **Activated: 01-03-12 Observation only. Closure projected 12/16**
6. **GOG-0278** Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgery Therapy (Extra Fascial Hysterectomy or Cone Biopsy with Pelvic Lymphadenectomy) for Stage IA1 (LVSI+) and IA2-IB1 (<2CM) Cervical Cancers **Activated: 10-01-12. Closure Projected 12/19**
7. **GOG-0279** A Phase II Trial Evaluating Cisplatin (NSC #119875) and Gemcitabine (NSC #613327) Concurrent with Intensity-Modulated Radiation Therapy (IMRT) in the Treatment of Locally Advanced Squamous Cell Carcinoma of the Vulva. **Activated: 07-02-12. Closure projected 09/19**
8. **GOG-0724/RTOG-0724** Phase III Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy with or without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy. **Activated by RTOG 9-16-09**

9. GOG-9929 A Phase I Trial of Sequential Ipilimumab after Chemoradiation for the Primary Treatment of Patients with Locally Advanced Cervical Cancer Stages IB2/IIA with Positive Para-Aortic Lymph Nodes Only and Stage IIB/IIIB/IVA with Positive Lymph Nodes **Activated:10-01-12. Closure projected 01/15**
10. GOG-0238 A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-only Recurrence of Carcinoma of the Uterine Corpus. **Activated: 02-25-08. Closure projected 05/2020.**
11. GOG-0275 A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-Day Methotrexate for the Treatment of Low-Risk Gestational Trophoblastic Neoplasia. **Activated: 06-29-09. Closure projected 6/2025**
12. GOG-0277 A Phase III Randomized Trial of Gemcitabine (NSC# 613327) plus Docetaxel (NSC# 628503) Followed by Doxorubicin (NSC# 123127) Versus Observation for Uterus-Limited, High-Grade Uterine Leiomyosarcoma. **Activated: 06-04-12. Closure projected 04/2031**
13. GOG-0264 A Randomized Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide and Cisplatin for Newly Diagnosed Advanced Stage and Recurrent Chemo-Naive Sex Cord-Stromal Tumors of the Ovary. **Activated: 02-08-10. Closure projected 04/2021.**
14. GOG-0281 A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (GSK1120212) in Patients with Recurrent or Progressive Low-grade Serous Ovarian Cancer or Primary Peritoneal Cancer. **Activated: 02-27-14. Closure projected 04/18**
15. GOG-0283 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. **Activated: 02-03-14. Closure projected 04/18**
16. **NRG- GY001 (RTM1303):** A Randomized Phase II XL-184 in women with recurrent clear cell carcinoma of the ovary, fallopian tube, or peritoneum (John H Farley) **Activated 4/1/15 closed to first stage 11/30/15**
17. **NRG-GY002 (DT1402):** A phase II evaluation of nivolumab (BMS-936558), a fully human antibody against PD-1, in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix. (Alessandro D Santin) **Activated 5/18/15 closed to first stage 08/24/15**
18. **NRG-GY003 (DT1413):** Phase II randomized trial of nivolumab with or without ipilimumab in patients with persistent or recurrent high-grade serous adenocarcinoma of ovarian, primary peritoneal, fallopian tube or endometrial origin (R Burger) **Activated 6/29/15 closed to first stage 10/07/15**
19. **NRG-GY004:** A Phase III study of the combination of cediranib and olaparib compared to standard platinum-based chemotherapy in women with first-line recurrent platinum-sensitive ovarian cancer (Joyce Liu) **Active.**
20. **NRG-GY005:** *An Integrated, Randomized Phase II-III Study of Olaparib and Cediranib in Recurrent Platinum-Resistant Ovarian Cancer (Secord/Lee)* **Active.**
21. **NRG-GY006:** A Randomized Phase II Trial of IMRT and Cisplatin Alone or in Combination with IV Triapine or Bevacizumab in Women with Stage IB2, II, IIIB or IVA cancer of the Uterine Cervix. (Kunos/Leath/ Mell) **active**

Gyn trials in OEWG pipeline

1. RTM1313: : A randomized phase II trial of paclitaxel/carboplatin versus Trametinib monotherapy in patients with stage III and IV low-grade serous carcinoma of the ovary or peritoneum (A Nickles-Fader).

Gyn trials in OEWG pipeline also approved by RSC/CPAC

1. **NRG-GY008** Phase II evaluation of BAY 806946 in patients with endometrial cancer PIK3CA and PIK3R1/R2 mutations (A. Santin) **Protocol under review CTEP**
2. **UC1304:** Evaluation of Biomarkers, Imaging, Sentinel Lymph Node(s), Quality of Life and Cost Effectiveness Study of Tailoring Adjuvant Therapy in Endometrial Cancer (STATEC) (Nicola Spirtos/Nadeem Abu-Rustum)—GCIG lymphadenectomy trial. **EORTC preparing response to CTEP review.**
3. **UC1406:** Randomized Pilot investigating relationship of short-term depo-provera compared to depo-provera plus entinostat on morphologic, biochemical and molecular changes in primary endometrioid adenocarcinoma of the uterine corpus [0211R (Linda Duska)] **LOI for entinostat submitted**
4. **OV1509:** A Randomized Phase II Trial of Neoadjuvant Carboplatin/Paclitaxel +/- the PD-1 inhibitor, Nivolumab, for the Treatment of Primary Bulky, Advanced Stage Epithelial Ovarian, Peritoneal, or Fallopian Tube Cancer. (Stephanie Gaillard)
5. **NRG-GY009 (OV1550) PTMA** A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Bevacizumab with and without Atezolizumab in Platinum Resistant Ovarian Cancer (Aghajanian/ Snyder)**protocol under review CTEP**
6. **DT1527:** A phase II trial of dose dense paclitaxel in recurrent endometrial cancer (129 series) (Gunderson and Moore) **LOI on hold will need new submission**

7. **OV1629:** (OV1611) 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) **RSC and CPAC reviewed and approved. GCSC/CTEP requested withdraw/ renumber resubmit to PRC**
- 8.

Gyn Trials under development by Gyn Committee

1. **OV1505:** 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 Moore)
2. **UC1506:** Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine) will submit to CCSC

New Gyn concepts for review

1. **DT1620:** A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Sara Temkin)
2. **UC1621: (UC1534)** A Phase II Study of pembrolizumab (MK-3475) in patients with Microsatellite Unstable (MSI), Persistent or Recurrent Endometrial Cancer (Nickles-Fader/Armstrong)
3. **DT1622:** A Phase II Evaluation of Veliparib in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (Salani Ritu)
4. **RT1625:** A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)
5. **RT1626:** A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SAbR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)
6. **RT1627:** A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
7. **DT1628:** A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)
8. **UC1630:** Randomized Two Arm Phase II Cross-Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma Patients who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)
9. **UC1631:** Phase II Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens(Maxwell/Powell/Rimel)
10. **RT1632:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Cell Carcinoma of the Ovary, Peritoneum or Fallopian Tube. (John Farley)

QUESTIONS / DISCUSSION

Translational Science GYN Workshop Agenda

Date: Friday, Jul 15, 2016
Start and End Time: 2:00 pm – 4:00 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

2:00 – 2:20	Opening Remarks TR Update Biorepository Update Navigator/Specimen Access	Michael Birrer, MD, PhD Heather Lankes, PhD, MPH Nilsa Ramirez, MD Nilsa Ramirez, MD
2:20 – 3:40	210 Subcommittee Update	
3:40 – 3:50	TS-GYN Project Updates GOG 0271 GOG 0286B Amendment GOG 8034 and 8042 GOG 8035 UC1601 Ovarian SPORE	Robert Edwards, MD Vickie Bae-Jump, MD Anil Sood, MD Krishnansu Tewari, MD Larry Maxwell, MD
3:50 – 4:00	Concept Review and Other Business	

New GYN Concepts

1. **NC1603:** Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (Ed Tanner)
2. **DT1620:** A window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Sara Temkin)
3. **UC1621: (UC1534)** A Phase II Study of pembrolizumab (MK-3475) in patients with Microsatellite Unstable (MSI), Persistent or Recurrent Endometrial Cancer (Nickles-Fader/Armstrong)
4. **DT1622:** A Phase II Evaluation of Veliparib in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (Salani Ritu)
5. **RT1625:** A Phase I/II Study of Pazopanib and PDR001 for the Treatment of recurrent Clear Cell Ovarian Cancer. (Floor Backes)
6. **RT1626:** A Phase II Trial of Combined anti-PDL1 (MSB0010718C) Immunotherapy (IT) with Stereotactic Ablative Radiotherapy (SABR) in Recurrent Clear Cell Ovarian Cancer (Kevin Albuquerque)
7. **RT1627:** A phase II evaluation of pembrolizumab with epacadostat in recurrent clear cell carcinoma of the ovary. (Lilian Gien)
8. **DT1628:** A phase II evaluation of nivolumab in recurrent, persistent or metastatic squamous cell carcinoma of the vulva. (Lilian Gien)

9. **UC1630:** Randomized Two Arm Phase II Cross-Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma Patients who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)
10. **UC1631:** Phase II Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens(Maxwell/Powell/Rimel)
11. **RT1632:** Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Cell Carcinoma of the Ovary, Peritoneum or Fallopian Tube. (John Farley)

QUESTIONS / DISCUSSION

Translational Science Lung Cancer Workshop Agenda

Date: July 15, 2016
Start/End Time: 4:00 – 6:00 PM
Chair: Bo Lu, MD, PhD

Learning Objectives:

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

1. Current Clinical Trials of combining radiotherapy with immunotherapy: relevant data in lung cancer,
2. Novel and evolving biomarkers for predicting response to immunotherapy, and
3. Mesothelin as a prognostic marker and therapeutic target for lung cancer.

WORKSHOP AGENDA

Intro/Overview: Bo Lu, MD, PhD

Speaker(s): Yang-Xin Fu, MD, PhD
Presentation Title: “Radiation-Induced DNA Damage to DNA Sensing: The Essential Role of T Cells in Radiation Therapy”

Speaker: Douglas Hooper, PhD
Presentation Title: “Immune Bias in Cancer”

Speaker(s): Amit Maity, MD, PhD
Presentation Title: “Combining Hypofractionated Radiation with Immune Checkpoint Blockade”

Speaker(s): Jianda Yuan, MD, PhD
Presentation Title: “Tumor Immunology Meets Oncology: Next Generation Biomarkers for Personalized Cancer Immunotherapy”

Speaker: Troy Tremaine
Presentation Title: “Blood-Based Proteins of the Immune System: Promising Biomarkers for Detecting Early Response and Pharmacodynamics Changes in Immuno-Oncology Clinical Trials”

Speaker: Jessica Donington, MD
Presentation Title: “Mesothelin as a Marker for Non-Small Cell Lung Cancer”

Uterine Corpus Committee Agenda

Date: Friday, July 15, 2016
Start and End time: 2:30 pm – 4:30 pm (Session I)

Date: Saturday, July 16, 2016
Start and End time: 10:00 am – 11:00 am (Session II)

Chair: David Scott Miller, MD
Co-Chair: Marcus Randall, MD

Learning Objectives

Following this activity, participants will be better able to:

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

Workshop Agenda

A. Introduction (Miller)

B. Review of Closed Studies

1. **GOG-0086P:** 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. **GOG-0130F** A Phase II evaluation of Ixabepilone (IND #59699, NSC #710428) in the treatment of recurrent or persistent carcinosarcoma of the uterus (**Carolyn K McCourt**)
3. **GOG-0184:** Tumor Volume-Directed Pelvic Plus or Minus Para-Aortic Irradiation followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for advanced Endometrial Carcinoma (Howard D Homesley) [[Gynecol Oncol 112: 543-52, 2009](#); [Gynecol Oncol 119: 538-42, 2010](#)]:
4. **GOG-0188** :Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [[Gynecol Oncol 120\(2\): 185-8, 2011](#)]:
5. **GOG-0209:** 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](#)]
6. **GOG-0210:** A Molecular Staging study of Endometrial Carcinoma (William T Creasman):
7. **GOG-0211:** An Investigation of the Relationship of Short Term Depo-Provera (Medroxyprogesterone Acetate) Exposure to the Morphologic, Biochemical, and Molecular Changes in Endometrial Adenocarcinoma (Richard Zaino) [[Mod Pathol 23: 270A, 2010](#)]:
8. **GOG-0229J:** A Phase II Evaluation of BMS582664 (Brivanib, IND#105029) An Oral, Multi targeted Growth Factor Tyrosine Kinase Inhibitor in the Treatment of Recurrent or Persistent Endometrial Cancer (229 series) (**Matthew A Powell**) [[Gyn Oncol 135: 38-43, 2014](#)]
9. **GOG-0229J:** A Phase II Evaluation of Cediranib (RECENTIN; AZD2171) in the Treatment of Recurrent or Persistent Endometrial Cancer (David P Bender) [doi:10.1016/j.ygyno.2015.04.018](https://doi.org/10.1016/j.ygyno.2015.04.018) :

10. **GOG-0229K** A Phase II Evaluation of BIBF 1120 (IND#113086) in the Treatment of Recurrent or Persistent Endometrial Carcinoma (Don S Dizon) [doi:10.1016/j.ygyno.2014.10.001](https://doi.org/10.1016/j.ygyno.2014.10.001) :
11. **GOG-0229L** Phase II Trial of AMG 386 (IND#111071), a Selective Angiopoietin 1/2 Neutralizing Peptibody, in Patients with Persistent/Recurrent Carcinoma of the Endometrium (229 Series) (Kathleen N Moore):
12. **GOG-0229O** 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):
13. **GOG-0233**: 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, Ila iY4 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) [J Clin Oncol 29(15s) (ASCO #5035): 340s, 2011; J Clin Oncol 29(15s) (ASCO #5042): 342s, 2011]:
14. **GOG-0242**: Second Curettage: First-Line Management for Patients with Persistent Low-Risk Gestational Trophoblastic Disease [GTN] (Raymond Osborne) [doi:10.1016/j.ygyno.2014.07.079](https://doi.org/10.1016/j.ygyno.2014.07.079):
15. **GOG-0248**: Randomized Phase II Trial of Temozolomide or the Combination of Hormonal Therapy plus Temozolomide in Women with Advanced or Recurrent Endometrial Cancer (Gini Fleming) [*Gynecol Oncol* 132:585, 2014]:
16. **GOG-0249**: Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy (McMeekin) [doi:10.1016/j.ygyno.2014.07.078](https://doi.org/10.1016/j.ygyno.2014.07.078):
17. **GOG-0258**: 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):
18. **GOG-0261**: 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**)
19. **GOG-0283** 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):
20. **GOG-0286B** 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):

C. Review of Active Studies

1. Endometrial Protocols:

- a. **GOG-0238**: A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus (Higinia R Cardenes) ??/154 accrued:

2. Uterine Sarcoma Protocols:

- a. **GOG-0277** 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) ??/216 accrued.

3. Gestational Trophoblastic Disease Protocols

- a. **GOG-0275** A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Management of Low Risk Gestational Trophoblastic Neoplasia (**Julian C Schink**)

D. Review of Approved Concepts/Protocols

1. **GOG-8038**: Epidemiologic Risk Factors and Endometrial Cancer Survival (Louise A Brinton):
2. **UC0905**: Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (**Mutch**)
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):
4. **GOG-8040 (UC1107)**: An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino)
5. **UC1306**: A randomized phase II study evaluating the role of maintenance therapy with cabozantinib in High Grade Uterine Sarcoma (HGUS) after stabilization or response to chemotherapy following surgery or in metastatic first line treatment (Martee L. Hensley)
6. **NRG-GY008 (DTM1419)**: 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): Supported 7/14.
7. **DT1527**: A Phase II Evaluation of Weekly Paclitaxel in the Treatment of Recurrent or Persistent Endometrial Carcinoma. (C. Gunderson);
8. **UC1406**: A randomized Pilot investigation of the relationship of short-term depo-provera (Medroxyprogesterone Acetate) (NSC #27408) Compared to depo-provera plus Vorinostat (SAHA) (NSC# 701852) on the Morphologic, Biochemical and Molecular Changes in Primary Endometrioid adenocarcinoma of the Uterine Corpus. (**Duska**):
9. **UC1506**: Translational Science for Uterine Carcinosarcoma Trials [GOG0261] (Douglas Levine)
10. **UC1601**: Molecular Alterations Associated with Racial Disparities, Outcome and Treatment Response in Black verses White Women with Endometrioid Endometrial Cancer and Uterine Serous Cancer. (L. Maxwell) CCSC
11. **UC1603**: Impact of Sentinel Lymph Node Biopsy and Adjuvant Therapy on Health Related Quality of Life in Endometrial Cancer (Tanner) PCOR

E. New Proposed studies

1. **UC1630**: Randomized Two Arm Phase II Cross-Over Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin or the PD-L1 inhibitor (PD-L1i), Durvalumab (MEDI4736) in Recurrent Serous Endometrial Adenocarcinoma Patients who Failed One or Two Prior Regimens (Maxwell/Powell/Rimel)
2. **UC1631**: Phase II Trial of the ATR inhibitor (ATRi), AZD6738 and Carboplatin in Recurrent Patients with Carcinosarcoma of the Uterus who Failed One or Two Prior Regimens(Maxwell/Powell/Rimel)

F. Studies from Other Committees for Review:

1. **NRG GY-TS001 (GOG-8041, CEM1304):** The Relationship of Racial Genetic Admixture and its Associated Protein Biomarkers with Endometrial Cancer Outcomes (Rodney P Rocconi) **Supported 7/13**
2. **DT1620** A window of opportunity pharmacodynamic trial of Triapine in uterine corpus serous adenocarcinoma (Sarah Temkin, MD)
3. **DT1621 (DT1534):** Phase II study of pembrolizumab (MK-3475) in patients with microsatellite unstable (MSI), persistent, or recurrent endometrial cancer. (A. Nickles-Fader)

G. New Business

1. Report from GOG Foundation
 - a. **GOG-3006** A PHASE II EVALUATION OF PAZOPANIB IN THE TREATMENT OF RECURRENT OR PERSISTENT LEIOMYOSARCOMA OF THE UTERUS (**Hensley**)
 - b. **GOG-3007** 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**): 54/72 accrued
 - c. **GOG-3010** A PHASE II STUDY OF FOLIC ACID TUBULYSIN CONJUGATE EC1456 IN PATIENTS WITH RECURRENT OR PERSISTENT ENDOMETRIAL CANCER (**Matei**)
2. Report from Subcommittee on Gestational Trophoblastic Disease (**Schink**)
3. Report from GOG0210 Scientific Advisory Board (**Mutch**)
4. Report from RTOG (**Klopp**)

NON-CME SESSIONS

All sessions are in alphabetical order.

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ONCOLOGY

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**NRG FUNCTIONAL IMAGING / QUANTITATIVE GROUP AGENDA
CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)**

Date: Friday, July 15, 2016
Start and End Time: 10:00 am – 12:00 pm
Chair: Feng-Ming (Spring) Kong, MD, PhD, FACR
Co-Chair: Mitchell Machtay, MD

10:00 – 10:10 Welcome / Introductions

Feng Ming (Spring) Kong, MD, PhD Indiana University
Mitchell Machtay, MD, Case Western University

10:10 – 10:25 Imaging guided SBRT in head and neck cancer: Safety, QA and Clinical Outcome

David Schwartz, MD
University of Texas Southwestern

10:30 – 10:45: PET volumetric index (PVI) for lung cancer (R21 funded, R01 concept)

Youlin Pu, MD
University of Chicago

**10:50– 11:10 Molecular Imaging for Guiding Post-Prostatectomy Radiotherapy
(R01 funded project, and possible new R01 concept)**

Ashesh Jani, MD, MSEE
Emory University Winship Cancer Center

**11:10– 11:30 Updates and comments from disease specific Liaisons
(add disease sites liaisons available)**

**11:30 – 12:00 Questions/Discussions
Kong/Machtay**

GYN Operations Committee Agenda

Date: Saturday, July 16, 2016

Time: 11:00 am - 12:00 pm

Chair: Larry Copeland, MD

Co-Chair: Fred Stehman, MD

AGENDA

I. General Business

- A. Call to order (*Copeland*)
- B. Approval of minutes of January 2016 (*Copeland*)

II. Committee on Experimental Medicine

CEM (*Birrer*)

Active Studies: 8005, 8006, 8007, 8008, 8009, 8010, 8011, 8013, 8014, 8015, 8016, 8017, 8020, 8022, 8023, 8024, 8025, 8028, 8031, 8033, 8034, 8036, 8039, 8042

Closed Studies: 220, 221, 235, 271

- A. Terminations
- B. Amendments
- C. Other Business

III. Developmental Therapeutics Committee

DTM (*Aghajanian*)

Active Studies: 265

Temporarily Closed: 286B

Closed Studies: 76HH, 86P, 130F, 170Q, 170R, 186G, 186H, 186I, 186J, 186K, 227G, 229G, 229I, 229L, 229O, 231D, 255, 260, 280

- A. Terminations
- B. Amendments
- C. Other Business

Phase I Sub-Committee (*Schilder*)

Active Studies: 9923, 9929

Closed Studies: 9924, 9926, 9927, 9928

- A. Terminations
- B. Amendments
- C. Other Business

IV. Cancer Prevention and Control Committee (*Alberts/Walker*)

Active Studies: 225, 237

Closed Studies: 199, 207, 214, 215, 244, 247, 256, 269, 8199

- A. Terminations
- B. Amendments

C. Other Business

V. Health Outcomes Research Committee (Wenzel)

Active Studies: 213, 278

Closed Studies: 147, 184, 199, 209, 212, 218, 240, 249, 252, 258, 259, 262, 267, 9902

- A. Terminations
- B. Amendments
- C. Other Business

VI. Committee on Cancer of the Uterine Corpus (Miller/Randall)

Active Studies: 238, 275, 277

Closed Studies: 184, 188, 209, 210, 242, 248, 249, 258, 261

- A. Terminations
- B. Amendments
- C. Other Business

VII. Committee on Cancer of the Cervix and Vulva (Monk/Koh)

Active Studies: 263, 270, 274, 278

Temporarily Closed: 279

Endorsed: 724 (RTOG-0724)

Closed Studies: 233, 240

- A. Terminations
- B. Amendments
- C. Other Business

VIII. Committee on Cancer of the Ovary (Bookman/DiSilvestro)

Active Studies: 213

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

- A. Terminations
- B. Amendments
- C. Other Business

IX. Rare Tumor Committee (Gershenson)

Active Studies: 264, 281, 283

Temporarily Closed:

Endorsed Protocols: E2607

Closed Studies: 187, 239, 241, 251, 254, 268

- A. Terminations
- B. Amendments
- C. Other Business

X. Pathology (Rogers)

XI. New Business

Immunotherapy and Immune Modulation Workshop

Date: Friday: July 15, 2016
State and End Time: 11:00 am – 12:30 pm
Co-Chairs: Harry Bear, MD, Marka Crittenden, MD, Mark Einstein, MD, James Hodge, MD,
Samir Khleif, MD

Cancer MoonShot 2020 Program

Presenters:

Patrick Soon-Shiong, M.D., FRCS (C), FACS
Chairman, Chan Soon-Shiong Family Foundation
Chairman and CEO, Chan Soon-Shiong Institute of Molecular Medicine
Chairman and CEO, NantKwest

Shahrooz Rabizadeh, PhD
Chief Scientific Officer, NantOmics, LLC, NantBioScience, Inc.

Korean Gynecology Oncology Group Meeting

Date: Friday, July 15, 2016
 Start and End time: 5:00 pm-7:00 pm
 Chair: Byoung-Gie Kim, M.D.(President of KGOG)
 Co-Chairs: YongMan Kim, M.D./JaeHoon Kim, M.D.(Vice President of KGOG)

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss the design and critical significance of new and ongoing NRG clinical trials
2. Identify and describe promising NRG clinical trial available in Korea
3. Discuss the roles of the KGOG to enable effective patient enrollment in a cooperative group setting.

Workshop Agenda

Time	Titles	Speakers
5:00-5:05	Welcome/Introduction	Byoung-Gie Kim, M.D.
5:05-6:00	Session I.	
	1. Update on ADX study	Charles A. Leath III, M.D.
	2. OV1509: A randomized phase II trial of neoadjuvant carboplatin/paclitaxel +/- PD-1 inhibitor for the treatment of primary bulky, advanced stage epithelial ovarian, peritoneal, or fallopian tube cancer	Stéphanie Gaillard, MD
	3. UC-1534 phase II study of pembrolizumab (MK-3475) in patients with microsatellite unstable(MSI), persistent or recurrent endometrial cancer	Amanda Nickles Fader, M.D.
6:00-7:00	Session II. KGOG Meeting	
	1. Update of active studies	Byoung-Gie Kim, M.D. DaeYeon Kim, M.D.
	2. New concepts and protocols	Sang Wun Kim, M.D. Yong Man Kim, M.D. Yun Hwan Kim, M.D. Jae-Weon Kim, M.D. Jae Hoon Kim, M.D. JeongYeol Park, M.D. Sang Young Ryu, M.D. Sung Jong Lee, M.D. Jong Min Lee, M.D. Chulmin Lee, M.D. Taek Sang Lee, M.D. Suk Joon Chang, M.D. Hakyun Chang, M.D. Seob Jeon, M.D.
	3. Questions/Discussion	

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

Date: Saturday, July 16, 2016
Start and End Time: 10:00 am – 12:00 pm
Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
Room:

WORKSHOP AGENDA

1. Meeting Summary
2. Report from CTN Subcommittee
3. Report from CRA Subcommittee
4. Report from Working Groups
5. Update on appointment of CRA/CTN to protocols and committee appointments
6. New business

QUESTIONS/DISCUSSION

EVALUATION



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AGENDA
NCORP PI & ADMINISTRATORS MEETING
SATURDAY, July 16, 2015
8:00 – 10:00 AM
Dallas, TX

8:00 a.m.	I. Welcome	D.L. Wickerham, MD
8:05 a.m.	II. NCI NCORP Report	W. McCaskill-Stevens, MD
8:30 a.m.	III. NCORP Administrative Update	S. Hine
8:50 a.m.	IV. Cancer Care Delivery Research Group	J. Lipscomb, PhD; David Cohn, MD
9:00 a.m.	V. Cancer Prevention and Control Committee	L. Kachnic, MD; D. Alberts, MD
9:10 a.m.	VI. Health Disparities survey results and K. Yeager Cultural Competency training update	
9:25 a.m.	VII. Pilot Grant and Travel Awardees	D.L. Wickerham, MD
9:30 a.m.	VIII. Q&A – Open discussion of NRG Oncology and NCORP Program	

Sarcoma Working Group Agenda

Date: Friday, July 15 2016

Time: 8:00AM – 10:00AM

CHAIR: DIAN WANG, MD, PHD, Chair
Peter Houghton, PhD, TRP Liaison

A. Active Studies --- **Update only**

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)

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)

C. New Study Concept:

1. Phase IIR Trial of Immunotherapy and SBRT for Metastatic Soft Tissue Sarcoma (Wong)
2. Phase Ib Study To evaluate Neoadjuvant p53/MDM2 inhibitor combined with IMRT for Soft Tissue Sarcomas with high risk margins predicted for local recurrence (Welliver, NCI PTMA)

D. Sarcoma TRP

1. Additional findings from the sarcoma cell line screen with approved and investigational oncology agents (Dr. Beverly A Teicher, NCI)
2. Preclinical evaluation of PARP inhibitor BMN673 to radiosensitize sarcoma (Iliakis): Update?

E: New Business

Translational Science GU Cancer Subcommittee Agenda

Date: Friday, July 15, 2016

Start/End Time: 2:00pm – 4:00pm

Chair: Felix Feng, MD (UCSF) / Alan Pollack, MD, PhD (Univ. of Miami)

- 2:00 – 2:05** Introduction and Welcome
(Felix Feng, MD & Alan Pollack, MD PhD)
- 2:05 – 2:35** “Investigating Radioresistance in Prostate Cancer”
(Ganesh Raj, MD, Professor of Urology, UT Southwestern)
- 2:35 – 2:45** “Integrating Biomarkers into NRG Clinical Trials: Where do We Stand?”
(Felix Feng, MD)
- 2:45 – 3:00** “A Biomarker-Stratified Trial of Salvage RT +/- ARN509”
(Dan Spratt, MD, University of Michigan)
- 3:00 – 3:25** “Integrating Molecular Imaging into Clinical Trials”
(Alan Pollack, MD PhD)
- 3:25 – 4:00** Update of Ongoing Projects:
- Lotan – ERG/PTEN on RTOG 9601
 - Nguyen – GenomeDx array on RTOG 9413, 9902, and 9202
 - Maher – Sequencing on RTOG 9601
 - Feng – GenomeDx on RTOG 9601
 - Hall – C reactive protein and other cytokines on RTOG 0521

Translational Science Head & Neck Cancer Subcommittee Agenda

Date: Friday, July 15, 2016

Start/End Time: 2:00 – 3:00 pm

Co-Chairs: Dr. Christine Chung, MD, Moffitt Cancer Center
Dr. Neil Hayes, MD, MPH, University of North Carolina, Chapel Hill

2:00 – 2:10 Introduction and Welcome
(Dr. Christine Chung, MD, Moffitt Cancer Center)

2:10 – 2:50 “The Human Genome, the Cancer Transcriptome, and Relevance in Clinical Trials of
Head and Neck Cancer”
(Dr. Neil Hayes, MD, MPH)

2:50 – 3:00 Conclusion and Adjournment
(Dr. Neil Hayes, MD, MPH)



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NRG Oncology wishes to acknowledge the following exhibitors:

**ABBVIE ONCOLOGY
BEST MEDICAL INTERNATIONAL
CARIS LIFE SCIENCES
CLOVIS ONCOLOGY
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JANSSEN PRODUCTS, LP
NATIONAL OVARIAN CANCER COALITION
NCI CIRB
NOVOCURE
PACIRA PHARMACEUTICALS
STRYKER**

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

Grand Hall/Conference Center - 1st. Floor

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

Exhibit hours are:

Friday, July 15, 2016 - 7:00 am - 5:00 pm

Saturday, July 16, 2016 - 7:00 am - 4:00 pm



If your organization would like to reserve exhibit space for upcoming NRG Oncology Semi Annual Meetings, please contact:
Denise Mackey, Director of Meetings and Exhibits: Phone: 267-519-6630 - Email: mackeyd@nrgoncology.org

EXHIBITOR OBJECTIVES

NRG Oncology wishes to acknowledge the following exhibitors.

AbbVie

AbbVie is a global, research-based biopharmaceutical company which combines the focus of a leading-edge biotech with the expertise and structure of a long-established pharmaceutical leader. AbbVie is committed to using unique approaches to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases.

Caris Life Sciences

Founded by David D. Halbert in 2008, Caris Life Sciences® is a leading biotechnology company focused on fulfilling the promise of precision medicine through quality and innovation. Caris Molecular Intelligence®, the company's patented offering to help physicians make more informed therapy decisions, with more than 90,000 patients profiled, provide oncologists with the most clinically actionable treatment options available to personalize cancer care today. Using a variety of advanced profiling technologies to assess relevant biological changes in each patient's tumor, Caris Molecular Intelligence connects biomarker data generated from a tumor with biomarker-drug associations supported by evidence in the relevant clinical literature through a proprietary bioinformatics rules engine. Since 2009, Caris Life Sciences has tracked clinical and outcome data for certain patients undergoing tumor profiling, and has observed that patients treated with drugs consistent with their tumor profile show a significant increase in overall survival. The company is also developing its ADAPT Biotargeting System™, a revolutionary and unbiased profiling platform with applications across therapy development, drug delivery, advanced diagnostics and disease monitoring. Currently being developed for cancer and other complex diseases, the ADAPT Biotargeting System is able to simultaneously measure millions of molecular interactions within complex biological systems in their natural state(s). Headquartered in Irving, Texas, Caris Life Sciences offers services throughout the U.S., Europe, Australia and other international markets. To learn more, please visit www.CarisLifeSciences.com.

Clovis Oncology

Clovis Oncology is a biopharmaceutical company targeting a specific subset of cancers, combining personalized medicine with companion diagnostics to direct therapeutics to those patients most likely to benefit. One product candidate is under active development: rucaparib which is in advanced clinical development for the treatment of ovarian cancer. We have received Breakthrough Therapy designation from the FDA for rucaparib.

Janssen Products, LP

Janssen Products, LP harnesses innovations in large- and small-molecule research to create important new therapeutic options for oncology and nephrology. The company is at the forefront of developing initiatives to ensure patients, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services, and quality care.

National Ovarian Cancer Coalition

The mission of the NOCC is to save lives by fighting tirelessly to prevent and cure ovarian cancer, and to improve the quality of life for survivors.

NCI CIRB

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

Novocure

Novocure is a private Jersey Isle oncology company pioneering a novel therapy for solid tumors called TFields. Novocure US operations are based in Portsmouth, NH and New York, NY. Additionally, the company has offices in Switzerland and Japan and a research center in Haifa, Israel. For additional information about the

Pacira Pharmaceuticals

Our primary focus lies in development in non-opioid products for post surgical pain control. Taking care of patients, today and tomorrow.

Stryker

Stryker promotes Vitagel RT3 Surgical Hemostat:

Vitagel Surgical Hemostat is the only product of its kind to combine Microfibrillar Collagen with Thrombin, Fibrinogen and Platelets. This unique combination of components is formulated to produce a safe and effective hemostat by forming a 3-D Scaffold of Collagen and Fibrin enhanced with activated Platelets.



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Save the Date for Houston!
February 9 - 12, 2017

NRG Oncology Semiannual Meeting
Marriott Marquis, Houston, TX

NRG Oncology Semiannual Meeting

*Save the date for these upcoming
NRG Oncology Semiannual Meetings!*

February 9 - 12, 2017
Marriott Marquis Houston
Houston, TX

July 13 - 16, 2017
Philadelphia Marriott Downtown
Philadelphia, PA

January 25 - 28, 2018
Phoenix Convention Center
Phoenix, AZ

July 12 - 15, 2018
Philadelphia Marriott Downtown
Philadelphia, PA

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