



July 16 - 19, 2015
Sheraton Hotel Downtown
Denver, Colorado

### NRG ONCOLOGY SEMIANNUAL MEETING



Faculty Disclosure Information/List	3
Welcome page	10
NRG Mission Statement	11
Educational Objectives	11
Accreditation/CME Credit Information	12
CME Credit Listing	13
Sheraton Hotel Floor Plan	14
Meeting Agenda	15
IT Resource Center	20
Symposia/Sessions/Special Events	
GYN Symposium	21
NRG Scientific Session - NRG Oncology Research	
Review	23
NRG Oncology Welcome Reception	24
CME Sessions/Workshop Agendas	
Brain Tumor Workshop	26
Breast Cancer Workshop	30
Cancer Prevention & Control Workshop	32
Cervix Workshop	34
Developmental Therapeutics Workshop	37
Gastrointestinal Cancer Workshop	42
Genitourinary Cancer Workshop	43
GYN Protocol Development Workshop	45

Head and Neck Cancer Workshop	49
Lung Cancer Workshop	51
Medical Physics Workshop	52
NRG Protocol B-51/1304 Workshop	53
NRG Protocols B-52, B-55, BR003 Workshop	54
Ovarian Cancer Workshop	55
Pathology Workshop	58
Patient Centered Outcomes Research (PCOR) Workshop	59
Protocol Support Committee (PSC) Workshops	61
Proton Working Group Workshop	67
Radiation Oncology Workshop	68
Rare Tumor Workshop	69
Surgical Oncology Workshop	71
Translational Science Workshop	72
Uterine Corpus Workshop	80
Non-CME Session Agendas	
GYN Operations Committee	85
NCORP PI and Administrator Meeting	88
NRG-CC003 Kickoff Meeting	89
Radiomics/Bioinformatics Working Group	90
Meeting Exhibitors Acknowledgement	91
Commercial Support Acknowledgement	94
Future Meeting Dates and Locations	95



Address: NRG Oncology, Four Penn Center, 1600 John F. Kennedy Blvd, Suite 1020, Philadelphia, PA 19103 www.nrgoncology.org

#### **FACULTY DISCLOSURE INFORMATION**



#### NRG Oncology Semiannual Meeting July 16-19, 2015 Denver, CO

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=""></company>
Planning Committee		
Aghajanian, Carol, MD		Clinical Trial Planning Meetings/Travel/Reimbursement: AbbVie.
Alberts, David, MD		Speaker/Consultant: Insys.
Allegra, Carmen, MD	X	
Alvarez, Ronald, MD		PI/Grant: Pfizer; Merrimack; Morphotek. Ad Board Consultant/Honorarium: GlaxoSmithKline.
Birrer, Michael, MD, PhD	X	
Bookman, Michael, MD		Compensated member of Independent Data Monitoring Committee: Genentech-Roche.  Compensated ad-hoc advisory boards for development of clinical trials using investigational (non-marketed) agents: Astra-Zeneca; AbbVie; Cerulean; Endocyte; Immunogen; Clovis Oncology; OxiGene; Sanofi-Aventis.
Bradley, Jeffrey, MD	Х	
Brown, Sally, RN, BSN, MGA	X	
Burger, Robert, MD		Advisory Board/Consultant Fee: Genentech; Oxigene. IDMC/Consultant: Janssen.
Chakravarti, Arnab, MD	X	
Covens, Allan, MD	X	
Crane, Christopher, MD		Consultant/Honorarium: Ventex.
Darling, Gail, MD DeLaney, Tom, MD	X	Author/Editor/Royalties: Up To Date; Wolters Kluwer Health. Consultant/Consulting Fees: Evidence for heart heath improvement; Monitor Deloitte Consulting.
DiSilvestro, Paul, MD	Х	
Edelman, Martin, MD		Research Funding: BMS; Eli Lilly; A Hospira; Clovis; Genentech; Halozyme; Endocyte; Merck.
Ellis, Matthew, BSc, MB, BChir, PhD, FRCP		License to manufacture/Income: Bioclassifier, LLC. Consultant/Honorarium: Novartis; Pfizer; Astra-Zeneca; Celgene.
Fusco, Nancy, RN, BSN	Х	
Ganz, Patricia, MD	X	
Gershenson, David, MD	X	

Gilbert, Mark, MD		Ad Board/Honorarium: Merck; Genentech; AbbVie; Heron;
		Cell Medica; Foundation Medimet.
Gomella, Leonard Gabriel, MD		Consultant/Honorarium: Dendreon; Janssen; Bayer;
Life. Thomas MD		Astellas; MDX Health.
Julian, Thomas, MD Kachnic, Lisa, MD	X	Royalties: UpToDate.
Naciffic, Lisa, MD		Consultant/Honorarium: Best Doctors.
Knudsen, Nancy, RN, BSN	X	Consultant forforaliam. Bost Bootors.
Koh, Wui-Jin, MD	X	
Komaki, Ritsuko, MD	Х	
Kopetz, Scott, MD, PhD		Ad hoc Consultant/Honorarium: Amgen; Roche; AstraZeneca; GSK; Bayer; Onyx; Medimmune; Sanofi; Plexxikon; Jannsen; Bristol-Myers Squibb; Agendia; Array Biopharma; Taiho Oncology.
Lankes, Heather, PhD, MPH	X	
Le, Quynh-Thu, MD Licavoli, Cindy, RN, BSN, MA	X	
Magliocco, Anthony, MD	^	Consultant/Honorarium: Ventana; Genoptix.
Mamounas, Eleftherios, MD, MPH		Speaker/Consultant/Honorarium: Genomic Health Inc.; Genentech Roche. Consultant/Honorarium: Celgene; Eisai; Pfizer; GlaxoSmithKline.
Mannel, Robert, MD		Advisory Board/Honorarium: Astra-Zeneca; Medimmune; Oxigene.
Mayadev, Jyoti, MD	Х	<b>y</b>
Mehta, Minesh P., MD		Consultant/Consulting Fee: Celldex; Elekta; Roche; Pharmacyclics.
Michaelski, Jeffrey M., MD	X	·
Miller, David, MD		PI/Grant: Eisai; Æterna Zentaris. Advisory Board/Honorarium: Genentech.
Monk, Bradley, MD		Researcher/Grants to institution: Novartis; Amgen; Genentech; Eli Lilly; Janssen/Johnson&Johnson Array; TESARO. Speaker/Honorarium: Roche/Genentech; Astra-Zeneca; Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion;
Movas, Benjamin, MD	X	ImmunoGen.
Neading, Joyce, RHIT, CTR	X	
Nolte, Susan, PhD, CRNP		Consultant/Honorarium: INSYS.
		Consultant/Honoranum. INS 15.
Paik, Soonmyung, MD	X	
Petersen, Ivy, MD	Х	
Randall, Marcus, MD	Х	
Ridge, John (Drew), MD, PhD, FACS	X	
Rodgers, William, MD, PhD	X	
Safran, Howard, MD Sandler, Howard, MD	X	Consultant/Honorarium: Medimmune; Bayer; Janssen; Evin.
		Investigator/Research Funding: Myriad.
Sartor, Oliver, MD		Consultant: Astellas; Bavarian-Nordic; Bayer; Bellicum; Biscayne; Johnson&Johnson Medivation; Oncogenex; Sanofi-Aventis; Teva; Tokai. Grant/Research Support: Bayer; Johnson&Johnson Progenics; Sanofi-Aventis.
Sauder, Bonnie, RN, BS	Х	
Schilder, Russell, MD		Ad Board/Honorarium: Millenium. Consultant/Honorarium: EMD Serano.
Shipley, William, MD	X	
Sohn, Jason, PhD	X	
Spirtos, Nicola, MD	X	
Stockman, Sharon, BA, C-CRP Sturgis, Erich, MD, MPH	X	
Sturgis, Erich, MD, MPH Thomas, Terri, MS, CCRC	X	
Trotti, Andy, MD	X	
Vicini, Frank, MD	X	
Vogelbaum, Michael, MD, PhD		Member of DSMB/Honorarium: Neuralstem, Inc. Founder, CMO, Chair SAC/Options, Equity Interest, IP:

	_	
		Infusion Therapeutics, Inc.
Werner-Wasik, Maria, MD	X	
Wenzel, Lari, PhD	X	Consolver/Harrageness Office
White, Julia, MD Wong, Stuart, MD	V	Speaker/Honorarium: Qfix.
Xiao, Ying, PhD	X	
Aldo, filig, Filb	^	
Committee Members/Speakers		
Committee members/opeakers		
Abrams, Ross, MD	Х	
Aghajanian, Carol, MD		Clinical Trial Planning Meetings/Travel/Reimbursement:
3 - 1,		AbbVie.
Alberts, David, MD		Speaker/Consultant: INSYS.
Allegra, Carmen, MD	Х	
Alvarez, Ronald, MD		PI/Grant: Pfizer; Merrimack; Morphotek.
		Ad Board Consultant/Honorarium: GlaxoSmithKline.
Bauman, Julie, MD		Scientific Advisor/Consulting Fee.
Beaverson, Lisa, BA, CCRP	X	
Benedict, Stanley, PhD		Speaker/Partial Travel Expense: Elekta. Editor/Royalty: CRC Press.
Beriwal, Sushil, MD		Consultant/Honorarium: Varian.
		DJMB Board/Honorarium: Xoft.
Bialy, Sally	X	
Birrer, Michael, MD, PhD	X	
Blessing, John, PhD	X	0
Bookman, Michael, MD		Compensated member of Independent Data Monitoring
		Committee: Genentech-Roche. Compensated ad-hoc advisory boards for development of
		clinical trials using investigational (non-marketed) agents:
		Astra-Zeneca; AbbVie; Cerulean; Endocyte; Immunogen;
		Clovis Oncology; OxiGene; Sanofi-Aventis.
Boyle, Elaine	Х	
Bovi, Joseph, MD	Х	
Bradley, Jeffrey, MD	Х	
Bradley, Teresa, PhD	Х	
Brown, Carol, MD, FACOG, FACS	Х	
Brown, Sally, RN, BSN, MGA	X	
Bruner, Deborah, RN, PhD	X	
Burger, Robert, MD		Advisory Board/Consultant Fee: Genentech; Oxigene.
2 1:14 1 142		IDMC/Consultant: Janssen.
Buyyounouski, Mark, MD Capala, Jacek, MSc, PhD	X	
Cella, David, PhD	^	Consultant/Honorarium: Clovis; Abbvie; Astra-Zeneca;
Cella, David, PhD		Bristol-Meyers Squibb.
Chase, Dana, MD, FACOG		Speaker/Honorarium: Roche Diagnostics.
Chakravarti, Arnab, MD	Х	Opeakon Tonoranani. Noono Biagnostico.
Chan, Annie, MD	X	
Chang, Albert, MD, PhD	X	
Chen, Ronald, MD, MPH		PI/Research Grant: Accuray, Inc.
		Consultant/Consulting Fee: Medivation/Astellas.
Chen, Allen, MD	Х	
Chetty, Indrin, PhD		Sponsored Research/Honorarium: Varian Medical
		Systems, Phillips Health Care.
Chmura, Steven, MD	X	
Chockalingam, Vanitha, B Tech, MBA	X	
Choy, Hak, MD	X	
Chung, Christine, MD	X	Occasion Alberta A 2 5 0 1 1 1
Coleman, Robert, MD		Consulting: AbbVie; AstraZeneca; Bayer; Caris Life
		Sciences; Celegene; Cerulean; Clovis Oncology; CritiTech
		Oncology; Genmab; ImmunoGen; Merck Sharp & Dohme; Merrimack; Millennium Pharmaceuticals; Nektar.
		Speaker: Astra-Zeneca.
		Amgen: Trial Scientific Steering Committee.
		Scientific/Advisory Board: Amgen; Bayer Healthcare, Inc.;
		Clovis Oncology; Eisai-Morphotek; ClaxoSmithKline;
		Janssen; Merck Sharp & Dohme; VentiRx (GOG).
		Fended Research: Array Bio Pharmaceuticals; Clovis
		Oncology; EMD Serano; Janssen; Merck; Millennium
	1	Pharmaceuticals; OncoMed Pharmaceuticals.
Corn, Ben, MD Covens, Allan, MD	X	

F =		
Crane, Christopher, MD		Consultant/Honorarium: Ventex.
Crane, Tracy, MS, RD	X	
Creasman, William, MD	Х	
Darling, Gail, MD	Х	
Dawson, Laura, MD		Co-applicant/Honorarium: Raysearch.
DeLaney, Tom, MD		Author/Editor/Royalties: Up To Date; Wolters Kluwer
		Health.
		Consultant/Consulting Fees: Evidence for heart heath
		improvement; Monitor Deloitte Consulting.
DeVries, Sandy, MA	X	
DiSilvestro, Paul, MD	Х	
Drapkin, Ron, MD, PhD	Х	
Eapen, Libni, MD	Х	
Edelman, Martin, MD		Research Funding: BMS; Eli Lilly; A Hospira; Clovis;
Edolinari, Martin, MB		Genentech; Halozyme; Endocyte; Merck.
Efstathiou, Jason, MD		Scientific Ad Board/Honorarium: Medivation/Astellas.
Elder, Eric, PhD	Х	Scientific Ad Board/Horiorandiff. Wedivation/Astellas.
	^	Additional Department of the control
Feng, Felix, Y. C., MD		Advisory Board Leader/Honorarium: Medivation/Astellas.
		PI/Grant Funding: Varian; Celgene.
		Advisory Board Member/Honorarium: GenomeDx
Field, Erica, MPH, MHA	X	
Fleming, Gini, MD		Concept/Study Co-PI: Mifepristone.
Ferris, Robert, MD, PhD, FACS		Consulting/Honorarium: ONO Pharmaceuticals; Merck;
		Astra-Zeneca; Celgene.
Followill, David, PhD	Х	
Fonzi, Frances, MPM, CCRP	Х	
Frank, Steven, MD		Director/Ownership Interest: C4 Imaging.
Traini, Gioron, ind		Speaker/Grant: Elekta.
		Speaker/Honorarium: Varian; IBA; Hitachi.
Fusco, Nancy, RN, BSN	Х	opeaker/Honoranam. Vanam, 15/1, Filiaem.
Galvin, James, DSc, PhD Ganz, Patricia, MD	X	
	^	1 6 6 10 10 10 10 10
George, Thomas, MD		Institutional Research/Research Support: Bristol-Myers
		Squibb; Bayer.
		Consultant: Bayer.
Gershenson, David, MD	X	
Gilbert, Mark, MD		Ad Board/Honorarium: Merck; Genentech; AbbVie; Heron;
		Cell Medica; Foundation Medimet.
Gillin, Mike, MD	Х	
Gillison, Maura, MD	Х	
	Х	
Goldstein, Desiree, RN, MSN	^	Occasion (III) Income in the Decidence of Income Decidence
Gomella, Leonard Gabriel, MD		Consultant/Honorarium: Dendreon; Janssen; Bayer;
		Astellas; MDX Health.
Gondi, Vinai, MD		Speaker/Honorarium: Apollo Cancer Hospital; University of
		Louisville.
		Author/Royalty: UpToDate.
Goodman, Karyn, MD	X	
Gore, Beth, MD	Х	
Green Sharpe, Patricia, RN, MSN, MHSA	Х	
Grosshans, David, MD, PhD	Х	
Havrilesky, Laura, MD	X	
Hering, Martha, RN, MHA	X	
Hernandez, LaTisa, PA, CIP, CCRC	X	
Hinrichs, Christian, MD	^	Posograh Funding: Kita Pharma: Lian Piatashnalalaisa
		Research Funding: Kite Pharma; Lion Biotechnololgies.
Jacobs, Sam, MD	X	
Julian, Thomas, MD	Х	
Kachnic, Lisa, MD		Royalties: UpToDate.
		Consultant/Honorarium: Best Doctors.
Knight, Debra	X	
Knudsen, Nancy, RN, BSN	Х	
Koh, Wui-Jin, MD	Х	
Komaki, Ritsuko, MD	Х	
Kong, Feng-Ming (Spring), MD		Speaker/Honorarium: Varian Medical System.
Konski, Andre, MD, MBA	+	Speaker/Honorarium/Travel Fee: Varian Medical Systems;
ROTORI, ATIGIO, MID, MIDA		
Kanatz Caatt MD DhD		US Oncology/McKesson.
Kopetz, Scott, MD, PhD		Ad hoc Consultant/Honorarium: Amgen; Roche;
		AstraZeneca; GSK; Bayer; Onyx; Medimmune; Sanofi;
		Plexxikon; Jannsen; Bristol-Myers Squibb; Agendia; Array
		Biopharma; Taiho Oncology.
Kudchadker, Rajat, PhD	X	

Scientific Advisor, BMS; ImClone, Sanoti-Aventis, Pitze El Lilly, Amgen, Statz, Sanote, Novatis, Generated: Bayer/Onyx, Abbott, Morphotek Biodesix, Clarinent, Cab Dr., Vertex, Synta, Celegre, Boehninger-Ingelheim, Mer Spaaker Bureau, El Lilly, Generatech; OSI; Imclone-BM DSMC Ell Lilly, Amgen, Synta, Agennix, Peregrine; AbbVe.  Lankes, Heather, PhD, MPH X Lee, Nancy, MD X Lessie, Kimberly, MD X Lessie, Kimberly, MD X Lessie, Kimberly, MD X Lessie, Cindy, RN, BSN, MA X Licavoli, Cindy, RN, BSN, MA X Licavoli, Cindy, RN, BSN, MA X Licavoli, Cindy, RN, BSN, MA X Lowenstein, Jessica, MS X Speaker/Honorarium: Bristof-Myers Squibb; Abbvie; Magliocco, Anthony, MD Marnouras, Eleftherics, MD, MPH Marnouras, Eleftherics, MPH M			
Le, Quyth-Thu, MD Leslie, Kimberty, MD Leslie, Kimberty, MD Leslie, Kimberty, MD Lislo, Kimp, MD Machtary, Milchell, MD Machtary, Milchell, MD Marchalski, Jeffray M. MD Marchalski, Jeffray M. MD McCalster-Afflick, Brenda McLeughlin, Tamara Mehta, Minesh P., MD Michalski, Jeffray M. MD Michalski, Jeffray M. MD Michalski, Jeffray M. MD Michalski, Jeffray M. MD Monk, Bradley, MD Monk, Bradley, MD Movass, Benjamin, MD Mova			OSI (Astellas); Merck; GlaxoSmithKline; Nektar; Clovis. Scientific Advisor: BMS; ImClone; Sanofi-Aventis; Pfizer; Eli Lilly; Amgen; Astra-Zeneca; Novartis; Genentech; Bayer/Onyx; Abbott; Morphotek; Biodesix; Clairient; Caris Dx; Vertex; Synta; Celgene; Boehringer-Ingelheim; Merck; Clovis; Hospira. Speaker Bureau: Eli Lilly; Genentech; OSI; Imclone-BMS. DSMC: Eli Lilly; Amgen; Synta; Agennix; Peregrine;
Lee, Nancy, MD Leavine, Douglas, MD Leavine, Douglas, MD Licavoli, Cindy, RN, SSN, MA Licavoli, Cindy, RN, SSN, MA Lin, Stevan, MD, PhD X Lowenstein, Jessica, MS X Machtay, Michell, MD Machtay, Michell, MD Manounas, Eleitherios, MD, MPH Manounas, Eleitherios, MD, MPH Margolocco, Anthony, MD Manounas, Eleitherios, MD, MPH Margolese, Richard, MD Margolese, Richard, M			
Lesile, Kimberly, MD  Liao, Xing, MD  Liao, Xing, MD  X  Liao, Xing, MD  X  Liao, Xing, MD  X  Lin, Steven, MD, PhD  X  Machtay, Mitchell, MD  Maglicco, Anthony, MD  Maglicco, Anthony, MD  Maglicco, Anthony, MD  Marincas, Elettherios, MD, MPH  Marincas, Elettherios, MD  Marincas, Elettherios, MD  Marincas, Elettherios, MD  Marincas, Elettherios, MD, MPH  Marincas, Elettherios, MD  Marincas, Elettherios, MD  Marincas, Alvaro, MD  X  Marincas, Alvaro, MD  X  McLaughlin, Tamara  McLaughlin, Tamara  X  McLaughlin, Tamara  X  McLaughlin, Tamara  X  Mell, Loren, MD  Mell, Loren, MD  Michaelski, Jeffrey M. MD  Michaelski, Jeffrey M. MD  Michaelson, Dror, MD, PhD  Michaelson, Dror, MD, PhD, PhD, PhD  Michaelson, Dror, MD, PhD, PhD, PhD, PhD, PhD, PhD, PhD, Ph			
Levine, Douglas, MD Licavoli, Cindy, RN, 8SN, MA Licavoli, Cindy, RN, 8SN, MA Lin, Stevan, MD, PhD X Lowenstein, Jessica, MS X Machtay, Mitchell, MD Machtay, Mitchell, MD Manounas, Eleitherios, MD, MPH Manounas, Manounas, MD, MD Manus, MD, MD Matuszak, Martha, PhD Matuszak, Martha, PhD McCalster-Afflick, Branda McLaughin, Tamara Mehta, Minesh P., MD McCalster-Afflick, Branda Mehta, Minesh P., MD Mell, Loren, MD Michalski, Jeffrey, M,			
Liao, Xing, MD Lin, Steven, MD, PhD X Lin, Steven, MD, PhD X Machtay, Mitchell, MD Maglicco, Anthory, MD Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Elettherios, MD, MPH  Marinca, Eletherios, MD  Marinca, Eletherios, MD			
Licavoli, Cindy, RN, BSN, MA  Lin, Steven, MD, PhD  Lowenstein, Jessica, MS  Machtay, Mitchell, MD  Machtay, Mitchell, MD  Machtay, Mitchell, MD  Marounas, Eleftherios, MD, MPH  Marounas, Eleftherios, MD  Marounas, Elefther			
Lin, Steven, MD, PhD  X  Machtay, Mitchell, MD  Maglicco, Anthory, MD  Maglicco, Anthory, MD  Mamounas, Eletherics, MD, MPH  Mamounas, Eletherics, MD, MPH  Mamounas, Eletherics, MD, MPH  Mamounas, Eletherics, MD, MPH  Mannell, Robert, MD  Marinez, Alvaro, MD  Marinez, Alvaro, MD  Mathas, Alvaro, MD  Mauszak, Martha, PhD  McCalster-Allink, Brenda  X  McLaughin, Tamara  Mehta, Minesh P., MD  Mitchalski, Jeffrey M., MD  Monk, Bradley, MD  Monk, Bradley, MD  Monk, Bradley, MD  Morsas, Benjamin, MD			
Lowenstein, Jessica, MS  X  Speaker/Honorarium: Bristol-Myers Squibb; Abbvie; Novocure; Eli Lilly.  Magliocco, Anthony, MD  Consultan/Honorarium: Ventana; Genoptix.  Speaker/Consultan/Honorarium: Genomic Health Inc.; Genether Roche. Consultan/Honorarium: Astra-Zeneca; Medimmun Oxigene.  Mannel, Robert, MD  Margolese, Richard, MD  Margolese, Richard, MD  Margolese, Richard, MD  Martinez, Alvaro, MD  Martinez, Alvaro, MD  McCalster-Afflick, Brenda  McLaughin: Tamara  Mehta, Minesh P., MD  McLaughin: Tamara  Mehta, Minesh P., MD  Michalski, Jeffrey M., MD  M			
Machtay, Mitchell, MD			
Novocure; Eli Lilly.		X	
Mamounas, Eleftherios, MD, MPH	•		Novocure; Eli Lilly.
Genentech Roche,   Consultant/Honorarium: Celgene; Eisai; Pfizer;   GlaxoSmithkfiline.			
Margolese, Richard, MD  Margolese, Richard, MD  Martinez, Alvaro, MD  Mauszak, Martha, PhD  Myadev, Jyoti, MD  X  McCalsiter-Afflick, Brenda  McLaughin, Tamara  Mehta, Minesh P., MD  Mclaughin, Tamara  Mehta, Minesh P., MD  Michalski, Jeffrey M., MD  Monk, Bradley, MD  Researcher/Crants to institution: Novartis; Take Pharmaceuticals.  Monk, Bradley, MD  Researcher/Crants to institution: Novartis; Amgen; Genentech.  Researcher/Crants to institution: Novartis; Amgen; TESARO, Speaker/Honorarium: Genentech.  Researcher/Crants to institution: Novartis; Amgen; TESARO, Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad.  Consultant/Honorarium: Roche/Genentech; Astra-Zeneca Myriad.  Movas, Benjamin, MD  X  Movas, Benjamin, MD  X  Notes, Susan, PhD, CRNP  Okrent, Kathryn, MA  X  Palk, Soonmyung, MD  X  Parker, William, PhD  X  Perez, Kim, MD  X  Putnick, Amada  X  Consultant/Advisor/Honorarium/Accuray.			Genentech Roche. Consultant/Honorarium: Celgene; Eisai; Pfizer; GlaxoSmithKline.
Martinez, Alvaro, MD  Matuszak, Martha, PhD  Matuszak, Martha, PhD  Mayadev, Jyoti, MD  McCaister-Afflick, Frenda  McLaughlin, Tamara  Mehta, Minesh P., MD  Michalski, Jeffrey M., MD  Miler, David, MD  Miler, David, MD  Mork, Bradley, MD  Movas, Benjamin, MD  Mutch, David, MD  Mutch, David, MD  X  Movas, Benjamin, MD  X  Mutch, David, MD  X  Movas, Benjamin, MD  X  Mutch, David, MD  X  Movas, PhD, CRNP  Okrent, Kathryn, MA  X  Parker, William, PhD  X  Parker, William, PhD  X  Perez, Kim, MD  Perez, Kim, MD  X  Perez, Kim, MD  X  Mord, Mord, MD  X  Mord, MD  X  Mord, Mord, MD  X  Mord, Mord, Mord, MD  X  Mord, Mord, MD  X  Mord, Mord, Mord, MD  X  Mord, Mord, MD  X  Mord, Mord, Mord, Mord, MD  X  Mord, Mo			
Matuszak, Martha, PhD			
Mayadev, Jyoti, MD  KCalister-Afflick, Brenda  McCalister-Afflick, Brenda  McCalister-Afflick, Brenda  Mehta, Minesh P., MD  Mehta, Minesh P., MD  Mell, Loren, MD  Mell, Loren, MD  Michalski, Jeffrey M., MD  Miller, David, MD  Monk, Bradley, MD  Monk, Bradley, MD  Researcher/Grants to institution: Novartis; Amgen; Genentech; Eil Lilly; Janssen/Johnsoná, Johnsoná, Array, TESARO, Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad.  Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  X  Notle, Susan, PhD, CRNP  Okrent, Kathryn, MA  X  Notle, Susan, PhD, CRNP  Okrent, Kathryn, MA  X  Paik, Soonmyung, MD  X  Perez, Kim, MD  X  Perez, Kim, MD  X  Peters, Ivy, MD  Rastogi, Priva, MD  X  Rastogi, Priva, MD  Rastogi, Priva, MD  Roch, Mack, MD  Consultant/Advisor/Honorarium/Accuray.		X	
McLaughlin, Tamara McLaughlin, Tamara McLaughlin, Tamara Mehta, Minesh P., MD Pilresearch Funding: Genelux Corp.; Merck. Co-l/Research Funding: Varian Medical Systems; Brist Myers Squibb. Michalski, Jeffrey M., MD Advisory Board/Honorarium: Medivation; Novartis; Take Pharmaceuticals. Miller, David, MD Pilresearcher/Grants to institution: Novartis; Arden; Genentech, Itality, Janssen/Johnson&Johnson Array, TESARO, Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO, Speaker/Honorarium: Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD X Mutch, David, MD X Notes, Susan, PhD, CRNP Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Advisory Board/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Advisory Board/Honorarium: INSYS.  Advisory Board/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Advisory Board/Honorarium: INSYS.  Advisory Boa			PI/Research Grant: Varian Medical Systems.
McLaughlin, Tamara Mehta, Minesh P., MD  Mehta, Minesh P., MD  Mell, Loren, MD  Michalski, Jeffrey M., MD  Miller, David, MD  Monk, Bradley, MD  Researcher/Grants to institution: Novartis; Aragen; Genentech; Eli Lilly, Janssen/Johnson&Johnson, Array; TESARO.  Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad.  Consultant/Consulting Fee: GlaxoSmithKline; Merck: TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  X  Neading, Joyce, RHIT, CTR  Notle, Susan, PhD, CRNP  Okrent, Kathryn, MA  X  Notles, Susan, PhD, CRNP  Okrent, Kathryn, MA  X  Parker, William, PhD  X  Perez, Kim, MD  X  Perez, Kim, MD  X  Petersen, Ivy, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  X  Punisk, Sonomy, MD, PhD, FACS  X  Roach, Mack, MD  Consultant/Advisor/Honorarium/Accuray.			
Mehta, Minesh P., MD  Consultant/Consulting Fee: Celldex; Elekta; Roche; Pharmacyclics.  Mell, Loren, MD  Michalski, Jeffrey M., MD  Advisory Board/Honorarium: Medivation; Novartis; Take Pharmaceuticals.  Miller, David, MD  Pl/Grant: Esia; Æterna Zentaris. Advisory Board/Honorarium: Genentech.  Monk, Bradley, MD  Researcher/Grants to institution: Novartis; Amgen; Genentech: Eli Lilly; Janssen/Johnson&Johnson Array, TESARO. Speaker/Honorarium: Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca Myriad. Consultant/Consulting Fee: ClaxoSmithKline; Merck; TESARO, Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  X  Mutch, David, MD  X  Notle, Susan, PhD, CRNP  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  V  Parker, William, PhD  X  Parker, William, PhD  X  Peters, Kim, MD  X  Petersen, Inv, MD  X  Petersen, Inv, MD  X  Pogue-Geile, Kay, PhD  Putnick, Amanda  X  Rastogi, Priva, MD  Rastogi, Priva, MD  Roca, Mack, MD  Consultant/Advisor/Honorarium/Accuray.			
Pharmacyclics.  Mell, Loren, MD  Pharmacyclics.  Pl/Research Funding: Genelux Corp.; Merck. Co-l/Research Funding: Varian Medical Systems; Brist Myers Squibb. Honorarium: Varian.  Michalski, Jeffrey M., MD  Michaelson, Dror, MD, PhD  Madvisory Board/Honorarium: Medivation; Novartis; Take Pharmaceuticals.  Miller, David, MD  Pl/Grant: Eisai; Æterna Zentaris. Advisory Board/Honorarium: Genentech.  Monk, Bradley, MD  Researcher/Grants to institution: Novartis; Amgen; Genentech; Eil Lilly; Janssen/Johnson&Johnson Array, TESARO. Speaker/Honorarium: Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  X  Neading, Joyce, RHIT, CTR  X  Nolte, Susan, PhD, CRNP  Okrent, Kathryn, MA  X  Paik, Soonmyung, MD  X  Perez, Kim, MD  X  Perez, Kim, MD  X  Perez, Kim, MD  X  Perez, Kim, MD  X  Rastogi, Priva, MD  X  Rasdogi, John (Drew), MD, PhD, FACS  X  Rocach, Mack, MD  Consultant/Advisor/Honorarium/Accuray.	McLaughlin, Tamara	X	
Co-l/Research Funding: Varian Medical Systems; Bristom Myers Squibb. Honorarium: Varian.			Pharmacyclics.
Michaelson, Dror, MD, PhD  Advisory Board/Honorarium: Medivation; Novartis; Take Pharmaceuticals.  Miller, David, MD  Pi/Grant: Eisai; Ætema Zentaris. Advisory Board/Honorarium: Genentech. Advisory Board/Honorarium: Genentech.  Monk, Bradley, MD  Researcher/Grants to institution: Novartis; Amgen; Genentech; Eli Lilly; Janssen/Johnson; Array, TESARO. Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO, Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  X  Neading, Joyce, RHIT, CTR  X  Nolte, Susan, PhD, CRNP  Consultant/Honorarium: INSYS.  Okrent, Kathryn, MA  X  Paik, Soonmyung, MD  X  Perez, Kim, MD  Petersen, Ivy, MD  X  Petersen, Ivy, MD  X  Pogue-Geile, Kay, PhD  X  Randall, Marcus, MD  X  Rastogi, Priva, MD  X  Rastogi, Priva, MD  X  Consultant/Advisor/Honorarium/Accuray.	Mell, Loren, MD		Co-I/Research Funding: Varian Medical Systems; Bristol- Myers Squibb.
Miller, David, MD Pharmaceuticals.  Miller, David, MD Pi/Grant: Eisai; Æterna Zentaris. Advisory Board/Honorarium: Genentech.  Researcher/Grants to institution: Novartis; Amgen; Genentech; Eli Lilly; Janssen/Johnson&Johnson Array; TESARO. Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD X Mutch, David, MD X Neading, Joyce, RHIT, CTR X Nolte, Susan, PhD, CRNP Consultant/Honorarium: INSYS.  Okrent, Kathryn, MA X Paik, Soonmyung, MD X Parker, William, PhD X Perez, Kim, MD X Petersen, Ivy, MD X Pogue-Geile, Kay, PhD X Putnick, Amanda X Randall, Marcus, MD X Rastogi, Priva, MD X Rastogi, Priva, MD X Rastogi, Priva, MD X Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.	Michalski, Jeffrey M., MD	X	
Advisory Board/Honorarium: Genentech.  Monk, Bradley, MD  Researcher/Grants to institution: Novartis; Amgen; Genentech; Eli Lilly; Janssen/Johnson&Johnson Array; TESARO. Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  X  Neading, Joyce, RHIT, CTR  X  Nolte, Susan, PhD, CRNP  Consultant/Honorarium: INSYS.  Okrent, Kathryn, MA  X  Paik, Soonmyung, MD  X  Perez, Kim, MD  X  Petersen, Ivy, MD  Petersen, Ivy, MD  Pugh, Stephanie, PhD  X  Putnick, Amanda  X  Randall, Marcus, MD  X  Rastogi, Priva, MD  Roch, Mack, MD  Consultant/Advisor/Honorarium/Accuray.			Pharmaceuticals.
Genentech; Eli Lilly; Janssen/Johnson&Johnson Array, TESARO. Speaker/Honorarium: Roche/Genentech; Astra-Zeneca Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion; ImmunoGen.  Movsas, Benjamin, MD  X  Mutch, David, MD  Neading, Joyce, RHIT, CTR  Nolte, Susan, PhD, CRNP  Okrent, Kathryn, MA  Paik, Soonmyung, MD  Parker, William, PhD  X  Perez, Kim, MD  Petersen, Ivy, MD  Petersen, Ivy, MD  Pugh, Stephanie, PhD  X  Puthick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Rastogi, Priva, MD  Roch, Mack, MD  Consultant/Advisor/Honorarium/Accuray.			Advisory Board/Honorarium: Genentech.
Mutch, David, MD  Neading, Joyce, RHIT, CTR  Nolte, Susan, PhD, CRNP  Okrent, Kathryn, MA  Paik, Soonmyung, MD  Parker, William, PhD  Perez, Kim, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Pugh, Stephanie, PhD  X  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  X  Consultant/Honorarium: INSYS.  Consultant/Honorarium: INSYS.  X  Consultant/Advisor/Honorarium/Accuray.			Genentech; Eli Lilly; Janssen/Johnson&Johnson Array; TESARO. Speaker/Honorarium: Roche/Genentech; Astra-Zeneca; Myriad. Consultant/Consulting Fee: GlaxoSmithKline; Merck; TESARO; Roche/Genentech; Gradalis; Advaxis; Astra-Zeneca; Verastem; Cerulean; Amgen; Vermillion;
Neading, Joyce, RHIT, CTR  Nolte, Susan, PhD, CRNP  Okrent, Kathryn, MA  Paik, Soonmyung, MD  Parker, William, PhD  Perez, Kim, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Putnick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  Consultant/Advisor/Honorarium/Accuray.			
Nolte, Susan, PhD, CRNP  Okrent, Kathryn, MA  Paik, Soonmyung, MD  Parker, William, PhD  Perez, Kim, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Putnick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  Consultant/Advisor/Honorarium/Accuray.			
Okrent, Kathryn, MA  Paik, Soonmyung, MD  Parker, William, PhD  Perez, Kim, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Pugh, Stephanie, PhD  Putnick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  X   X   X  X  X  X  X  X  X  X  X  X		^	Consultant/Honorarium: INISVS
Paik, Soonmyung, MD  Parker, William, PhD  Perez, Kim, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Pugh, Stephanie, PhD  Putnick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  X   X  Consultant/Advisor/Honorarium/Accuray.		Y	Consultativi tottoratiutii. IINOTO.
Parker, William, PhD  Perez, Kim, MD  Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Pugh, Stephanie, PhD  Putnick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  X   X  Consultant/Advisor/Honorarium/Accuray.			
Perez, Kim, MD  Petersen, Ivy, MD  X  Pogue-Geile, Kay, PhD  Pugh, Stephanie, PhD  X  Putnick, Amanda  X  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  X  Consultant/Advisor/Honorarium/Accuray.			
Petersen, Ivy, MD  Pogue-Geile, Kay, PhD  Pugh, Stephanie, PhD  Putnick, Amanda  Randall, Marcus, MD  Rastogi, Priva, MD  Ridge, John (Drew), MD, PhD, FACS  Roach, Mack, MD  X  Consultant/Advisor/Honorarium/Accuray.			
Pogue-Geile, Kay, PhD X Pugh, Stephanie, PhD X Putnick, Amanda X Randall, Marcus, MD X Rastogi, Priva, MD X Ridge, John (Drew), MD, PhD, FACS X Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.			
Pugh, Stephanie, PhD X Putnick, Amanda X Randall, Marcus, MD X Rastogi, Priva, MD X Ridge, John (Drew), MD, PhD, FACS X Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.			
Putnick, Amanda X Randall, Marcus, MD X Rastogi, Priva, MD X Ridge, John (Drew), MD, PhD, FACS X Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.			
Rastogi, Priva, MD X Ridge, John (Drew), MD, PhD, FACS X Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.		Х	
Ridge, John (Drew), MD, PhD, FACS X Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.	Randall, Marcus, MD		
Roach, Mack, MD Consultant/Advisor/Honorarium/Accuray.			
		X	
Consultant/Stipend/International Atomic Energy Agency	Roach, Mack, MD		Consultant/Advisor/Honorarium/Accuray. Consultant/Stipend/International Atomic Energy Agency.

		Consultant/Honorarium/Consulting Fee: Ferring Pharma.
		Consultant/Honorarium: Janssen (Johnson&Johnson);
		Bayer; Astellas; Millenium; GenomeDx.
		Speaker/Honorarium: Varian.
Robinson, Clifford, MD		PI/Grant: Varian Medical Systems.
Rodgers, William, MD, PhD	X	
Rodriguez, Cristina, MD	Х	
Rodland, Karin, PhD	Х	
Rosen, Mark, MD	Х	
Rosenthal, David, MD		Ad Board/Honorarium: Bristol-Myers Squibb; Merck Serano.
Safran, Howard, MD	Х	Corano.
Salama, Joseph, MD		Spouse/Research Funding: Merck; GlaxoSmithKline;
Calama, Goseph, MD		Bristol-Myers Squibb. Research Funding: AbbVie.
Sandler, Howard, MD		Consultant/Honorarium: Medimmune; Bayer; Janssen;
caraio, rioraia, ind		Evin.
Cortor Oliver MD		Investigator/Research Funding: Myriad.  Consultant: Astellas; Bavarian-Nordic; Bayer; Bellicum;
Sartor, Oliver, MD		Biscayne; Johnson&Johnson Medivation; Oncogenex; Sanofi-Aventis; Teva; Tokai. Grant/Research Support: Bayer; Johnson&Johnson
		Progenics; Sanofi-Aventis.
Sauder, Bonnie, RN, BS	X	
Schilder, Russell, MD		Ad Board/Honorarium: Millenium.
		Consultant/Honorarium: EMD Serano.
Schoen, Robert, MD		Lecture/Honorarium: Medial.
Shipley, William, MD	Х	
Sherman, Eric, MD		Consultant/Honorarium: Eisai; Bayer.
Skinner, Heath, MD	Х	
Sohn, Jason, PhD	Х	
Spirtos, Nicola, MD	Х	
Stehman, Fredrick, PhD	Х	
Stockman, Sharon, BA, C-CRP	Х	
Sturgis, Erich, MD, MPH	Х	
Suhayda, Lynne, RN, MSEd	Х	
Sun, Alex, MD	Х	
Suntharalingam, Mohan, MD	Х	
Thomas, Alexandra, MD		Stockownership: Johnson & Johnson.
Thomas, Terri, MS, CCRC	Х	
Thomson, Cynthia, PhD, RD, CSO		Consultant/Honorarium: Produce for Better Health. Reviewer/Honorarium: NIH; AICR. Speaker/Honorarium: Academy of Nutrition & Dietetics.
Trotti, Andy, MD	Х	
Tsien, Christina, MD	Х	
Ulin, Ken, PhD	Х	
Urbanic, James, MD	Х	
Valero, Vicente, MD	Х	
Vicini, Frank, MD	Х	
Videtic, Greg, MD	X	
Vogelbaum, Michael, MD, PhD		Member of DSMB/Honorarium: Neuralstem, Inc. Founder, CMO, Chair SAC/Options, Equity Interest, IP: Infusion Therapeutics, Inc.
von Gruenigen, Vivian, MD	Х	
Walters-Page, Linda, MA	Х	
Wang, Dian, MD	Х	
Wapnir, Irene, MD	Х	
Waqar, Siaima, MD	Х	
Wenzel, Lari, PhD	Х	
White, Julia, MD		Speaker/Honorarium: Qfix.
Whitney, Charles, MD	Х	
Wickerham, Larry, MD	Х	
Willenberg, Kelly, MBA, BSN, CCRP, CHRC, CHC		Consultant/Consulting Fee: Kelly Willenberg, LLC.
	Х	, , , , , , , , , , , , , , , , , , ,
Wilson, Christina, RN, BSN		
Wilson, Christina, RN, BSN Wolmark, Norman, MD	X	
Wolmark, Norman, MD	X	
Wolmark, Norman, MD Wong, Stuart, MD		Speaker/Honorarium: Philips.
Wolmark, Norman, MD Wong, Stuart, MD Xia, Ping, PhD		Speaker/Honorarium: Philips.
Wolmark, Norman, MD Wong, Stuart, MD	Х	Speaker/Honorarium: Philips.  Invention/Licenseship: Varian Medical Systems.

	Member/Advisor	y Board: Dara Biosciences, Inc.

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

<b>=</b> 1		
Educational Planning Committee		
Alvarez, Ronald D., MD		PI/Grant: Pfizer; Merrimack; Morphotek.
Chair		Ad Board Consultant/Honorarium: GlaxoSmithKline.
Farley, John, MD		
Member	Х	
Horowitz, Neil, MD		
Member	Х	
Mackey, Denise		
Staff	Х	
Reese, Jill		
Staff	X	
Sharp, Mary		
Staff	X	
Shumaker, Lauren		
Staff	Х	
Small, Michelle		
Staff	X	
Stehman, Frederick, MD		
Vice Chair	Х	
Tew, William, MD		
Member	Х	

LAS - 06/24/15

#### NRG ONCOLOGY SEMIANNUAL MEETING

#### July 16 - 19, 2015 - Denver, Colorado

# Welcome!

It is with much enthusiasm that we welcome our research community to the NRG Oncology Semiannual Meeting in Denver, Colorado, July 16 - 19, 2015.

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 GYN summer Symposium titled, "Rational Combination Targeted Therapies for Gynecologic Cancers," with noted oncologists and scientists serving as speakers and moderators. The speakers will focus their presentations on rationale for combinations of targeted therapies. Once this rationale has been elucidated specific combinations for selected gynecologic malignancies along with preliminary efficacy data will be presented.
- 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, lung, prostate and gynecologic cancers.
- A half-day educational session for nurses and clinical research associates will take place Thursday afternoon.
- At the NRG Oncology General Session on Saturday, Group leadership will provide updates on topics of significance for our members and the research community.
- An introductory kick-off session for our soon to be activated protocol NRG-CC003, "A Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer," will be held on Friday morning.

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 Denver!

Sincerely,



Walter J. Curran, MD NRG Oncology Group Chair

Walty Curren, J. MD



Philip J. DiSaia, MD NRG Oncology Group Chair



Norman Wolmark, MD NRG Oncology Group Chair

Ol libra,

Mudolmalk

#### NRG ONCOLOGY SEMIANNUAL MEETING

#### 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 biasfree presentation. Please see the insert to this program for the complete disclosure list

#### **CME INFORMATION**



**Continuing Medical Education Program** 

#### Accreditation Statement

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

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

#### AMA PRA Category 1 Credits™

The GOG Foundation, Inc. designates this live activity for a maximum of **22.25** *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 Committee/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:**

Overall evaluations are included in Final Agenda Program Books. Print name 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 15, 2015

If your name is not on the evaluation, you will not receive a certificate. Any questions regarding evaluations/CME certificates may be directed to: <a href="mailto:jreese@gog.org">jreese@gog.org</a>

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 <a href="mailto:lcalhoun@gog.org">lcalhoun@gog.org</a>.

Fax: 301-261-3972

Online: https://www.nrgoncology.org

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

Michelle N. Small, Associate 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. for Denver, CO - July 16 - 19, 2015 - AMA PRA Category 1 Credits™

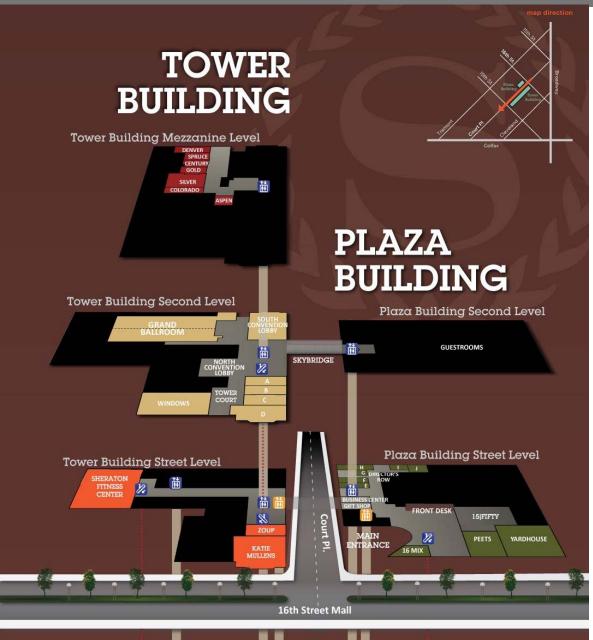
Detailed credit hours will be listed on your certificate. Please allow 4-6 weeks for receipt.

GYN Symposium -	"Rational Combination	<b>Targeted Therapies</b>	for Gynecologic Cancers "
-----------------	-----------------------	---------------------------	---------------------------

GTN Symposium - Rational Combination Pargeted Therapies for Gynecologic Cancers
Brain Tumor Workshop
Breast Cancer Workshop
Cancer Prevention & Control (CPC) Workshops
Cervix Workshop
Gastrointestinal Cancer Workshop
Genitourinary Cancer Workshop
GYN Developmental Therapeutics Workshops
GYN Protocol Development Workshop
Head & Neck Cancer Workshop
Lung Cancer Workshop
Medical Physics Workshop
NRG Protocol B-51/1304 Workshop
NRG Protocol s B-52, B-55, and NRG BR003 Workshop
NRG Scientific Session NRG Oncology Research Review
Ovarian Cancer Workshop
Pathology Workshop
Patient Centered Outcomes Research (PCOR) Workshop
Protocol Support Committees (PSC) Workshop
Proton Working Group Workshop
Radiation Oncology Workshop
Rare Tumor Workshop
Surgical Oncology Workshop
Translational Science Workshop
Uterine Corpus Workshop

All non- MD's will receive a certificate of attendance

The GOG Foundation, Inc. is accredited by the ACCME to provide continuing medical education (CME) for physicians.







Sheraton Denver Downtown Denver, Colorado July 16 – 19, 2015

Thursday, July 16, 2015	
6:30 am – 8:30 am	Symposium Breakfast
7:00 am – 6:00 pm	Registration/CME/Information Desk
9:30 am - 10:00 am	Symposium Coffee Break
12:00 pm – 1:00 pm	Symposium Lunch
12:00 pm – 6:00 pm	IT Resource Room/Internet Café
4:00 pm – 6:00 pm	Exhibit Setup
8:00 am – 12:00 pm	Imaging and Radiation Oncology Core (IROC) Executive Committee *
8:00 am – 2:30 pm	GYN Summer Symposium - "Rational Combination
	Targeted Therapies for Gynecologic Cancers"
8:00 am – 5:00 pm	GYN Chart Review *
9:00 am – 1:00 pm	SOCRA Certification Exam
11:30 am – 1:30 pm	GOG Foundation, Inc. CWG Meeting *
1:00 pm – 2:00 pm	VisionTree Workshop
1:30 pm – 3:30 pm	GOG Foundation, Inc. Membership Committee *
3.00 4.00	Lucasiana Thausana and Insurance Bio dialoticas Michigan
2:00 pm – 4:00 pm	Immune Therapy and Immune Modulation Workshop
2:00 pm – 6:00 pm	Clinical Trials Nurses/Clinical Research Associates Educational Session
	Lucational Session
4:00 pm – 6:00 pm	GYN Developmental Therapeutics/Phase
	1/Translational Science Workshops
4:00 pm – 6:00 pm	Patient Centered Outcomes Research (PCOR)
	Workshop
4:00 pm – 6:00 pm	GOG Foundation, Inc. Board of Directors *
5:00 pm – 7:00 pm	NRG Oncology Japan Meeting
6:00 pm – 8:00 pm	NCORP Concept Review (Invitation Only)
6:00 pm – 8:00 pm	Clinical Research Associates Subcommittee *
6:30 pm – 8:30 pm	Clinical Trials Nurse Subcommittee *
8:00 pm – 10:00 pm	Ancillary Projects Committee*



Sheraton Denver Downtown Denver, Colorado July 16 – 19, 2015

Friday, July 17, 2015	
6:30 am – 8:30 am	Continental Breakfast
7:00 am - 5:00 pm	Exhibits
7:00 am – 6:00 pm	Registration/CME/Information Desk
7:00 am – 6:00 pm	IT Resource Room/Internet Café
10:00 am – 10:30 am	General Coffee Break
2:00 pm – 3:30 pm	General Coffee Break
7:00 am – 8:00 am	NRG Radiomics Bioinformatics Working Group
7:00 am – 8:00 am	GYN PDC Executive Session *
7:00 am – 9:00 am	Protocol 210 Subcommittee
7:00 am – 9:00 am	Protocol Support Committee Working Groups *
7:00 am – 12:00 pm	GYN RT Case Review
8:00 am – 9:00 am	NRG SDMC Executive Committee *
8:00 am – 9:00 am	NRG-CC003 Kick-Off
8:00 am – 10:00 am	Ovarian Cancer Workshop
8:00 am – 10:00 am	Scientific Session – NRG Oncology Research Review
8:00 am – 5:00 pm	GYN Chart Review *
8:00 am – 5:00 pm	Pathology Workshop & Review
0.00 cm 11.00 cm	Low Crade Cliente Morking Craws*
9:00 am – 11:00 am	Low-Grade Glioma Working Group*
10:00 am – 11:00 am	International Members Meeting *
10:00 am – 11:30 am	Publications Committee *
10:00 am – 12:00 pm	Functional Imaging Working Group
10:00 am – 12:00 pm	Cervix Cancer Workshop
10:00 am – 12:00 pm	Sarcoma Working Group
11:00 am - 12:00 pm	Protocol 225 Information Session
11:00 am – 12:30 pm	Immune Therapy and Immune Modulation Workshop
11:00 am – 1:00 pm	Neurosurgical Subcommittee
11:30 am – 1:30 pm	NRG Oncology Foundation Board of Directors *
•	•
12:00 pm – 1:00 pm	Cancer Care Delivery Research Committee
12:00 pm – 2:00 pm	Elderly Working Group
1:00 pm – 2:00 pm	New Investigators Committee
1:00 pm – 2:00 pm	Pathology Committee *
1:00 pm – 4:00 pm	Brain Tumor Core Committee *
1:30 pm – 3:00 pm	Translational Science Breast Cancer Subcommittee

Revised 6/25/15 \*Sessions for Committee Members



Sheraton Denver Downtown Denver, Colorado July 16 – 19, 2015

Friday, July 17, 2015 1:30 pm – 3:30 pm	Radiation Oncology Workshop
1:30 pm – 3:30 pm	Translational Science GU Cancer Subcommittee
1:30 pm – 4:30 pm	Cancer Prevention and Control Workshop
-	CTN/CRA Breakout Sessions
1:30 pm – 5:30 pm	CIN/CRA Dieakout Sessions
2:00 pm – 3:00 pm	Translational Science Head & Neck Cancer
	Subcommittee
2:00 pm – 4:00 pm	Translational Science GYN Subcommittee
2:00 pm – 4:00 pm	Rare Tumor Workshop
2.00 4.00	NDC Broke and B 54/4204 Wandark are
3:00 pm – 4:00 pm	NRG Protocol B-51/1304 Workshop
3:00 pm – 4:00 pm	RTOG Foundation Board of Directors *
3:00 pm – 4:30 pm	Communications Committee *
3:00 pm – 5:00 pm	Uterine Corpus Cancer Workshop
3:00 pm – 5:00 pm	Health Disparities Committee (Elderly & Special
	Populations Working Group)
3:00 pm – 6:00 pm	Head & Neck Cancer Core Committee *
3:30 pm – 6:00 pm	Medical Physics Workshop
4:00 pm – 5:30 pm	Human Research Committee *
4:00 pm – 6:00 pm	Translational Science Lung Cancer Subcommittee
4:00 pm – 6:00 pm	Genitourinary Cancer Core Committee *
4:00 pm – 6:00 pm	Brain Tumor Workshop
4:00 pm – 6:00 pm	Translational Science GI Cancer Subcommittee
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group Meeting
5.00	2700 5 1 11 2 1 1
6:00 pm – 7:00 pm	RTOG Foundation Advisory Board *
6:00 pm – 8:00 pm	NRG Oncology Welcome Reception
6:00 pm – 9:00 pm	Breast Cancer Working Group *
7:30 pm – 9:30 pm	GOG Foundation ICT Dinner (By invitation only)
7:30 pm – 9:30 pm 7:30 pm – 10:00 pm	Translational Science Brain Cancer Subcommittee



Sheraton Denver Downtown Denver, Colorado July 16 – 19, 2015

Saturday, July 18, 2015	
6:30 am - 8:30 am	Continental Breakfast
7:00 am – 3:00 pm	IT Resource Room/Internet Café
7:00 am – 5:00 pm	Registration/CME/Information Desk
7:00 am – 5:00 pm	Exhibits
2:00 pm – 3:30 pm	General Coffee Break
2.00 p.m 0.00 p.m	General Gones Break
6:30 am – 7:55 am	Surgical Oncology Workshop
6:45 am – 8:30 am	Proton Working Group Workshop
5115 am - C155 am	Troton tronding croup tronding
7:00 am – 8:00 am	NRG SDMC Data Management Working Group *
7:00 am – 8:00 am	NRG SDMC IT Working Group *
7:00 am – 8:00 am	NRG SDMC Statistical Working Group *
7:00 am – 8:30 am	Medical Oncology Committee
7:00 am – 9:00 am	GI Colorectal Cancer Subcommittee *
7.00 am 3.00 am	di colorectal cancel Subcommittee
8:00 am – 9:30 am	Safety Review Committee *
8:00 am – 10:00 am	NCORP PI & Administrators Meeting
8:00 am – 10:00 am	Developmental Therapeutics/Phase I Workshops
8:00 am – 10:00 am	Genitourinary Cancer Workshop
8:00 am – 10:00 am	Head & Neck Surgical Subcommittee
8:00 am – 10:00 am	Lung Cancer Core Committee *
8:00 am – 5:00 pm	GYN Chart Review *
9:00 am – 10:00 am	Quality Assurance Audit Meeting *
9:00 am – 12:00 pm	Breast Cancer Workshop
10:00 am – 11:00 am	Ovarian Cancer Workshop
10:00 am – 11:00 am	Cervix Cancer Workshop
10:00 am - 11:00 am	Uterine Corpus Cancer Workshop
10:00 am – 11:00 am	Protocol Support Committee Study Presentations
10:00 am – 11:30 am	Membership Committee *
10:00 am – 12:00 pm	GI Non-Colorectal Cancer Subcommittee * Protocol 225 Workshop
10:00 am – 12:00 pm 10:00 am – 12:00 pm	Protocol 0199 Subcommittee Meeting *
10:00 am – 12:00 pm	Translational Science Workshop
10:00 am – 12:00 pm	Head & Neck Cancer Workshop
11:00 am - 12:00 pm	GYN Operations Committee
11:00 am – 12:00 pm	Protocol Support Committee Business Meeting*

Revised 6/25/15 \*Sessions for Committee Members



Sheraton Denver Downtown Denver, Colorado July 16 – 19, 2015

Saturday, July 18, 2015	
12:00 pm – 1:00 pm	NRG Protocol B-52/B-55 and NRG BR003 Workshops
12:00 pm – 1:00 pm	Patient Advocates Meeting *
12:00 pm – 1:00 pm	Voting Members PI Meeting *
1:00 pm – 2:30 pm	NRG Oncology General Session
2:30 pm – 4:00 pm	GYN Protocol Development Workshop
2:30 pm – 4:30 pm	Gastrointestinal Cancer Workshop
2:30 pm – 4:30 pm	Lung Cancer Workshop
3:00 pm – 4:00 pm	Canadian Members Meeting
3:00 pm – 4:00 pm	VA/MTF Meeting
4:00 pm – 5:00 pm	Lung Cancer Surgical Subcommittee
4:30 pm – 7:30 pm	Research Strategy Meeting *

Sunday, July 19, 2015	
7:00 am – 9:00 am	Executive Committee Meeting *

# Information Technology Resource Center

NRG Semi-Annual
Meeting
Denver, CO
July 16-19, 2015

Sheraton Denver Downtown Governor's Square 17

Open Thur. Jul 16: 12PM-6PM Fri. Jul 17: 7AM-6PM Sat. Jul 18: 7AM-1PM



http://www.nrgoncology.org



#### The Resource Center will feature:

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

- п Medidata RAVE
- n CTSU OPEN
- ⊓ User Accounts

Available services include:

- □ Internet Access
- п Email
- Printing

TRIAD Training Sessions

To email from the Resource Center, make sure you have access to Webbased 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 <a href="mailto:support@gogstats.org">support@gogstats.org</a> prior to the meeting for more information.

# GYN Symposium - "Rational Combination Targeted Therapies for Gynecologic Cancers" Thursday, July 16, 2015 (NRG Oncology Semiannual Meeting) Sheraton Hotel - Denver, Colorado

Program Chair	John H. Farley, MD	
	St. Joseph Hospital and Medical Center	

#### **Presentation Agenda**

Presentation Agenda					
Time	TOPIC:	SPEAKER/MODERATOR			
7:00 AM	REGISTRATION				
8:00 AM	WELCOME	Program Chairs			
8:05-9:00	SESSION I: Combining Targeted Therapies: Hypothesis to Reality	Moderator: John H. Farley, MD			
8:05-8:35	The Future of Targeted Therapy Development	S. Percy Ivy, MD			
8:35-9:00	Design of Phase I Combination Trials with Targeted Therapy	William Brady, PHD			
9:00-10:10	SESSION II: Novel PARP Inhibitor, Anti- Angiogenesis Combinations	Moderator: John H. Farley, MD			
9:00-9:20	Veliparib and Bevacizumab for the treatment of Ovarian Cancer (Discuss GOG-280 and GOG-9923)	Katherine M. Bell-McGuinn, MD, PhD			
9:20-9:40	Cediranib and Olaparib for the Treatment of Recurrent Ovarian Cancer (Discuss upcoming trials)	Ursula A. Matulonis, MD			
9:40-10:00	Everolimus (RAD001) and Bevacizumab for the Treatment of Recurrent Ovarian Cancer (Discuss 186G)	William P. Tew, MD			
10:00-10:10	Questions for panel				
10:10-10:40					
10:40-12:10	SESSION III: Novel MAPK/PI3K Inhibitor Combinations	Moderator:			
		Russell J. Schilder, MD			
10:40-11:00	Combining MEK and PI3K-Pathway Inhibitors for the Treatment of LGSC and Endometrial Cancer	Shannon N. Westin MD, MPH			
11:00-11:20	Novel mTOR and Aromatase Inhibitors Combinations for the Treatment of Recurrent Endometrial Cancer	Brian M. Slomovitz, MD			
11:20-11:40	The PI3K-ARID1A-IL-6 Axis in Ovarian Clear Cell Carcinoma: The Hunt for New Targets	Russell J. Schilder, MD			
11:40-12:00	Regulatory Considerations for Combinational Targeted Therapeutics in Gynecologic Cancer	Gwynn Ison, MD			
12:00-12:10	Questions for panel				
12:10-1:00	BREAK (LUNCH)				
1:00-2:30	SESSION IV: Immunomodulators PD-1 Inhibitor Combinations	Moderator: Samir N. Khleif, MD			
1:00-1:25  Non Immune Combinations with Nivolumab in Patients with Gynecologic Cancer  Paul Sabbatini, MD					

2:15-2:30	Questions for panel	,	
1:50-2:15	Immune Combination Therapy, Strategies and Design   Samir N. Khleif, MD		
1:25-1:50	Nivolumab and Ipilimumab for the Treatment of Ovarian Cancer and Cervical Cancer	Robert A. Burger, MD	

#### PROGRAM DESCRIPTION:

The GOG Foundation, Inc. will have a summer 2015 Educational Symposium titled "Rational Combination Targeted Therapies for Gynecologic Cancers" with noted Oncologists and Scientists serving as speakers and moderators. The targeted audiences are members and non-members of the NRG research teams to include: Gynecologic Oncologists, Medical Oncologists, Radiation Oncologists, Pathologists, and other MDs engaged in oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, and other interested Allied Health professionals. The speakers will focus their presentations on rationale for combinations of targeted therapies. Once this rationale has been elucidated specific combinations for selected gynecologic malignancies along with preliminary efficacy data will be presented.

#### **LEARNING OBJECTIVES:**

**1.** To identify the routinely abnormal genetic pathways that are activated in a specific Gynecologic Cancer and suggest combinations of targeted agents that can be used to treat the malignancy.

#### **GOG COMMITTEE ON EDUCATIONAL ACTIVITIES**

Ronald Alvarez, MD (Committee Chair)	Neil Horowitz, MD	
University of Alabama School of Medicine	Brigham and Women's Hospital	
Birmingham, AL	Dana Farber Partners Cancer Care	
	Boston, MA	
Frederick Stehman, MD (Co-Chairman)		
Indiana University School of Medicine	William P. Tew, MD	
Indianapolis, IN	Memorial Sloan Kettering Cancer Center	
	New York, NY	
Sarah Bernstein, RN, MS, AOCN		
Walter Reed National Military Med Ctr.	Michelle N. Small, BSHA (Staff)	
Bethesda, MD	Assoc. Director, Education Programs & CME Compliance	
	GOG Education Program	
John Farley, MD	msmall@gog.org	
St. Joseph Hospital and Medical Center		
Phoenix, AZ	Jill Reese (Staff)	
	CME Administrator	
	GOG Education Program	
	jreese@gog.org	

#### NRG Scientific Session - NRG Oncology Research Review

Date: Friday, July 17, 2015 Start and End Time: 8:00 am - 10:00 am

Co-Chairs Carmen Allegra, MD; Deborah Bruner, PhD; Fred Stehman, MD; Maria Werner Wasik, MD

Moderator Carmen Allegra, MD

#### **Learning Objectives:**

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

- 1. Discuss the role of the NRG Oncology Publications Guidelines in the development of publications based on NRG Oncology data and activities.
- 2. Discuss the results of recently reported trials for high-risk prostate cancer, non-small-cell lung cancer, breast cancer, and recurrent ovarian, peritoneal primary and fallopian tube cancer.
- 3. Describe the potential role of docetaxel in hormone-sensitive prostate cancer.
- 4. Discuss the limitations of high-dose conformal radiotherapy for patients with stage III non-small-cell lung cancer and the lack of benefit from the addition of cetuximab.
- 5. Identify the limitations of the PIK3CA and PAM50 intrinsic subtypes as predictive biomarkers for response to adjuvant trastuzumab in women with breast cancer.
- 6. Describe the role of anastrozole and tamoxifen in the treatment of postmenopausal women with ductal carcinoma in situ.
- 7. Discuss the role of bevacizumab in the treatment of recurrent ovarian, peritoneal primary and fallopian tube cancer.

#### **WORKSHOP AGENDA**

8:00 – 8:25 am	Introduction and Review NRG Oncology Publications Guidelines Audience Poll	Deborah Bruner, PhD Carmen Allegra, MD
8:25 – 9:00 am	A phase III protocol of androgen suppression (AS) and 3DCRT/IMRT vs AS and 3DCRT/IMRT followed by chemotherapy (CT) with docetaxel and prednisone for localized, highrisk prostate cancer <b>RTOG 0521</b> . 2015 American Society of Clinical Oncology (ASCO).	Howard Sandler, MD
	Standard-dose versus high-dose conformal radiotherapy with concurrent and consolidation carboplatin plus paclitaxel with or without cetuximab for patients with stage IIIA or IIIB non-small-cell lung cancer <b>RTOG 0617</b> : a randomised, two-by-two factorial phase 3 study. Lancet Oncology.	Jeffrey Bradley, MD
	Discussant and Q&A	Chris Crane, MD
9:00 – 9:40 am	Intrinsic subtypes, PIK3CA mutation, and the degree of benefit from adjuvant trastuzumab in the <b>NSABP B-31</b> Trial. Journal of Clinical Oncology.	Katherine Pogue-Geile, PhD
	Primary results of <b>NRG Oncology/NSABP B-35</b> : A clinical trial comparing anastrozole with tamoxifen in postmenopausal patients with ductal carcinoma in situ undergoing lumpectomy with radiotherapy. 2015 American Society of Clinical Oncology (ASCO).	Richard Margolese, MD
	Discussant and Q&A	Larry Wickerham, MD
9:40 – 10:00 am	A phase III randomized controlled clinical trial of carboplatin and paclitaxel alone (CT) or in combination with bevacizumab followed by bevacizumab (CTB) and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, peritoneal primary and fallopian tube cancer: an <b>NRG Study</b> . 2015 Society of Gynecologic Oncology.	Robert Coleman, MD
	Discussant and Q&A	Fred Stehman, MD
	= 1000000000000000000000000000000000000	NRG Scientific Session

# WELCOME TO DENVER!



# NRG Oncology Welcome Reception

Plaza Foyer, Plaza Building - Concourse Level Friday, July 17, 2015 - 6 pm - 8 pm





# CME WORKSHOP/SESSIONS



Advancing Research. Improving Lives.™

#### **Brain Tumor Workshop Agenda**

Date: Friday, July 17, 2015
Start and End Time: 4:00 pm - 6:00 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**

#### 4:00 – 4:10 Opening Remarks and Introduction

#### 4:10 - 5:10 Review of active studies

#### **ACTIVE STUDIES:**

	STUDY	NAME	DX	START	N	COMMENTS
1	0834	Phase III Trial on Concurrent and Adjuvant Temozolomide Chemotherapy in Non-1p/19q Deleted Anaplastic Glioma: The CATNON Intergroup Trial	AG		687/748	III: CATNON 76 randomized from NRG (153 enrolled)

	STUDY	NAME	DX	START	N	COMMENTS
2	1071	NCCTG N0577/Endorsed Study: Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma	AG	9/09	56/488	III: CODEL 19 enrolled from NRG
3	1205	Randomized Phase II Trial of Concurrent Bevacizumab and Re-Irradiation Versus Bevacizumab Alone as Treatment for Recurrent Glioblastoma	rGBM	12/12	95/178	RT vs. Bev/RT
4	1114	Phase II Randomized Study of Rituximab, Methotrexate, Procarbazine, Vincristine, and Cytarabine With and Without Low-Dose Whole-Brain Radiotherapy for Primary Central Nervous System Lymphoma	PCNSL	9/11	78/89	IIR PCNSL
5	1270	NCCTG N107C/Endorsed Study: A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared With Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease	Brain Mets	7/11	180/192	III: Tumor bed SRS vs WBRT 65 enrolled from NRG
6	1119	Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients With Brain Metastasis From HER2-Positive Breast Cancer: A Collaborative Study of RTOG and KROG	Brain Mets	7/12	52/143	WBRT +/- Lapatinib
7	0631	Phase II/III Study of Image- Guided Radiosurgery/SBRT for Localized Spine Metastasis RTOG CCOP Study	Spine Mets	8/09	239/240	SBRT vs 8 Gy single fx; protocol revised

	STUDY	NAME	DX	START	N	COMMENTS
8	1470 A071101	Randomized Phase II Trial of Bevacizumab +/- HSP vaccine in Patients with Recurrent Glioblastoma	rGBM	5/13	41/222	IIR: rGBM; 6 enrolled from NRG
9	BN 001	Hypofractionated Dose escalated Photon IMRT or PBT versus Conventional Photon Irradiation with Concomittant and Adjuvant Temozolomide in Newly Diagnosed GBM	nGBM	11/14	49/576 Photon: 41/288 Proton: 8/288	IIR: GBM
10	BN 002	Phase I Study of Ipilimumab, Nivolumab, and the Combination in Patients with Newly Diagnosed Glioblastoma	nGBM	Jun 2015 (anticipated)	0/42	I: GBM
11	RTOGf 3503	Randomized Phase Ii Trial Of Novottf-100a Plus Bev versus Chemotherapy Plus Bev in Bev- Refractory rGBM	IIR:	Jun 2015 (anticipated)	0/140	IIR: rGBM (Bev Exposed)

#### 5:10 – 5:45 Review of developing studies/concepts

#### **DEVELOPING STUDIES/CONCEPTS:**

	NAME	SITE	COMMENTS
BENIGN			
Rogers	Phase III trial of observation versus irradiation for a gross totally resected grade II meningioma	III: Meningioma	2014 BSC requires ph III; discussions with EORTC
GBM			
Sulman	Phase IIR nGBM unmethylated; ABT 888 + RT vs RT	IIR/III: GBM	New preclinical data?
Lassman	Phase III nGBM EGFR vIII/amp ABT 414	III: GBM	In development as RTOGf
Cahill	Phase II pilot EGFRvIII Rindopepimut	II: GBM	In development as RTOGf
Puduvalli		rGBM	AT13387 CRADA Hsp90 inhibitor
Palmer	MGMT-selected TMZ or RT +/- TTF	Elderly GBM III	
METS			

	NAME	SITE	COMMENTS
Gondi	CC003: PCI HA WBRT	IIR	Approved
Brown	CC001: BM; WBRT + Memantine +/- HA	III	Approved
Sperduto	Dev concept ICI in melanoma brain met +/- SRS		
Burri	Pre vs post-op tumor bed SRS	Brain Mets	

5:45 – 5:55 Questions/Discussions

5:55 – 6:00 Closing Remarks

#### **Breast Cancer Workshop Agenda**

Date: Saturday, July 18, 2015 Start and End Time: 9:00 am - 12:00 pm

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, and new classes of targeted therapies that may be used in breast cancer treatment clinical trials.

#### **WORKSHOP AGENDA**

9:00 - 9:15	Welcome/Update	Norman Wolmark, MD
9:15 - 9:35	Report from the Breast Working Group Meeting	Eleftherios Mamounas, MD Julia White, MD
9:35 - 9:50	<b>NRG BR-001</b> A Phase 1 Study of Stereotactic Body Radiotherapy (SBRT) for the Treatment of Multiple Metastases	Joseph Salama, MD
9:50 - 10:05	NRG BR-002 A Phase IIR/III Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer	Steve Chmura, MD, PhD
10:05 – 10:20	NRG BR-003 A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel with or without Weekly Carboplatin in Women with Node-Positive or High-Risk Node-Negative Triple Negative Invasive Breast Cancer	Vicente Valero, MD
10:20 - 10:35	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	Priya Rastogi, MD
10:35 – 10:55	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
10:55 – 11:10	NSABP-B-50-I/GBG 77/Roche BO27938 A Randomized, Multicenter, Open-Label Phase III Study to Evaluate the Efficacy and Safety of	Eleftherios Mamounas MD Priya Rastogi MD Breast Ca

**Breast Cancer** 

	Trastuzumab Emtansine Versus Trastuzumab as Adjuvant Therapy for Patients with HER2-Positive Primary Breast Cancer Who Have Residual Tumor Present Pathologically in the Breast or Axillary Lymph Nodes Following Preoperative Therapy	
11:10 – 11: 20	<b>SWOG 1207/NSABP-53</b> 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
11:20 - 11:35	<b>Penelope (NSABP B-54-I)</b> Phase III Study Evaluating Palbociclib, a Cyclin-Dependent Kinase 4/6 Inhibitor in Patients with Hormone-Receptor-Positive, HER2-Normal Primary Breast Cancer with High Relapse Risk After Neoadjuvant Chemotherapy	Priya Rastogi, MD, Eleftherios Mamounas MD
11:35 – 11:45	Primary Results, NRG Oncology/NSABP B-35: A Clinical Trial of Anastrozole vs Tamoxifen in Postmenopausal Patients with DCIS	Richard Margolese, MD
11:45 - 12:00	<b>ECOG 2112:</b> 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

#### **Cancer Prevention and Control Workshop**

Co-Chair: David S. Alberts, MD
Co-Chair: Lisa Kachnic, MD
Start and End time: 1:30-4:30pm

Session I: Friday, July 17, 2015 8:00 am – 9:00 am CC003 Kick-off Informational Session Session II: Friday, July 17, 2015 11:00 am – 12:00 pm GOG-225 Informational Session

Session III: Friday, July 17, 2015 1:30 pm – 4:30 pm CPC Workshop

Session IV Saturday, July 18, 2015 10:00 am – 12:00 pm GOG-225 Workshop

Session V: Saturday, July 18, 2015 10:00 am - 12:00 pm GOG-199 Subcommittee (closed)

#### **WORHSHOP AGENDA**

#### SESSION I - CC003 Kick-off Informational Session

Friday, July 17, 2015 8:00 am - 9:00 am

NRG-CC003: Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance for Small Cell Lung Cancer

Presentations with question and answer session.

Welcome and Introductions – Erica Field, MPH, MHA; NRG Project Administrator

Background - Vinai Gondi, MD; CC003 Co-Principal Investigator

Protocol Overview - Minesh Mehta, MD and Vinai Gondi, MD; CC003 Co-Principal Investigators

Credentialing and Central Review – Vinai Gondi, MD; CC003 Co-Principal Investigator

Cognitive Testing - Vinai Gondi, MD; CC003 Co-Principal Investigator

Correlative Imaging Plans - Clifford Robinson, MD; Joseph Bovi, MD CC003 Imaging Co-Chairs

Comparative Effectiveness Plans -- Andre Konski, MD, MBA, CC003 Comparative Effectiveness Co-Chair

#### SESSION II - GOG-0225, Information Session

Friday, July 17, 2015 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

**Cynthia Thomson, PhD,RD, CSO**, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona

**Tracy Crane, MS, RD,** Research Specialist, Sr., LIVES Study Coordinator -Study co-chair and coordinator will be available to answer questions regarding ongoing study

#### SESSION III - NRG CPC Committee Workshop

Friday, July 17, 2015 1:30 pm - 4:30 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:

Cancer Prevention & Control

- 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)
- RTOG-1203 A Randomized Phase III Study of Standard Vs. IMRT Pelvic Radiation for Post-Operative Treatment of Endometrial and Cervical Cancer (A. Klopp, A. Yeung)
- 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)

#### C. Review of Concepts & Protocols in Development:

- CC003 (1432): Seamless Phase II/III of PCI Vs. PCI with Hippocampal Sparing for SCLC (V. Gondi)
- NC1427/CPC-1206: 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)
- A randomized phase II/III trial of intensity modulated proton (IMPT) vs. photon (IMRT) for cognitive preservation in patients with low grade glioma (D. Grosshans)
- Phase II Esophageal (proton vs. photon) (S. Lin)
- Phase III Proton vs. Photon Oropharynx Trial (S. Frank)
- Nasopharynx HPV (-) and EBV (-) (A. Chan, N. Lee)
- Colon Polyp Surveillance Trial (Pinsky and Schoen)
- Survivorship Care Plans for Patients With Breast Cancer (R. Chen)

#### 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; Cynthia Thomson, PhD; Noah Kauff, MD

#### E. Working Group Reports

#### **SESSION IV - CPC Training GOG-0225**

Saturday, July 18, 2015 10:00 -12:00 pm 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

**Cynthia Thomson, PhD, RD, CSO**, Professor, Mel and Enid Zuckerman College of Public Health, Director, Canyon Ranch Center for Prevention & Health Promotion, University of Arizona

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

#### QUESTIONS/DISCUSSION

**EVALUATION** 

#### SESSION V - GOG-199 Subcommittee (closed)

#### Saturday, July 18, 2015 10:00 am-12:00 pm

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

Cancer Prevention & Control

#### **Cervix Cancer Workshop**

Date: Friday, July 17, 2015

Start and End time: 10:00 am - 12:00 pm (Session I)

Date: Saturday, July 18, 2015

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 17, 2015 10:00 am – 12:00 pm

#### A: Introduction

1. Welcome and review of minutes from January 2015; Introduction of new members, 10:00 - 10:05

#### B: Scientific updates/discussion

- 1. Update on NCI-Gynecologic Cancer Steering Committee organization and priorities (David Gaffney), 10:05 10:15
- 2. Update from the Gynecologic Cancer Intergroup meeting on cervical cancer, Chicago, Illinois, June 2015 current and planned GCIG clinical trials (William Small, Bradley Monk), **10:15 10:30**
- 3. Update on Developmental Therapeutics and Committee on Experimental Medicine initiatives in cervical and vulvar cancer (John Farley), **10:30 10:45**
- C: Previously approved concepts in development 10:30 10:40
  - 1. NRG-GY006 (CV1421 -previously CVM1304): 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 Kunos, Charles Leath, Loren Mell)

Approved by GCSC, Sept 2014

D: New directions/proposed concepts (primary review by cervical cancer committee) 10:40 - 11:45

N/A

E: New Concepts from other committees (secondary review by cervical cancer committee) 11:45 - 12:00

Cervix

 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 sarcoma. (A. Shoushtari)

SESSION II: Sat, July 18, 2015 10:00 am – 11:00 am

#### F: Closed Studies

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

#### G: 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 480; enrolled XX
- 3. GOG-0270: Groningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-V) II, An observational study (Brian Slomovitz)
  - a) Opened January 3<sup>rd</sup>, 2012; Accrual Goal ~1500; enrolled XX
- 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; enrolled XX
- GOG 0278: "Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgical Therapy for Stage IA1-IB1 (≤2cm) Cervical Cancer." (Al Covens)
  - a) Activated October 1, 2012, Accrual Goal 200; enrolled XX
- 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; enrolled XX
- 7. 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; enrolled XX

#### H: Reports from Other Committees and Groups / Discussion of Concepts to Other Committees 10:30 - 10:45

- a) Publications Subcommittee
- b) Health 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:
- I) Patient/Community/Advocacy
- I: Wrap up and questions 10:45 11:00

## **Developmental Therapeutics Workshop Agenda**

#### GYN Developmental Therapeutics/Phase I/Translational Science Workshop

Date: Thursday, July 16, 2015 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 16, 2015

## Combined GYN Developmental Therapeutics/Phase I/Translational Science Meeting

4:00 PM – 4:05 PM	Introduction, Drs. Aghajanian and Birrer
4:05 PM – 4:20 PM	Project Team Applications (PTA) update, Carol Aghajanian, MD
4:20 PM – 4:40 PM	Update on translational research GOG86P, Doug Levine, MD
4:40 PM – 5:00 PM	Cyclin-E: Targeting cell-cycle dependencies in ovarian cancer, Ron Drapkin, MD, PhD
5:00 PM – 6:00 PM	Review of new concepts

- 5-10 minute presentation of concept (by proposing investigator)
- Review of concept

### **Developmental Therapeutics/Phase I Workshop**

Date: Saturday, July 18, 2015 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. Participants will become familiar with the current status of phase I, phase II studies that are under development and activated for accrual.
- 2. Immune Therapy and Immune Modulation workshop will present an update from Thursday, July 16, 2015 (2:00 4:00 PM) and plan for integration and prioritization.

- 3. 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.
- 4. Recommendations for action by the GYN Protocol Development committee will be summarized.

#### Saturday, July 18, 2015

## 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 HPV Immunology, Christian S. Hinrichs, M.D.

#### 9:15 AM – 9:25 AM Cervical Cancer (Carol Aghajanian, MD)

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

#### 9:25 AM - 9:35 AM Endometrial Cancer (Carol Aghajanian, MD)

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

## 9:35 AM - 9:50 AM Ovarian Cancer (Robert Coleman, MD)

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

#### 9:50 AM - 10:00 AM Sarcoma (Carol Aghajanian, 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) Active for accrual

#### **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) Safety Lead-In in progress

#### **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) Active for accrual. Continuous regimens completed (ASCO 2015 GYN Cancer oral presentation).

#### **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 specimens: FFPE for FANC-D2 foci formation by IHC shipped to Ohio State 12/3/14. ASCO 2015 GYN Cancer poster presentation. Manuscript in preparation.

#### **Endometrial Cancer**

• 9920 A phase I study of IV doxorubicin plus intraperitoneal (IP) paclitaxel and IV or IP cisplatin in endometrial cancer patients at high risk for peritoneal failure (S McMeekin). No TR specimens collected. Manuscript drafted.

## **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 GYN Cancer poster presentation. Manuscript in preparation.
- 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. Presented at ASCO 2013.
   PK, immune monitoring and pharmacogenomics specimens collected (plasma and whole blood) completed. Manuscript drafted.
- 9927 A phase I trial of pegylated liposomal doxorubicin (PLD), carboplatin, veliparib and bevacizumab in recurrent platinum sensitive ovarian, primary peritoneal and fallopian tube cancer (L Landrum). TR specimens: FFPE for BRCA mutational analysis, promoter methylation and IHC. Manuscript drafted.
- 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 GYN cancer poster presentation. 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. **Second stage accrual in progress** 

• **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). **Active for accrual** 

#### **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:**

#### **New Concepts**

- DT1527: A Phase II Evaluation of Weekly Paclitaxel in the Treatment of Recurrent or Persistent Endometrial Carcinoma. (C. Gunderson)
- **UC1534**: Phase II study of pembrolizumab (MK-3475) in patients with microsatellite unstable (MSI), persistent, or recurrent endometrial cancer. (A. Nickles-Fader)

### 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) Active for accrual (randomized phase II portion)
- DT1439 A randomized phase I/II study of paclitaxel/carboplatin/cediranib versus paclitaxel/carboplatin/placebo as initial
  therapy for measurable stage III or IVA, IVB, or recurrent endometrial cancer (D Bender) Under development. GCSC review in
  progress.

## Recurrent/metastatic disease

- **DT1419** 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) **Under development. CTEP review in progress.**
- **DT1512** Phase I/II study of megestrol acetate, entinostat, and azacitidine in advanced, persistent, or recurrent endometrial carcinoma (C McCourt) **Under development**

#### **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 GYN Cancer oral abstract presentation. Manuscript in preparation.
- 229J A phase II evaluation of cediranib in the treatment of recurrent or persistent endometrial carcinoma (D Bender). TR completed. Presented at SGO 2015 (Gynecol Oncol 137(S1): 1-210, 2015). Manuscript in preparation.
- 229L A phase II trial of AMG386, a selective angiopoietin 1/2 neutralizing peptibody, in patients with persistent/recurrent carcinoma of the endometrium (K Moore). No TR specimens collected. Presented at SGO 2015 (Gynecol Oncol 137(S1): 1-210, 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). **Active for 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 pending specimens shipped to Dr. Levine 12/2014 (229N specimens included). Abstract submitted ESGO 2015.
   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. Presented at 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). In follow-up. No TR specimens collected.
- 186I A randomized phase II evaluation of single agent bevacizumab and combination bevacizumab with fosbretabulin tromethamine (CA4P) in the treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (B Monk). Presented at IGCS 2014. No TR specimens collected. 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). Presented 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 epithelia ovarian, fallopian tube or primary peritoneal cancer (U Matulonis). TR: BIQSFP, MET IHC Center for Molecular Oncologic Pathology (CMOP) DFCI. 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). In follow-up. TR pending.
- 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). Closed to patient entry 3/16/15. 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 in preparation.

#### **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 pending (FFPE for immunohistochemical analysis of pre-treatment class III beta-tubulin) – shipped to Dr. Lomme 10/2014. Manuscript in preparation.

QUESTIONS/DISCUSSION/EVALUATION

## **Gastrointestinal Cancer Workshop Agenda**

Date: Saturday, July 18, 2015
Start and End Time: 2:30 pm – 4:30 pm
Colorectal Chair: Carmen Allegra, 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. Understand the various mutations and gene expression levels associated with GI cancers and how to use this information to better select therapy.
- 2. Understand the various roles of radiation therapy in the optimal management of patients with GI cancers.

<b>WORKSHOP AG</b>	ENDA	
2:30 – 2:35	Introduction and Opening Remarks	Christopher Crane, MD Carmen Allegra, MD
2:35 – 3:25	CRC SUBCOMMITTEE N1048: Intergroup PROSPECT Trial	Thomas George, MD
	TNT: Platform Update	Thomas George, MD
	SWOG 1406: BRAF Mutant Trial/ HER-2 Study	Scott Kopetz, MD
	NCI MATCH/PDX: Incorporation of PDX into MATCH	Scott Kopetz, MD Carmen Allegra, MD
	National Trial of Surveillance Colonoscopy (NToSC): rschoen@pitt.edu	Robert Schoen, MD
	FC-7: Cetuximab + neratenib in quad-negative advanced CRC	Sam Jacobs, MD
	ARGO FC-13: Randomized colon adjuvant trial with regorafenib	Carmen Allegra, MD
3:25 – 4:20	NON-CRC SUBCOMMITTEE	
	<b>0848</b> : A Phase III Trial Evaluation both Erolotinib and Chemoradiation As Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma	Ross Abrams, MD
	<b>1010</b> : A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of Her2-Overexpressing Esophageal Adenocarcinoma	Howard Safran, MD
	<b>CALGB 80803</b> : Endorsed Study: Randomized Phase II Trial of PET Scan- Directed Combined Modality Therapy in Esophageal Cancer	Karyn Goodman, MD
	<b>1112</b> : Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma	Laura Dawson, MD
	1201: Ph IIR SMAD-4 directed IMRT pancreas	Christopher Crane, MD
	NRG GI- 001: Ph II/III Chemo +/- Hypofractionated XRT intrahepatic cholangioca	Christopher Crane, MD
4:20 – 4:30	Review of Developing Trials  NRG GI-XXX: Adjuvant PD1 Inhibition Following Trimodality Therapy For High Risk, Node +, Esophagogastric Cancer  NRG GI-XXX: Concurrent (ADXS11-001) with 5FU/MMC and radiation for	Howard Safran, MD
	locally advanced anal cancer	Kim Perez, MD

## **Genitourinary Cancer Workshop Agenda**

Date: Saturday, July 18, 2015
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.

WOMMSHO! A		
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 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	Alvaro A. Martinez, MD, and Howard Sandler, 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 ReStaging	Howard Sandler, MD
9:05 - 9:35	Review of Pending Studies	
RTOG 1429	Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and Enzalutamide	Dror Michaelson, MD, PhD
RTOG 1218	A Randomized Phase II/III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) versus Conventional Post-Prostatectomy Radiation Therapy for Adverse Pathologic Features or PSA Recurrence	Mark Buyyounouski, MD

(formerly RTOG 1322)	A Phase III Trial of Salvage Radiotherapy with Standard vs. Enhanced Androgen Deprivation Therapy (with Enzalutamide) in Patients with Post-Prostatectomy PSA Recurrences With Aggressive Disease Features	Felix Y. C. Feng, MD
	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
	Androgen Deprivation Therapy With or Without Radiation Therapy in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial	Ronald Chen, MD, MPH

#### 9:35 – 9:55 Other issues

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

9:55 – 10:00	Review of Closed Studies
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 9910	A Phase III Trial to Evaluate the Duration of Neoadjuvant Total Androgen Suppression (TAS) and Radiation
	Therapy (RT) In Intermediate-Risk Prostate Cancer
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
ROTG 0831	A Randomized, Double-Blinded, Placebo-Controlled Phase III Trial to Evaluate the Effectiveness of a
	Phosphodiesterase 5 Inhibitor, Tadalafil, in Prevention of Erectile Dysfunction in Patients Treated with
	Radiotherapy for Prostate Cancer
Other	RTOG 0526: A Prospective Phase II Trial of Transperineal Ultrasound-Guided Brachytherapy for Locally Recurrent
Closed	Prostate Adenocarcinoma Following External Beam Radiotherapy
Studies	
	RTOG 0622: A Phase II Trial of Samarium 153 Followed By Salvage Prostatic Fossa 3D-CRT or IMRT Irradiation In

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**

Date: Saturday, July 18, 2015
Start and End Time: 2:30 pm – 4:00pm
Chair: Robert S. Mannel, MD
Co-chair: Ronald Alvarez, 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. <u>General Business</u>

- A. Call to order (Mannel)
- B. Approval of minutes from February 2015 (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. <u>Committee on Cancer of the Uterine Corpus</u> (Miller)

- 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.
- 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) EORTC requesting our endorsement.
- 3. PORTEC-4, "A Randomised Phase III Trial Comparing Vaginal Brachytherapy (two doses schedules: 21 or 15 Gy HDR in 3 fractions) and Observation after Surgery in patients with Endometrial Carcinoma with High-Intermediate Risk Features.
- 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 Endometriod adenocarcinoma of the Uterine Corpus. (Duska)
- 5. UC1506 Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine)
- 6. **UC1528**: Phase III randomized trial of every-3-week carboplatin and paclitaxel versus dosedense weekly paclitaxel in combination with carboplatin in patients with stage III and IV or recurrent endometrial cancer: defining a new backbone chemotherapy regimen for advanced and recurrent endometrial cancer. (J. Hurteau)
- 7. **UC1533**: Randomized phase III trial of single agent doxorubicin versus gemcitabine plus docetaxel as first-line therapy for metastatic uterine leiomyosarcoma. (M. Huang)
- 8. **UC1534**: Phase II study of pembrolizumab (MK-3475) in patients with microsatellite unstable (MSI), persistent, or recurrent endometrial cancer. (A. Nickles-Fader)

#### **DT Corpus**

- a. DT1415: A randomized, placebo controlled phase II study of weekly paclitaxel plus ganetespib (Heat Shock Protein 90 Inhibitor) vs. weekly paclitaxel plus placebo in the treatment of recurrent or persistent endometrial carcinoma (V Makker)
- b. 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)
- c. DT1439: A randomized phase II-III study of carboplatin, paclitaxel and cediranib (multi-tyrosine kinase inhibitor) versus carboplatin and paclitaxel in measurable stage III, IVA and IVB or recurrent serous and high grade endometrioid endometrial cancer (Bender)
- d. DT1512: Phase I/II study of megestrol acetate, entinostat, and azacitidine in advanced, persistent, or recurrent endometrial carcinoma. (Carolyn McCourt)
- e. **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)
- b. *GOG-8040*: An investigation of the heterogeneity of gene expression, epidemiology and behavior of endometrial carcinoma (Soslow)
- c. **UC1528**: Phase III randomized trial of every-3-week carboplatin and paclitaxel versus dose-dense weekly paclitaxel in combination with carboplatin in patients with stage III and IV or recurrent endometrial cancer: defining a new backbone chemotherapy regimen for advanced and recurrent endometrial cancer. (J. Hurteau)
- d. **UC1533**: Randomized phase III trial of single agent doxorubicin versus gemcitabine plus docetaxel as first-line therapy for metastatic uterine leiomyosarcoma. (M. Huang)

#### PCOR corpus: N/A

## III. Committee on Cancer of the Ovary (Bookman)

- 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. NRG-GY004 (OV1403): 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
- 3. NRG-GY005 (OV1405): An Integrated, Randomized Phase II-III Study of Olaparib and Cediranib in Recurrent Platinum-Resistant Ovarian Cancer (Secord/Lee)
- 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)
- 5. 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)

6. OV1511: 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)

#### DT Ovary:

- a. 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 or fallopian tube (R Burger)
- b. DT1502: A Phase I-II study of intraperitoneal aldesleukin (IL-2) and intravenous pembrolizumab in patients with metastatic ovarian cancer (John Chan)

#### PCOR Ovary:

- a. OV1403 AND OV1405 PRO Incorporated in Phase II component of OV1405 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. NRG-GY001 (RT1303): A Randomized Phase II XL-184 in women with recurrent clear cell carcinoma of the ovary, fallopian tube, or peritoneum (John H Farley).
  - 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)
  - d. RT1507: A phase II trial of Cediranib in recurrent ovarian sex-cord stromal tumors. (Danielle Vicus)
  - e. RT1508: A phase II evaluation of enzalutamide for recurrent sex cord-stromal ovarian tumors. (Lilian Gien)
  - f. RT1510: Inhibition of CYP17 (17  $\alpha$ -hydroxylase/C17, 20-lyase) with abiraterone as a treatment for recurrent granulosa cell tumors of the ovary. (Stephanie Gaillard)  $2^{nd}$  priorty after 1508
  - g. RT1529: A Phase II multicenter open-label study of romidepsin (Istodax®) in combination with carboplatin and etoposide followed by romidepsin (Istodax®) in patients with advanced small cell carcinoma of the ovary hypercalcemic type (SCCOHT). (J. Farley)
  - h. RT1530: A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide, bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type. (K. Schmeler)
  - *i.* **RT1531**: A randomized phase II trial of Temozolomide and cisplatin versus nivolumab (BMS-936558) in patients with completely resected mucosal sarcoma. (D. Vicus)
  - j. 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 sarcoma. (A. Shoushtari)

## **Translational Science**

- a. TS1514: Immuno Score Determination as Predictive Biomarkers for Clinical Outcome in GOG-0262 Population (Samir Khleif)
- **b.** RT1529: A Phase II multicenter open-label study of romidepsin (Istodax®) in combination with carboplatin and etoposide followed by romidepsin (Istodax®) in patients with advanced small cell carcinoma of the ovary hypercalcemic type (SCCOHT). (J. Farley)
- c. RT1530: A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide,

- bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type. (K. Schmeler)
- **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-rish localized or locoregionally advanced mucosal sarcoma. (A. Shoushtari)
- f. UC1534: Phase II study of pembrolizumab (MK-3475) in patients with microsatellite unstable (MSI), persistent, or recurrent endometrial cancer. (A. Nickles-Fader)

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

1. NRG-GY006 (CV1421): A Randomized Phase II Trial of Radiation therapy and cisplatin alone or in combination with IV Triapine in Women with newly diagnosed bulky Stage IB2, II, IIIB or IVA cancer of the Uterine Cervix. (Kunos/Leath/ Mell).

#### DT Cervix

a. 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)

#### **RT Cervix**

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

## VI. <u>Health Outcomes Research Committee</u> (Wenzel)

#### A. Proposed studies

- UC1528: Phase III randomized trial of every-3-week carboplatin and paclitaxel versus dose-dense weekly paclitaxel in combination with carboplatin in patients with stage III and IV or recurrent endometrial cancer: defining a new backbone chemotherapy regimen for advanced and recurrent endometrial cancer. (J. Hurteau)
- RT1530: A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide, bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type. (K. Schmeler)
- 3. **RT1532**: A randomized trial of Adjuvant Pembrolizumab, adjuvant chemotherapy, or expectant observation following neoadjuvant pembrolizumab and surgical resection of high-rish localized or locoregionally advanced mucosal sarcoma. (A. Shoushtari)
- 4. **UC1533**: Randomized phase III trial of single agent doxorubicin versus gemcitabine plus docetaxel as first-line therapy for metastatic uterine leiomyosarcoma. (M. Huang)

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

#### A. Proposed Studies

- 1. NRG-CC002 (ELD1301): Preoperative Assessment in Elderly Women with Gynecologic Cancers (Amina Ahmed)
- 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)

## **Head and Neck Cancer Workshop Agenda**

Date: Saturday July 18th. 2015 **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.
- 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 newlylaunched studies.
- 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.
- 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.
- 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.
- 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.
- 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

WORKSHOP AGENDA	4	
10:00 - 10:10	Report on publications and protocol closed to active accrual	Quynh 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-R)	Cristina Rodriguez, MD (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 (Paul Harari, MD, Merrill Kies, MD)
NRG HN001	Individualized NPC treatment based on post-RT EBV DNA (Phase III) (RTOG 1305)	Nancy Lee, MD (Dimitri Colevas, MD)
NRG HN0002	Phase IIR dose de-escalation study for Human Papillomavirus-Positive, Good- Prognosis Advanced-Stage Oropharyngeal Cancer (RTOG 1333)	Sue Yom, MD

## 10:35 – 11:00 Review of developing studies

RTOG 3507	ReRT +/- Pembrolizumab in Locoregionally recurrent HNSCC	Stuart Wong, MD (Shomo Koyman, MD)
NRG HN1438	PD1 inhibition +/- SBRT in patients with oligometastasis	Allen Chen, MD (Nooshin Hashemi, MD)
RTOG3504	Phase IIR of Cetuximab +/- Nivolumab (PD1 antibody) or Cisplatin +/- Nivolumab in intermediate/high risk HNSCC	Maura Gillison, MD (Robert Ferris, MD, PhD)
NRG HN1520	Phase IIR of Adjuvant Chemoradiotherapy +/- anti-PD1 (or PD-L1) mAb in High Risk, HPV(-) PULA HNSCC with Window Biomarkers (WG 2)	Julie Bauman, MD
NRG HN1436	RT +/- Afatinib for high risk cutaneous SCC (Phase IIR)	Mohan Suntharalingam, MD (Randal Weber, MD)
NRG HN?	RT+ Cetuximab vs. RT + Pembro in patients age $\geq$ 70 with locally advanced HNSCC	Loren Mell, MD

## 11:10 – 11:15 Discussion

## 11:15 – 11:50 Presentations & Updates

Translational Research Program update	Christine Chung, MD
HN Surgical Committee update	Erich Sturgis, MD,
NCI H&N Steering Committee Update	MPH Robert Ferris, MD

## 11:50 – 12:00 New Business

## **Lung Cancer Committee Workshop Agenda**

Date: Saturday, July 18, 2015
Start and End Time: 2:30 pm – 4:30 pm
Chair: Jeffrey D. Bradley, MD

Co-Chair: Marty Edelman, MD; Gail Darling, MD; Ritsuko Komaki, MD

#### **Learning Objectives**

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

- 1. Recognize critical aspects of developing and conducting a clinical trial in Lung (LU) cancer therapy research in a cooperative group setting.
- 2. Identify and describe the design and status of new LU 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 LU 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.

#### **WORKSHOP AGENDA**

#### Session I – Active Studies

A. Committee Overview Jeffrey Bradley, MD

B. Subcommittee Reports

a. Thoracic Surgery
b. Medical Oncology

C. Lung-MAP (SWOG S-1400)

D. ALCHEMIST Trial (Alliance)

E. RTOG 1306/ALLIANCE 31101:EM4-ALK and EGFR Mutant

F. RTOG 1308: Protons vs Photons for St III NSCLC

G. RTOG 0839: Randomized Ph II Pre-Op Chemo/RT ± Panitumumab

Marty Edelman, MD

H. RTOG 0937: Randomized Ph II Pre-Op Chemo/RT ± Panitumumab Marty Edelman, MD
L. CALGB 30610/RTOG 0538: Intergroup Phase III Ritsuko Komaki, MD
RTOG 1106/ACRIN: Adaptive RT in Stage III Spring Kong, MD

K. NRG-LU001: PhaseIIR: ChemoRT ± Metformin Heath Skinner, MD, PhD

L. Session I – Active Studies

### Session II – Concepts in Development

A. Chemo/RT +/- Nivolumab for Stage III (RTOG Foundation Trial)

James Urbanic, MD

a. Contract development with BMS

B. NRG-CC1432: Hippocampal Avoidance for PCI (Small Cell) Vinai Gondi, MD, Alex Sun, MD

C. 2<sup>nd</sup> Generation ALK for Stage IV Jeffrey Bradley, MD

### **QUESTIONS / DISCUSSION**

Jeffrey Bradley, MD

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

Date: Friday, July 17, 2015
Start and End Time: 3:30 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.

Workshor A		
3:30 – 3:35	Introductions (5 min)	Ying Xiao, PhD
3:35 – 3:45	NCI Communications (10 min)	Jacek Capala, MSc.,PhD
3:45 – 4:00	NRG QA Report (15 min)  IROC Houston  IROC Philadelphia RT (Contouring & Dosimetry)  IROC Philadelphia Imaging	David Followill, PhD James M. Galvin, DSc Mark Rosen, MD
4:20 - 5:20	Disease Site Reports (20min)  Breast  Brain  GI  GU  GYN  H&N  Lung  Other (NCORP)  Modality Technology Reports (60min)	Ying Xiao, PhD Fangfang Yin, PhD William Parker, PhD Rajat Kudchadker, PhD., DABR Ying Xiao, PhD Ping Xia, PhD Martha M. Matuszak, PhD Eric S. Elder, PhD
4.20 - 3.20	<ul> <li>Particle Therapy</li> <li>SBRT</li> <li>IMRT</li> <li>IGRT</li> <li>IGBT</li> <li>Motion Management</li> <li>Imaging</li> <li>Emerging technologies</li> </ul>	Mike Gillin, PhD Indrin Chetty, MS Martha M. Matuszak, PhD Fangfang Yin, PhD Ying Xiao, PhD Ying Xiao, PhD Ying Xiao, PhD Jason Sohn, PhD
5:20 - 5:35 5:35- 5:45 5:45 - 6:00	NCTN Collaborations (15min)	Ken Ulin, PhD
5.45 T 0.00	Questions/ Discussions	Madical Dkr

## NRG Protocol B-51/1304 Workshop

Date: Friday, July 17, 2015 Start and End Time: 3:00 pm - 4:00 pm

## **Learning Objectives**

Following this activity, participants will be better able to:

- 1. Discuss the key eligibility criteria of the study
- 2. Describe the treatment arms of the study.
- 3. Discuss methods to optimize accrual to the trial.

A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall 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

3:00 -3:15	Overview of the clinical trial	Thomas B. Julian, MD
3:15 -3:30	Treatment arms	Julia White, MD
3:30 – 3:45	Best practices for optimizing accrual	Discussion and audience participation
3:45 - 4:00	Questions/Discussion/Evaluation	

## NRG Protocols B-52, B-55, and NRG BR003 Workshop

Date: Saturday, July 18, 2015 Start and End Time: 12:00 pm - 1:00 pm

### **Learning Objectives**

Following this activity, participants will be better able to:

- 1. Discuss the study design and key inclusion criteria of 2 breast cancer clinical trials.
- 2. Identify critical aspects of the correlative science of the clinical trials.

Educational need for presentations of the following protocols: NRG BR003 protocol is a new protocol that will be activated prior to the meeting. It is anticipated that investigators and research staff will benefit from an opportunity to discuss the protocol and its implementation. The B-55/BIG 6-13 was presented during the February 2015 NRG Oncology meeting and based on the discussion at the meeting and the ongoing calls to the Clinical Coordinating Department (Pittsburgh Office) regarding the trial, investigators and research staff will derive an educational benefit from the presentation and the opportunity to discuss the protocol. An amendment to the B-52 Protocol will be activated later this summer. Investigators and research staff will derive an educational benefit from a brief discussion of the upcoming amendment.

#### **WORKSHOP AGENDA**

12:00- 12:15	Overview of NRG BR003
17:00-17:15	CIVELLEM OF MRG BROOS

Vicente Valero, MD

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

12:15-12:20 Clinical Logistics

Lynne Suhayda, RN, MSEd

12:20-12:30 Questions/Discussion

**12:30 -12:40** Overview of NSABP B-55/BIG 6-13

Priya Rastogi, MD

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

12:40-12:45 Clinical Logistics

Lynne Suhayda, RN, MSEd

12:45-12:50 Questions/Discussion

**12:50-12:55** NSABP B-52 Update

Priya Rastogi, MD

A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab With or Without Estrogen Deprivation

**12:55-1:00** Evaluation

### **Ovarian Workshop Agenda**

Date: Friday, July 17, 2015

Start and End Time: Session I: 8:00 am - 10:00 am

Date: Saturday, July 18, 2015

Start and End Time: Session II: 10:00 am - 11:00 am

Chair: Michael A Bookman MD
Co-Chair: Paul DiSilvestro MD

#### **Learning Objectives**

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

- 1. Discuss the status and significance of new and ongoing GOG/NRG clinical trials on the treatment of ovarian 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 the NRG
- 4. Assure strict quality control of GOG/NRG clinical trials

### **Workshop Agenda**

- I General
  - a. Overview of Workshop Agenda
  - b. Disclosures and Potential Conflict of Interest
  - c. NRG Integration Update
  - d. Status of Ancillary Data Proposals
  - e. Overview of Recent Clinical Research in Ovarian Cancer (including GCIG)
  - f. Changes in Committee Membership, if applicable
  - g. Research Strategy Committee Update
  - h. GCSC Research Priorities and GCIG update
- II Review of Closed Studies (Non-Terminated)
  - a. Updated List (JUN2014): 175, 178, 215, 212, 218, 252, 262, 3001
  - b. GOG0212 Phase III maintenance chemotherapy (Larry Copeland) Opened MAR 2005, closed JAN 2014, continues under review as events accumulate.
  - c. GOG0252 Phase III IP vs IV (with bevacizumab) Opened JUL 2009, closed NOV 2011, continues under review, primary analysis pending events.
  - d. GOG0262 and <u>ACRIN6695</u>. Primary chemotherapy outcomes presented ESGO 2014 (J Chan), manuscript submitted with extended analysis. Perfusion imaging results promising and may be used in neaoadjuvant trials in the future.
  - e. GOG3001 TRINOVA3 Phase III trebananib, Activated JUL 2012, amended study design reducing overall accrual to 1000 patients. Closed to accrual 28JAN2014. Anticipate PFS data late 2015 (B Monk).
  - f. GOG0273 Chemotherapy, Elderly Population (V von Gruenigen, G Fleming). Accrual completed to Arm 3 (modified dose-dense weekly paclitaxel) and closed 04JUN2014.
  - g. Update regarding NRG-CC002 "Preoperative Assessment and Postoperative Outcomes of Elderly Women with Gynecologic Cancers" Presentation of data from Arm 3, discussion of Olaparib-cedarinib phase I concept, activation of pre-surgical assessment protocol, and potential future studies.
- III Prioritized Discussion (Activated and Approved Studies Under Development)
  - a. PARP Inhibition Front-Line Phase III (Partners GOG3005).
    - Update on GOG9923 phase I trial for dose/schedule with concurrent chemotherapy and veliparib (K Bell-McGuin).

55

Ovarian

- Phase III activated, site recruitment ongoing, first patient pending.
- B. AstraZeneca (GOG-3004, SOLO1) PARPi Maintenance Phase III.
  - Activated within GOG and selected global sites AUG 2013, approved by WIRB.
  - Accrual complete (except China).
  - Expected first analysis at 206 PFS events, approximately 36 months after first enrollment.
- C. Randomized Phase II Concepts, NACT
  - Neoadjuvant, molecular targeted interventions with pre/post biopsies, combined clinical and molecular endpoints. Clinical endpoints initially defined by PFS while establishing reference database of RO interval cytoreduction as possible surrogate marker for future trials.
  - NRG-GY007 (OV1310) 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 GCSC approved 5/1/2015 (R. Burger/C. Landen/R Buckanovich)
  - Request for new proposals distributed DEC 2014, three concepts approved for further development to be reviewed at meeting: see below.
    - Status of Randomized Trials in Recurrent Disease
  - GOG0213 Phase III randomization to surgical component (R Coleman) ongoing
    - Surgical Accrual
    - O Discussion of primary analysis of chemotherapy +/- bevacizumab (R Coleman, M Brady)
  - Randomized phase II trials managed with Developmental Therapeutics (R Burger)
  - Olaparib and Cediranib vs Chemotherapy, Phase III, Recurrent Disease
    - NRG-GY004 Olaparib and Cediranib vs chemotherapy in platinum-sensitive recurrent disease, phase III, reviewed by GCSC JUN 2014, s/p recent CTEP consensus review April,2015 (J Liu)
    - NRG-GY005 Olaparib and Cediranib vs chemotherapy in platinum-resistant recurrent disease, sequential randomized phase II followed by phase III, reviewed by GCSC JUN 2014, s/p recent CTEP consensus review April, 2015 (J-M Lee)
- IV Studies and Reports from Other Committees and Working Groups
  - a. Cancer Treatment in the Elderly (Fleming)
    - Update regarding NRG-CC002 "Preoperative Assessment and Postoperative Outcomes of Elderly
      Women with Gynecologic Cancers" Presentation of data from Arm 3, discussion of Olaparib-cedarinib
      phase I concept, activation of pre-surgical assessment protocol, and potential future studies.

56

- b. Report from Phase I (Schilder)
- C. Report from DT (Burger).
- d. Report from QOL
- e. Report from CEM (Birrer)
- f. Report from ACRIN (Schilder)
- **V** New Business, General Questions, Discussion

Proposed Concepts for Review and Protocols under Development Primary Review (Under Development within Ovarian Committee)

Ovarian

- 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. 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)
- 3. OV1511: 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)

Additional concepts pending finalization of concept submissions for July, 2015 meeting

## Secondary Review (Under Review from Other Committees)

- 1. RT1529: A Phase II multicenter open-label study of romidepsin (Istodax®) in combination with carboplatin and etoposide followed by romidepsin (Istodax®) in patients with advanced small cell carcinoma of the ovary hypercalcemic type (SCCOHT) (J. Farley)
- 2. RT1530: A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide, bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type (K. Schmeler)

57

#### **Future priorities of the Ovarian Committee**

VI Evaluation

Ovarian

## **Pathology Workshop**

Date: Friday, July 17, 2015 Start and End time: 8:00 am - 5:00 pm

Chair: William Rodgers, PhD, MD
Co-Chair: Anthony Magliocco, MD
Co-Chair: Soonmyung Paik, MD

## **Learning Objectives**

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

- 1. Apply standardized criteria for evaluation of gynecologic neoplasms
- 2. Discuss current diagnostic criteria for gynecologic 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 for gynecologic neoplasms
- 6. Become familiar with Digital slide review technology

Educational Need: To better understand the role of pathological diagnosis in the conduct of clinical trials to treat gynecologic malignancy

#### **WORKSHOP AGENDA**

- A. Review slides and eligibility for current active protocols

  Each case is reviewed by a two-pathologist team, with input from a referee pathologist as needed.
- B. Business Meeting
  - Orientation for new Pathologists
  - HIPAA Requirements
  - Reports from Cervix, Corpus, and Ovarian Committees
  - Report from Translational Science Committee
  - Update NRG Oncology
  - Pathologist representation on NRG Scientific Committees
- C. Review of new concepts and protocols, Discussion topics:

Pathology eligibility criteria

Pathology review recommendations

Special pathology review/support, e.g. TMA construction

1 List new concepts and protocols for review by Pathology Committee July 2015

QUESTIONS / DISCUSSION EVALUATION

## Patient Centered Outcomes Research (PCOR) Workshop Agenda

Date: Thursday, July 16, 2015 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

	I. Announcements	PI/Person Reporting
4:00 – 4:30	Composite Endpoints Panel	Laura Havrilesky, MD
		David Cella, PhD
	Comments	Stephanie Pugh, PhD
	Audience Q & A	
4:30 - 4:50	II. NRG PCOR and Comparative Effectiveness Subcommittee Updates	Patricia Ganz, MD
	, and a second s	Ben Movsas, MD
		Lari Wenzel, PhD
	HA-PCI Trial: Randomized Phase II/III Trial of Prophylactic Cranial Irradiation	Andre Konski, MD
	with or without Hippocampal Avoidance (HA) for Small Cell Lung Cancer (SCLC)	
4:55 – 5:00	PCORI Update	Ben Movsas, MD
5:00 - 5:45	III. Developing NCTN trials: Comments on PRO, QOL, and CER endpoints	
	Protocol: Phase II/III Esophageal Trial	Steven Lin, MD
	NRG-CC003: Phase IIR/III Trial of Prophylactic Cranial Irradiation with or without	Ben Corn, MD
	Hippocampal Avoidance for Small Cell Lung Cancer	
	Concept: A Phase II Open-Label Trial of Pegylated Liposomal Doxorubicin plus	Dana Chase, MD
	Bevacizumab in Elderly Platinum-Resistant Ovarian Cancer Patients	
	GY004: A Phase III Study Comparing Single-Agent Olaparib or the Combination	Lari Wenzel, PhD
	of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary	
	Peritoneal Cancer	
	<b>GY005:</b> A Randomized Phase II/III Study of the Combination of <b>C</b> ediranib and	Lari Wenzel, PhD
	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)	

	Concept: A Phase II/III Trial Evaluating ADXS11-001 with Mitomycin, 5-Fluorouracil (5-FU) and IMRT for Locally Advanced Anal Cancer	Ben Movsas, MD
	<b>GU1430:</b> Phase III Trial of Androgen Ablation Alone as Compared to Androgen Ablation Followed by External Beam Radiotherapy for Newly Diagnosed Clinically Node-Positive Prostate Cancer	Ben Movsas, MD
	(Note: Approved by GU Steering Committee at NRG and NRG scientific council)  GU1437: Phase III Study of Radium 223 plus ADT vs. ADT Alone in Patients Ineligible or Refusing Docetaxel (Note: Approved by GU Steering Committee at NRG and NRG scientific council)	Ben Movsas, MD
5:45 - 6:00	IV. New GYN Concepts	Patricia Ganz, MD Ben Movsas, MD
	UC1528: Phase III Randomized Trial of Every-3-Week Carboplatin and Paclitaxel versus Dose-Dense Weekly Paclitaxel in Combination with Carboplatin in Patients with Stage III & IV or Recurrent Endometrial Cancer: Defining a New Backbone Chemotherapy Regimen for Advanced and Recurrent Endometrial Cancer (J. Hurteau)	Lari Wenzel, PhD
	RT1530: A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide, bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type (K. Schmeler)	
	UC1533: Randomized Phase III trial of Single Agent Doxorubicin versus Gemcitabine plus Docetaxel as First-Line Therapy for Metastatic Uterine Leiomyosarcoma (M. Huang)	
	V. Other Business	

## 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 (activating 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 (activating 8/15)

**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-IIIB NSCLC (activated 2/14)

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

Date: Thursday, July 16, 2015
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 Facilitators: Sally Brown RN, BSN, MGA and Bonnie Sauder RN, BS

## **Learning Objectives**

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

- 1. Discuss the multidisciplinary approach to successful clinical trial accrual
- 2. Analyze a qualifying clinical trial
- 3. Apply CMS's clinical trial policy
- 4. Outline payor issues including Medicare and Medicare Advantage plans
- 5. Recognize the scientific rationale for the NCI Match trial
- 6. Discuss NCI-Match schema, eligibility, study participation, and drug selection process

#### **WORKSHOP AGENDA**

<u>Time</u>	<u>Topic</u>	<u>Speakers</u>
2:00 - 2:15	Welcome	Sally Brown RN, BSN
2:15 - 3:00	Successful Clinical Trial Accrual- "It takes a village"	Robert Mannel MD
3:00 - 5:00	Clinical Trial Billing for Cooperative Group Trials	Kelly Willenberg MBA, BSN, CCRP, CHRC,
CHC		
5:00 - 6:00	ECOG-ACRIN MATCH/EAY 131	Brenda McCalister-Afflick CCRP

### QUESTIONS/DISCUSSION/EVALUATION

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

Date: Thursday, July 16, 2015
Start and End Time: 6:30 pm - 8:30 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: Bonnie Sauder RN BS, Nancy Fusco RN, BSN

#### **Learning Objectives**

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

- 1. Describe the roles and responsibilities for disease site/ committee appointments.
- 2. Discuss and prioritize the current activities for work groups.
- 3. Discuss and initiate PSC plans for semi-annual meetings.

- 1. Roll Call
- 2. Approval of Minutes from May 21, 2015
- 3. Working Group Reports
- 4. Update to representation on disease sites/committees
- 5. Review/Discuss meeting agendas

#### 6. New Business

## QUESTIONS/DISCUSSION/EVALUATION

# Protocol Support Committee Workshop Clinical Research Associate Subcommittee (CLOSED)

Date: Thursday, July 16, 2015
Start and End Time: 6:00 pm – 8:00 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. Describe the process and future plans for appointments of CRAs to NRG Oncology committees
- 2. Identify educational needs of both new and experienced CRAs
- 3. Explain the functions and activities of the Protocol Support Committee Working Groups
- 4. Discuss the role of the CRA Subcommittee and identify opportunities for member participation

#### **WORKSHOP AGENDA**

- 1. Attendance
- 2. Approval of February 2015 CRA/CTN Subcommittee Meeting minutes
- 3. Discuss CRA Site and Modality Committee appointments
- 4. Review of February 2015 meeting evaluations
- 5. Working Group Reports
- 6. Discuss meeting schedules and educational needs
- 7. Goals and Projects
- 8. Other business

#### QUESTIONS/DISCUSSION/EVALUATION

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

Date: Friday, July 17, 2015
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 Facilitators Sally Brown RN, BSN, MGA and Bonnie Sauder RN, BS

#### **Learning Objectives**

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

- Select and provide the PSC with 4 or more potential topics and speakers for the educational session in January 2016
- 2. Identify and establish groups to explore alternatives to live educational presentation

### **WORKSHOP AGENDA**

1. Evaluate educational session of 7/16/2015

- 2. Update on SoCRA exam
- 3. Discuss 4 hour educational session in January 2016
- 4. Discuss methods to provide education to research staff

## QUESTIONS/DISCUSSION EVALUATION

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

Date: Friday, July 17, 2015
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

## **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. Approval of minutes from Conference Call
- **3.** Review top priorities for the working group: Outline tentative plan:
  - a. Welcome packet:
    - i. distribution, evaluation, and annual review process
    - ii. Identify potential new topics/areas to develop
  - b. Develop Mentor Program with selection/application process
  - c. Review and establish timeline for goals/projects
- 4. Meeting Plan: Conference calls and Working meetings at NRG Oncology Semi-Annual Business Meeting

## QUESTIONS/DISCUSSION EVALUATION

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

Date: Friday, July 17, 2015
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

Room:

#### **Learning Objectives**

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

- 1. Review current process of circulating protocols for review
- 2. Discuss how to track 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 methods for updates and corrections of existing protocols upon group implementation

#### **WORKSHOP AGENDA**

- 1. Review current Protocol review process
- 2. Review progress to date
- 3. Protocol review assignments
- 4. Update from NRG leadership
- 5. Update on Funding sheets and Medicare analysis
- 6. Meeting plan: conference calls needed or address each study
- 7. Replacement member review current roster
- 8. Other business

#### QUESTIONS/DISCUSSION/EVALUATION

Protocol Support Committee Workshop Quality Control Working Group (CLOSED)

Date: Friday, July 17, 2015
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

Room:

#### **Learning Objectives**

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

- 1. Discuss common audit findings and ways to improve protocol data management at their site.
- 2. Demonstrate knowledge of Clinical Trial Management Systems (CTMS).

#### **WORKSHOP AGENDA**

Review and approval of minutes from February 6, 2015

7:00 AM to 8:00 AM Common Audit Findings Member of the NRG Oncology Audit Team

8:00 AM to 9:00 AM Clinical Trials Monitoring Systems Working Group Members

QUESTIONS/DISCUSSION EVALUATION

# Protocol Support Committee Workshop CTN/CRA Breakout Sessions

Date: Friday, July 17, 2015
Start and End Time: 1:30 pm- 5:30 pm
Chair: Susan Nolte, PhD, CRNP

Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC Program Facilitators: Sally Brown RN, BSN, MGA and Bonnie Sauder RN, BS

Room:

## All sessions run concurrently (50 minutes/session)

#### **Learning Objectives**

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

- 1. Discuss how to identify, access and track appropriate patients for a clinical trial
- 2. Identify tools to facilitate communication among physicians, patients, nurses and CRA's
- 3. Discuss the study design and key inclusion criteria of Protocol NRG BR003
- 4. Identify critical aspects of the correlative science of NRG BR003
- 5. Discuss the rationale for use of carboplatin in triple negative breast cancer
- 6. Discuss how to get started with the CIRB
- 7. Identify what is needed to utilize the CIRB
- 8. Discuss how to navigate CIRB studies
- 9. Identify CTSU applications including the website Dashboard feature and the Roster Update Management System
- 10. Describe the process for submission of research ideas and concept development
- 11. Describe the process of protocol development through final approval
- 12. Review the format of the NRG Oncology Protocol Template
- 13. Interpret clinical trial billing rules

QUESTIONS/DISCUSSION/EVALUATION

- 14. Summarize billing compliance issues for discussion
- 15. Discuss the study design and key inclusion/exclusion criteria of Protocols RTOG 1112 & NRG GI 001
- 16. Learn about the structure, leadership and services provided by IROC
- 17. List the three tissue bank locations, type of specimens housed at each location, and contact information for staff.
- 18. Identify specimen requirements, collection, processing and shipping of tissue bank specimens

<u>Topic</u>	<u>Speaker</u>
CTSU	Martha Hering RN, MHA, Vanitha Chockalingam B Tech, MBA
IROC	Jessica Lowenstein MS, DABR
Clinical Trial Development:	
NRG Processes and NCI Requirements	Francy Fonzi MPM, CCRP, Linda Walters-Page MA, Kathryn Okrent MA
Organizational Tips	Cindy Licavoli RN, BSN, MA, Patricia Green Sharpe RN, MSN, MHSA,
	Christina Wilson BSN, RN
Overview of NRG BR003	Vincente Valero MD
CMS Billing Compliance	Kelly Willenberg MBA, BSN, CCRP, CHRC, CHC
NRG Oncology Audits	John Blessing PhD, Tamara McLaughlin, Elaine Boyle, Sally Bialy
Using the CIRB	Desiree Goldstein RN, MSN, Nancy Knudsen RN, BSN, LaTisa
Hernandez,	
	Amanda Putnick
Tissue Banking	Lisa Beaverson BA, CCRP, Heather Lankes PhD, MPH, Theresa
	Bradley PhD, Sandy DeVries MA
Overview of RTOG 1112 & NRG GI 001	Laura Dawson MD

## Protocol Support Committee Workshop Protocol/Study Presentations

Date: Saturday, July 18, 2015
Start and End Time: 10:00 am - 11:00 am
Chair: Susan Nolte, PhD, CRNP

Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC

#### **Learning Objectives**

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

- 1. Discuss the study design and key inclusion/exclusion criteria of Protocol NRG HN 002
- 2. Identify the role of FDG-PET/CT imaging as a predictive imaging marker for disease control
- 3. Discuss rationale for treatment arms.

## **WORKSHOP AGENDA**

TopicSpeakerOverview of NRG HN 002- Randomized Phase II trial for PatientsSue Yom MDWith P16 positive, non-smoking associated, locoregionally advanced

Oropharyngeal Cancer

QUESTIONS/DISCUSSION/EVALUATION

# Protocol Support Committee Workshop PSC Business Meeting

Date: Saturday, July 18, 2015
Start and End Time: 11:00 am - 12:00 pm
Chair: Susan Nolte, PhD, CRNP

Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC

## **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
- 6. Future goals/direction

## QUESTIONS/DISCUSSION/EVALUATION

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

Date: Saturday, July 18, 2015
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.

6:45 – 6:50	Welcome/Introduction	
6:50 –6:55	Update on Proton Center Credentialing by IROC Houston	David Followill, PhD
6:55 – 8:10	Protocols/ Concepts	
6:55 - 7:15 6:55 - 7:05 7:05 - 7:15	Protons in liver studies  RTOG 1112 - Ph III, SBRT, sorafenib, hepatocellular ca (L.Dawson)  NRG-GI001 - Ph IIR/III RT for liver confined unresectable cholangiocarcinoma	Laura Dawson, MD Tom Delaney, MD
7:15 – 7:25	RTOG 1205-Ph IIR bevacizumab + IMRT recurrent GBM	Christina Tsien, MD
7:25 – 7:35	NRG-BN001 Brain: 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	Minesh Mehta, MD
7:35 – 7:45	RTOG 1308 Phase III Randomized Trial Comparing Overall Survival after Photon versus Proton Radiochemotherapy 60-70 GyRBE for Inoperable Stage II-IIIB NSCLC	Jeffrey Bradley, MD Xing Liao, MD
7:45 – 8:10	Phase II/III Randomized Studies of IMRT vs. IMPT for Nasopharyngeal and Oropharyngeal Carcinomas, Low Grade Brain Tumors, and NSCLC	Drs. DeLaney, Annie Chan, Steven Frank, David Grosshans, Steven Lin
8:10 - 8:20	Other Business	Tom DeLaney, MD
8:20 - 8:30	Questions	

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

Date: Friday, July 17, 2015
Start and End Time: 1:30 pm – 3:30 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.

1:30 – 1:35	Welcome / Introduction	Jeff Michalski, MD
1:35 – 2:10	Update on NCTN Cooperative Groups  a. NRG Oncology Group Update	Jeff Michalski, MD
	<ul> <li>b. Imaging and Radiation Oncology Core (IROC) RT Update</li> <li>c. Imaging and Radiation Oncology Core (IROC) Imaging Update</li> <li>d. RT Case Reviews at the NRG February Meeting</li> </ul>	Ivy Petersen, MD Frank Vicini, MD James Galvin, DSc Jeff Michalski, MD Ivy Petersen, MD Frank Vicini, MD
2:10 – 2:25	NCI Imaging Research Priorities/Opportunities	Ying Xiao, PhD
2:25 – 2:35	Overview of Medical Physics	Ying Xiao, PhD
2:35 – 2:45	Review RTOG/NRG Studies with Imaging and Oncology Trial	Jeff Michalski, MD
2:45 – 3:20	Disease Site Liaisons Reports  a. Brain b. Breast c. Gyn d. GI e. GU f. Head and Neck g. Lung h. Sarcoma i. Outcomes	Christina Tsien, MD Steven Chmura, MD Sushil Beriwal, MD Laura Dawson, MD Jeff Michalski, MD Sue Yom, MD Greg Videtic, MD Dian Wang, MD Jason Efstathiou, MD
3:20 – 3:25	Other Business	
3:25 -3:30	Questions/Discussion	

### **Rare Tumor Workshop**

Date: Friday, July 17, 2015 Start and End Time: 2:00 pm - 4:00 pm

Chair: David M. Gershenson, MD

Co-Chair: Allan L. Covens, MD

#### **Learning Objectives**

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

- 1. Outline challenges and potential solutions involved in conducting clinical trials of rare gynecologic malignancies, including the mechanism of international collaborations
- 2. Discuss emerging and ongoing GOG clinical trials on rare gynecologic cancers
- 3. Discuss promising translational research objectives and priorities for future clinical trials
- 4. Discuss rationale for triaging women with specific rare tumors to separate clinical trials

#### **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

RT1205: MaGIC 3-cohort trials for low-, intermediate, and high-risk patients with malignant germ cell tumors (COG) (Gershenson, Covens, Hurteau, etc.)

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 (Nickles Fader)

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

RT1508: A phase II evaluation of enzalutamide for recurrent sex cord-stromal ovarian tumors (Gien)

**RT1529**: A Phase II multicenter open-label study of romidepsin (Istodax®) in combination with carboplatin and etoposide followed by romidepsin (Istodax®) in patients with advanced small cell carcinoma of the ovary hypercalcemic type (SCCOHT) (J. Farley)

**RT1530**: A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide, bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type (K. Schmeler)

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

**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 (A. Shoushtari)

#### C. Other Business

QUESTIONS/DISCUSSION/EVALUATION

## **Surgical Oncology Committee Agenda**

Date: Saturday July 18, 2015
Start and End Time: 6:30 am - 7:55 am
Chair: Thomas Julian, M.D.

Co-Chairs: Drew Ridge, M.D.; Nick Spirtos, M.D.

## **Learning Objectives**

Following this activity, participant will be better able to:

- 1. Provide information on the latest developments related to the NCTN and NRG Oncology
- 2. Describe different aspects of the field of surgical oncology such as QA/QC.
- 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	Jeff Michalski, M.D.
	Radiation Oncology Committee Update	Corey Langer, M.D.
6:45 – 7:00	Update on NCTN Cooperative Groups	
	a. BOLD TF Update	Thomas Julian, M.D.
	b. NRG Oncology Group Update	Thomas Julian, M.D., Nick Spirtos M.D., Drew Ridge, MD
7:00 – 7:10	QA/QC Session	Charles Whitney, M.D.
7:10 – 7:45	Disease Site Liaisons Reports (very brief update on	
	developments)*	
	a. Brain	Michael Vogelbaum, M.D.
	b. Breast	Irene Wapnir, M.D.
	c. Gynecology- Endometrial Cancer Update	Nick Spirtos, M.D.
	d. GU	Lenny Gomella, M.D.
	e. Head and Neck	Erich Sturgis, M.D.
	*Liaison to provide a 5 minute update on latest	
	surgical advancement	
7:45 – 7: 55	Questions/Discussion	

#### **Translational Science Workshop Agenda**

Date: Saturday, July 18, 2015
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 NRG 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 recognize the emerging proteomics in epithelial ovarian cancer

#### **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 – 10:40	CPTAC Update (Ovarian)	Karin Rodland, PhD
10:40 – 11:05	U10 Update (Head & Neck)	Christine Chung, MD, MS
11:05 – 11:30	NRG Oncology Immunotherapy Trials	Adam Dicker, MD, PhD
11:30 – 12:00	Translational Research Subcommittees Reports/Discussion	Michael Birrer, MD, PhD

## **ACTIVE STUDIES**

#### **Active Breast Trials:**

- NSABP-B-47: A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer.
- 2. **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.
- 3. **NSABP B-52**: A Randomized Phase III Trial Evaluating Pathologic Complete Response Rates in Patients with Hormone Receptor-Positive, HER2-Positive, Large Operable and Locally Advanced Breast Cancer Treated with Neoadjuvant Therapy of Docetaxel, Carboplatin, Trastuzumab, and Pertuzumab (TCHP) With or Without Estrogen Deprivation.
- 4. **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. *(pre-activated on 6/3/14)*
- 5. RTOG 1119: Phase IIR WBRT + Concurrent Lapatinib for Brain Metastasis from HER2-Positive Breast Cancer

6. **RTOG 1005**: A Phase III Trial Of Accelerated Whole Breast Irradiation With Hypofractionation Plus Concurrent Boost Versus Standard Whole Breast Irradiation Plus Sequential Boost For Early-Stage Breast Cancer (closing to enrollment on 6/20/14; has met target accrual)

#### Breast trials in the OEWG Pipeline:

- 1. **BR001**: Dose escalation Hypofract. SBRT in Breast, Lung and Prostate Oligometastasis (CTEP/CIRB approved; preactivation planned for June 30, 2014)
- 2. **BR002**: PhIIR/III SBRT+Surgical ablation, Breast Oligometastasis; CTEP Approved; protocol is in development (preactivation planned for October 2014)

#### Breast trials under development by Breast committee:

- 1. Adjuvant TNBC proposal of paclitaxel with or without carboplatin
- 2. A Phase II trial assessing the accuracy of predicting pathologic response using breast imaging and image guided-tumor bed biopsies in patients with operable breast cancer with complete clinical tumor response after neoadjuvant chemotherapy. (A draft of the concept is out to the team for review). RSC sent to CPAC, CPAC sent back to Breast committee.

#### **Active Brain trials**

- 1. **RTOG 1205**: Phase IIR of Concurrent Bevacizumab/Re-Irradiation vs. Bevacizumab in Recurrent GBM (Accrual 37/178)
- 2. **RTOG 1122**: Phase IIR Double-Blinded Placebo-Controlled Study of Bevacizumab +/- AMG 386 in Recurrent GBM (Accrual 116/127)
- 3. RTOG 1114: Phase IIR of Chemo +/- WBRT for Primary CNS Lymphoma. (Accrual 50/89)
- 4. **RTOG 0834**: Phase III Concurrent and Adjuvant Temozolomide Chemotherapy in Non-1p/19q Deleted Anaplastic Glioma (EORTC-CATNON) (Accrual 552/748; NRG 66/100)

#### Brain trials in the OEWG Pipeline:

- BN001: Ph IIR Hypofx Dose-Escalated Photon IMRT or Proton RT vs. Conventional Photon RT with Concomitant/Adjuvant Temozolomide in Newly Diagnosed GBM (CTEP Approved; protocol is in development (preactivation planned for August 2014)
- 2. **BN002:** Ph I Ipilimumab, Nivolumab, and the Combination in Newly Diagnosed GBM (CTEP Approved; protocol is in development (pre-activation planned for November 2014)

#### Brain Trials approved by CPAC: numbers one and two priority by CPAC

- 1. Phase II/III Veliparib for Unmethylated Newly Diagnosed GBM. (A draft of the concept is out to the team for review; seeking corporate support). CPAC priority 1
- 2. Phase IIR Valcyte for Newly Diagnosed GBM. (A draft of the concept is out to the team for review; seeking corporate support). CPAC priority 2

#### Brain trials under development by Brain committee

- **1.** Phase II R Placebo-Controlled WBRT with Concurrent Veliparib for Brain Metastasis from HER2-Negative Breast Cancer (A draft of the concept is out to the team for review; seeking corporate support).
- 2. Phase III Meningioma. (A draft of the concept is out to the team for review).

#### **Active GI Trials**

1. RTOG 1010: A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of Her2-Overexpressing Esophageal Adenocarcinoma. (Accrual 137/160)

- 2. RTOG 1201 A Phase II Randomized Trial of High Versus Standard Intensity Local or Systemic Therapy for Unresectable Pancreatic Cancer. (Accrual 0/288; redesign in progress; obtained drug & corporate support )
- 3. 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 (Accrual 338/950)
- **4. RTOG1112** Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy followed by Sorafenib in Hepatocellular Carcinoma (Accrual 19/368)

#### GI Trials in the OEWG Pipeline:

1. **GI001**: Randomized Phase III Study of Focal Radiation Therapy for Unresectable Localized Intrahepatic Cholangiocarcinoma (CTEP/CIRB approved; pre-activation planned for July 2014)

#### **Active GU Trials**

- 1. **RTOG 1115**: Phase III 3D-CRT/IMRT, GnRH agonist vs. 3D-CRT/IMRT, GnRH, TAK-700 for high risk prostate cancer (Accrual 205/900)
- 2. RTOG 0924: Phase III intermediate to high risk prostate cancer + or Pelvic RT. (Accrual 598/2580)
- 3. **RTOG 0815**: Phase III low to intermediate risk localized prostate cancer short term ADT (androgen deprivation therapy) vs no ADT. (Accrual 1191/1520)
- 4. **RTOG 0534** Phase III Salvage RT for biochemically recurrent prostate cancer after radical prostatectomy: whole pelvis vs. prostate bed +/- short term ADT (Accrual 1600/1764)
- 5. RTOG 0926 Phase II T1 Bladder cancer RT and Cisplatin. (Accrual 19/37)

#### GU Trials in the OEWG Pipeline:

- 1. **GU001:** Phase IIR/III postoperative adjuvant IMRT following cystectomy for pT3-T4 urothelial bladder cancer (CTEP Approved; protocol is in development (pre-activation planned for September 2014)
- Phase IIR/III conventional vs. hypofrax RT (IGRT/IMRT) post-prostatectomy (Approved by CTEP but placed "on-hold" for >1000 pt study. Note that our original design was smaller, but the trial size was increased after GU Steering review. (Per CTEP new OEWG clock will be provided if hold is lifted)

#### **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. **(Accrual 34/110)**
- 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. (Accrual 399/700)
- 3. **RTOG 1008:** Concurrent radiation-chemotherapy for high-grade salivary gland cancer (Phase II-R) First phase IIR trial in salivary gland cancers, which are rare tumors. (Accrual 95/120)
- 4. **RTOG 1016:** IMRT/IGRT plus cisplatin or cetuximab for HPV+ Oropharyngeal Carcinoma (Phase III) Near complete accrual First definitive study to address the role of cetuximab vs. cisplatin in HPV+ oropharyngeal carcinoma. (Accrual 904/1000)
- 5. **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. (**Accrual Phase IIR 49/200**)
- 6. **RTOG 1221:** Transoral Endoscopic H&N Surgery + RT+/-Chemo vs. CRT for HPV(-) Oropharyngeal carcinoma (Phase IIR) First study to address the role of transoral resection (either with Robot or laser) in patients with HPV negative OPC. (Accrual 0/144)

7. **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 needs adjuvant chemotherapy and the type of adjuvant chemotherapy that they would need -Activated 4/2014

#### H&N trials in the OEWG pipeline

- 1. **HN002:** A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Opharyngeal Cancer (CTEP Approved; protocol is in development (pre-activation planned for September 2014)
- 2. **CTEP LOI 9760/RTOG 1329:** Phase IIR of Cisplatin+/- Nivolumab (PD1 antibody) or Cetuximab +/- Nivolumab in intermediate/high risk HNSCC *Response to mass solicitation for Nivolumab; CTEP did not approve will remove from this list for next CPAC meeting*

#### H&N Trials in development by H&N committee:

1. **RTOG 1309**: A Randomized Phase II Study of Re-Irradiation plus Cisplatin and Paclitaxel With or Without Nimorazole for Inoperable or High Risk Resected Recurrent or Second Primary Head and Neck Carcinoma Arising in a Previously Irradiated Field. *The concept is under development, pending successful negotiation for drug and support from the company that makes nimorazole.* 

#### **Active Lung Trials**

- 1. RTOG 1306: Randomized Phase II Study of Individualized Combined Modality Therapy for NSCLC (Accrual 9/234)
- 2. **RTOG 1308**: Phase III Randomized Trial Comparing Overall Survival After Photon vs. Proton Chemoradiotherapy for Inoperable Stage II-III NSCLC (activated February 2014; Accrual 1/560)
- 3. **RTOG 1106/ACRON 6697**: Randomized Phase II Trial of Individualized Adaptive Radiotherapy Using During-Treatment FDG-PET/CT in Locally Advanced NSCLC (Accrual 37/150)
- 4. **RTOG 0937**: Randomized Phase II Study Comparing Prophylactic PCI Alone to Prophylactic PCI and Consolidative Extra-Cranial RT for SCLC (Accrual 79/154)
- 5. **RTOG 0839**: Randomized Phase II Study of Pre-Operative Chemoradiotherapy +/- Panitumumab Followed by Consolidation Chemotherapy in Potentially Operable NSCLC (Accrual 52/97)

#### Lung trials in the OEWG Pipeline:

- LU001:\_Randomized Phase II Trial of Concurrent Chemoradiotherapy +/- Metformin in NSCLC (CTEP/CIRB approved; pre-activation planned for August 2014)
- 2. **CTEP LOI 9660**/RTOG 1328: Randomized, Double Blinded Phase II Trial with Safety Lead In of Cisplatin and Etoposide Plus Thoracic RT Followed by Nivolumab/Placebo for NSCLC *Response to mass solicitation for Nivolumab; CTEP put on hold our plan is to withdraw. Will remove from this list for next CPAC meeting*

#### Lung Trials approved by CPAC:

#### (Note concepts below are waiting HQ determination for NCI submission date.)

- 1. Randomized Phase IIR with maintenance chemo +/- SBRT for patients with Stage IV NSCLC (limited to 4 or fewer mets) (lyengar) **CPAC priority 5**
- 2. Local ablation (surgery or SBRT) +/- pazopanib for sarcoma with limited metastases (Wang) CPAC priority 7
- 3. LungART Phase III randomized trial of surgery +/- post op RT for resected NSCLC; EORTC trial. CPAC priority 9

#### **Active Gyn Trials**

1. GOG-0170-R A Phase II Evaluation of Dalantercept (NSC# 757172 IND# 116598) A Novel Soluble Recombinant Activin Receptor-Like Kinase 1 (ALK-1) Inhibitor Receptor-Fusion Protein, in the Treatment of Persistent

- Recurrent or Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma. **Activated: 11-05-12. Temp closure 10-2-13. Will not open to second stage of accrual.**
- 2. GOG-0186-H A Randomized Phase II Evaluation of Weekly Paclitaxel (NSC #673089) Versus Weekly Paclitaxel with Oncolytic Reovirus (REOLYSIN® NSC # 729968, BB-IND # 13370) in the Treatment of Recurrent or Persistent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer . Activated: 12-6-10. Closed 9-2-14.
- **3.** GOG-0186-K A Randomized Phase II Study of NCI Supplied Cabozantinib (NSC #761968 IND#116059) Versus Weekly Paclitaxel (NSC #673089) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer. **Activated: 11-6-12. Closed 5-5-14.**
- 4. 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.
- 5. GOG-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 (IND#110072) Activated: 12-13-10. Closed 3-16-15.
- 6. 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 06/16.
- 7. GOG-9924 A Phase I Pharmacokinetic Study of Intraperitoneal CTEP-Supplied Agent Bortezomib (PS-341, NSC 681239, IND#58443) and Carboplatin (NSC# 241240) in Patients with Persistent or Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer **Activated**: **04-05-10**. **Closed 07-12-14**.
- 8. GOG-9928 A Phase I Study of Intraperitoneal EGEN-001 (IL-12 Plasmid Formulated with PEG-PEI-Cholesterol Lipopolymer) (IND #12,484) Administered in Combination with Pegylated Liposomal-Doxorubicin (PLD, DOXIL (NSC #712227) or Lipodox (NSC #673089) in Patients with Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer Activated: 07-09-12. Closed 4-27-15.
- 9. GOG-0076-HH A Limited Access Phase I/II Trial of Paclitaxel, Cisplatin and CTEP Supplied Agent ABT-888 (Veliparib) (IND#77840NSC#737664) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix. Activated: 03-14-11. Closed 01-8-14, will not re-open for Phase II portion.
- 10. 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.
- 11. 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.**
- **12.** 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.**
- **13.** 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.**
- 14. 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.
- 15. GOG-0274/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.**
- **16.** 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.**

- 17. GOG-0229-L A Phase II Trial of AMG 386 (IND#111071), a Selective Angiopoietin 1/2 Neutralizing Peptibody, in Patients with Persistent/Recurrent Carcinoma of the Endometrium. Activated: 06-06-11. Temp closure\* 8/6/12. Closure projected 04/16.
- **18.** GOG-0229-O 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 **Activated: 09-30-13. Closure projected 04/17.**
- 19. GOG-0231-D A Phase II Evaluation of MLN8237 (NSC #747888, IND #113149) in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus. Activated: 08-06-12. Temp closure\* 6/3/13, will not open to second stage of accrual.
- 20. 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.**
- 21. 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. Activated 6-29-09. Closed 7-28-14.
- **22.** 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.**
- 23. 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. Activated: 03-17-14. Closure projected 10/17.
- 24. 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.
- 25. 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.
- 26. 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.**
- 27. 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. Temporarily closed 12-19-14. Closure projected 04/18.**
- 28. **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.**
- 29. 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).
- 30. 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) Number 1 priority in clear cell category. Activated 4-1-15.

#### Gyn trials in OEWG pipeline

- 1. **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)
- NRG-GY006 (CV1421): 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)
- 3. 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 CPAC

- 1. NRG-GY004 (OV1403): 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)
- 2. NRG-GY005 (OVM1405): An Integrated, Randomized Phase II-III Study of Olaparib and Cediranib in Recurrent Platinum-Resistant Ovarian Cancer (Second/Lee)
- 3. 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.

#### Gyn Trials grandfathered by NRG

- 1. **OVM1404**: A Randomized Phase II Study Evaluating IMGN853 in Combination with Carboplatin versus Carboplatin doublet (paclitaxel, gemcitabine, liposomal doxorubicin) in Adult Patients with Platinum Sensitive Ovarian Cancer (Kathleen N Moore)
- 2. **DTM1401**: Randomized phase II study of paclitaxel/carboplatin +/- OMF-54F28 (a receptor decoy of Wnt ligands) in patients with stage I-IV or recurrent uterine carcinosarcoma (S McMeekin)
- 3. **NRG-GY007 (OVM1310)**: Randomized Controlled Phase II parallel translational trial of ruxolitinib and LDE225, novel agents targeting the chemo-resistant tumor cell population, during front-line neo-adjuvant therapy of advanced ovarian, fallopian tube, or primary peritoneal carcinoma. (P2PT-Neo) (Burger/Landen)

#### Gyn Trials under development by Gyn Committee

- 1. **UC1403**: A randomized phase II-III study of carboplatin, paclitaxel and cediranib (multi-tyrosine kinase inhibitor) versus carboplatin and paclitaxel in measurable stage III, IVA and IVB or recurrent serous and high grade endometrioid endometrial cancer (Bender)
- 2. DTM1411: A phase II study of IMGN853 in recurrent endometrial cancer (K Moore) Await phase I data.
- 3. **DTM1415**: A randomized, placebo controlled phase II study of weekly paclitaxel plus ganetespib (Heat Shock Protein 90 Inhibitor) vs. weekly paclitaxel plus placebo in the treatment of recurrent or persistent endometrial carcinoma (V Makker)
- **4. PORTEC-4,** "A Randomized Phase III Trial Comparing Vaginal Brachytherapy (two doses schedules: 21 or 15 Gy HDR in 3 fractions) and Observation after Surgery in patients with Endometrial Carcinoma with High-Intermediate Risk Features

#### **New Gyn concepts for review**

- 1. T\$1501: Molecular Biomarkers for Cervical Cancer Prognosis. (Xiao Wei Wang)
- 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. **UC1506**: Translational Science for Uterine Carcinosarcoma Trials (Douglas Levine)
- 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. **RT1510**: Inhibition of CYP17 (17  $\alpha$ -hydroxylase/C17, 20-lyase) with abiraterone as a treatment for recurrent granulosa cell tumors of the ovary. (Stephanie Gaillard)

- **6. OV1511**: 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)
- **7. DT1512**: Phase I/II study of megestrol acetate, entinostat, and azacitidine in advanced, persistent, or recurrent endometrial carcinoma. (Carolyn McCourt)
- 8. RT1513: Theranostics in Cervical Neuroendocrine Tumors. (Sue O'Dorisio)
- 9. **TS1514**: Immuno Score Determination as Predictive Biomarkers for Clinical Outcome in GOG-0262 Population (Samir Khleif)
- 10. **RT1528**: Phase III Randomized Trial of Every-3-Week Carboplatin and Paclitaxel versus Dose-Dense Weekly Paclitaxel in Combination with Carboplatin in Patients with Stage III & IV or Recurrent Endometrial Cancer: Defining a New Backbone Chemotherapy Regimen for Advanced and Recurrent Endometrial Cancer (J. Hurteau)
- 11. **RT1529:** multicenter open-label study of romidepsin (Istodax®) in combination with carboplatin and etoposide followed by romidepsin (Istodax®) in patients with advanced small cell carcinoma of the ovary hypercalcemic type (SCCOHT) (J. Farley)
- 12. **RT1530:** A randomized phase II study of ifosfamide-carboplatin-etoposide (ICE) alternating with vincristine-doxorubicin-cyclophosphamide (VDC) vs. vinblastine, cisplatin, cyclophosphamide, bleomycin, doxorubicin, and etoposide (VPCBAE) as first-line therapy in women with small cell carcinoma of the ovary, hypercalcemic type (K. Schmeler)
- 13. **RT1531:** A randomized phase II trial of Temozolomide and Cisplatin versus Nivolumab (BMS-936558) in patients with completely resected mucosal melanoma (D. Vicus)
- 14. **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 (A. Shoushtari)
- 15. **UC1533**: Randomized Phase III trial of Single Agent Doxorubicin versus Gemcitabine plus Docetaxel as First-Line Therapy for Metastatic Uterine Leiomyosarcoma
- 16. **UC1534**: Phase II Study of Pembrolizumab (MK-3475) in patients with microsatellite unstable (MSI), persistent or recurrent endometrial cancer (A. Nickels-Fader)

**QUESTIONS / DISCUSSION** 

#### **Uterine Corpus Committee Agenda**

Date: Friday, July 17, 2015

Start and End time: 3:00 pm - 5:00 pm (Session I)

Date: Saturday, July 18, 2015

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 GOG 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 the GOG

#### Workshop Agenda

A. Introduction (Miller)

#### B. Review of Closed Studies

- GOG0086P: A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab(NSC #704865, IND #7921), paclitaxel/carboplatin/temsirolimus (NSC #683864, IND#61010), and ixabepilone (NSC#710428 IND # 59699)/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (Carol Aghajanian) presented at ASCO.
- 2. **GOG0130F** A Phase II evaluation of Ixabepilone (IND #59699, NSC #710428) in the treatment of recurrent or persistent carcinosarcoma of the uterus **(Carolyn K McCourt)**
- GOG0184: Tumor Volume-Directed Pelvic Plus or Minus Para-Aortic Irradiation followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for advanced Endometrial Carcinoma (Howard D Homesley) (Gynecol Oncol 112: 543-52, 2009; Gynecol Oncol 119: 538-42, 2010): To be reviewed by Mutch.
- 4. GOG0188: Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens) [Gynecol Oncol 120(2): 185-8, 2011]: To be reviewed by Leslie
- 5. GOG0209: A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer (David Scott Miller) [Gynecol Oncol 125: 771-3, 2012] final event recently, data mature and under analysis
- 6. GOG0210: A Molecular Staging study of Endometrial Carcinoma (William T Creasman): To be reviewed by Mutch see committee report
- 7. GOG0211: 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]: To be reviewed by Leslie.

- 8. <u>GOG0229I</u>: 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. <u>GOG0229J</u>: A Phase II Evaluation of Cediranib (RECENTIN; AZD2171) in the Treatment of Recurrent or Persistent Endometrial Cancer (David P Bender): **To be reviewed by Leslie**
- **10.** <u>GOG0229K</u> A Phase II Evaluation of BIBF 1120 (IND#113086) in the Treatment of Recurrent or Persistent Endometrial Carcinoma (Don S Dizon): **To be reviewed by Miller** [Gynecol Oncol 133(s1)55]
- 11. GOG0229L 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): To be reviewed by Miller
- 12. GOG0233: Utility Of Pre-Op Fdg-Pet/Ct Scanning Prior To Primary Chemoradiation Therapy To Detect Retroperitoneal Lymph Node Metastasis In Patients W/Locoregionally Advanced Ca Of The Cervix (Ib2, Ila ¡Ý4 Cm, IIB-Iva) Or Endometrium (Gr 3 Endometrioid Endometrial Ca; Serous Papillary Ca, Clear Cell Ca, Or Ca (Any Grade); And Grade 1 Or 2 Endometrioid Endometrial Ca With Cervical Stromal Involvement Overt In Clinical Exam Or Confirmed By Endocervical Curettage) (Michael Gold) [J Clin Oncol 29(15s) (ASCO #5035): 340s, 2011; J Clin Oncol 29(15s) (ASCO #5042): 342s, 2011]: To be reviewed by Miller
- **13.** <u>GOG0242</u>: Second Curettage: First-Line Management for Patients with Persistent Low-Risk Gestational Trophoblastic Disease [GTN] (Raymond Osborne) **To be reviewed by Schink**
- **14.** GOG0248: Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy plus Temsirolimus in Women with Advanced or Recurrent Endometrial Cancer (Gini Fleming) [Gynecol Oncol 132:585, 2014]: **To be reviewed by Leslie**
- **15.** <u>GOG0249</u>: Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 Cycles Paclitaxel/Carboplatin Chemotherapy (McMeekin) manuscript in preparation
- 16. GOG0250:A Randomized Phase III Evaluation of Docetaxel (NSC #628503) and Gemcitabine (NSC #613327) Plus G-CSF with Bevacizumab (NSC #704865, IND #7921) versus Docetaxel (NSC #628503) and Gemcitabine (NSC #613327) Plus G-CSF with Placebo in the Treatment of Recurrent or Advanced Leiomyosarcoma of the Uterus. NCI-Supplied Agent Bevacizumab (NSC #704865, IND #7921) (Hensley) [Gynecol Oncol 133: 3 (SGO #2), 2014]
- 17. <u>GOG0258</u>: 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): To be reviewed by Miller
- **18.** <u>GOG0261</u>: 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.** <u>GOG 9920</u>: A Phase I Study of IV Plus Peritoneal (IP) Chemotherapy in Endometrial Cancer Patients at High Risk for Peritoneal Failure (D. Scott McMeekin) **To be reviewed by Miller**

#### C. Review of Active Studies

1. Endometrial Protocols:

a. <u>GOG0238</u>: 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) 86/154 accrued: **To be reviewed by Schink** 

#### 2. Uterine Sarcoma Protocols:

a. <u>GOG0277</u> 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)

#### 3. Gestational Trophoblastic Disease Protocols

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

#### D. Review of Approved Concepts/Protocols

- GOG-8038: Epidemiologic Risk Factors and Endometrial Cancer Survival (Louise A Brinton): To be reviewed by Mutch
- 2. <u>UC0905:</u> Risk Stratification Models in Endometrial Cancer: Clinico-pathologic Analysis of GOG-0210 (Mutch)
- GOG-8032 (UC1102): A clinico-pathologic analysis of high grade uterine carcinomas (grade 3 endometrioid, serous, and clear cell carcinoma) and carcinosarcomas from GOG #210 (Richard Zaino): To be reviewed by Mutch
- 4. **GOG-8040 (UC1107):** An Investigation of the Heterogeneity of Gene Expression, Epidemiology and Behavior of Endometrial Carcinoma. (Louise Brinton, Richard Zaino) **To be reviewed by Mutch**
- 5. **UC1205**: A Randomized Phase III trial of 3 versus 6 cycles of chemotherapy, with or without vaginal cuff brachytherapy, in patients with high-risk Stage I-II endometrial cancer (D. Scott McMeekin) tabled, pending 249 replacement
- 6. **UC1214:** A three-arm Phase III randomized trial of chemotherapy alone (carboplatin-paclitaxel x 6 cycles) versus chemotherapy (carboplatin-paclitaxel x 3 cycles) with vaginal brachytherapy versus vaginal brachytherapy alone for patients with intermediate risk endometrial cancer **(Powell)**
- UC1304 Evaluation of Biomarkers, Imaging, Sentinel Lymph Node(s), Quality of Life and Cost Effectiveness Study of Tailoring Adjuvant Therapy in Endometrial Cancer (STATEC) GCIG lymphadenectomy trial (Nicola Spirtos/Nadeem R Abu-Rustum)
- 8. **GOG3007 (UC1305)**: A Randomized Phase II Trial of the Combination of Everolimus and Letrozole or Hormonal Therapy (Tamoxifen/Megestrol Acetate) in Women with Advanced, Persistent, or Recurrent Endometrial Carcinoma. (0248R) (**Brian M. Slomovitz**)
- 9. **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)**
- 10. **DTM1415:** A Randomized, Placebo Controlled Phase II Study of Weekly Paclitaxel plus Ganetespib (Heat Shock Protein 90 Inhibitor) vs. Weekly Paclitaxel plus placebo in the Treatment of Recurrent or Persistent Endometrial Carcinoma and Uterine Carcinosarcoma (Vicky Makker):

- 11. **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. **To be reviewed by Miller**
- 12. **DT1439 (UC1403):** A randomized phase II-III study of carboplatin, paclitaxel and cediranib (multi-tyrosine kinase inhibitor) versus carboplatin and paclitaxel in measurable stage III, IVA and IVB or recurrent serous and high grade endometrioid endometrial cancer (Bender): **To be reviewed by Miller**
- 13. 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): To be reviewed by Leslie
- 14. **PORTEC-4**, "A Randomized Phase III Trial Comparing Vaginal Brachytherapy (two doses schedules: 21 or 15 Gy HDR in 3 fractions) and Observation after Surgery in patients with Endometrial Carcinoma with High-Intermediate Risk Features (Viswanathan)

#### E. New Proposed studies

- 1. **UC1506:** 258R translational component (Levine): **To be reviewed by Mutch**
- UC1528: Phase III Randomized Trial of Every-3-Week Carboplatin and Paclitaxel versus Dose-Dense
  Weekly Paclitaxel in Combination with Carboplatin in Patients with Stage III & IV or Recurrent Endometrial
  Cancer: Defining a New Backbone Chemotherapy Regimen for Advanced and Recurrent Endometrial
  Cancer (J. Hurteau)
- 3. **UC1533**: Randomized Phase III trial of Single Agent Doxorubicin versus Gemcitabine plus Docetaxel as First-Line Therapy for Metastatic Uterine Leiomyosarcoma (M. Huang)
- 4. **UC1534**: Phase II Study of Pembrolizumab (MK-3475) in patients with microsatellite unstable (MSI), persistent or recurrent endometrial cancer (A. Nickels-Fader)

#### F. Studies from Other Committees for Review:

- 1. **GOG-8041 CEM1304**: The Relationship of Racial Genetic Admixture and its Associated Protein Biomarkers with Endometrial Cancer Outcomes (Rodney P Rocconi) **Supported 7/13: To be reviewed by Mutch**
- 2. **ORC1301**: Comparative effectiveness of surgical approaches to the treatment of endometrial cancer (Laura J Havrilesky) Supported 1/13: **To be reviewed by von Gruenigen. Rolled into UC 1304.**
- 3. **DT1512:** Phase I/II study of megestrol acetate, entinostat, and azacitidine in advanced, persistent, or recurrent endometrial carcinoma (McCourt):
- 4. **DT1527:** A phase II Evaluation of Weekly Paclitaxel in the Treatment of Recurrent or Persistent Endometrial Carcinoma (C. Gunderson)

#### G. New Business

1. Report from Subcommittee on Gestational Trophoblastic Disease (Schink
--

Action:

2. Report from GOG0210 Scientific Advisory Board (Mutch)

Action:

3. Report from RTOG (Klopp) Open Trial RTOG 1203 (TIME-C)

# NON-CME SESSIONS



Advancing Research. Improving Lives. $^{\text{\tiny TM}}$ 

#### **GOG Operations Committee**

Date: Saturday, July 18, 2015
Start and End 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 February 2015 (Copeland)

#### II. <u>Committee on Experimental Medicine</u>

#### **CEM** (Birrer)

Active Studies: 8005, 8006, 8007, 8008, 8009, 8010, 8011, 8013, 8014, 8015, 8016, 8017,

 $8020,\,8022,\,8023,\,8025,\,8028,\,8031,\,8033$ 

Closed Studies: 136, 220, 221, 235, 271

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

#### III. <u>Developmental Therapeutics Committee</u>

#### **DTM** (Aghajanian)

Active Studies: 2290, 265, 286B

Temporarily Closed:

*Closed Studies*: 76HH, 86P, 127W, 130F, 131H, 170J, 170P, 170Q, 170R, 186G, 186H, 186I, 186J, 186K, 227G, 229G, 229H, 229J, 229K, 229L, 229N, 230D, 231D, 255, 260, 280

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

#### Phase I Sub-Committee (Schilder)

Active Studies: 9923, 9929

Closed Studies: 9920, 9924, 9926, 9927, 9928

#### A. Terminations

B. Amendments

C. Other Business

#### IV. <u>Cancer Prevention and Control Committee</u> (Alberts/Walker)

Active Studies: 225, 237

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

A. Terminations

B. Amendments: GOG-0225 (attached)

C. Other Business

#### V. <u>Health Outcomes Research Committee</u> (Wenzel)

Active Studies: 213, 249, 258, 278

Closed Studies: 147, 184, 199, 209, 212, 218, 222, 240, 252, 259, 262, 267, 9902

A. Terminations

B. Amendments

C. Other Business

#### VI. <u>Committee on Cancer of the Uterine Corpus</u> (Miller/Randall)

Active Studies: 238, 275, 277

Closed Studies: 184, 188, 209, 210, 242, 248, 249, 250, 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, 279

Endorsed: 724 (RTOG-0724)

Closed Studies: 219, 222, 233, 240, 8906

- A. Terminations
- B. Amendments:
  - a. GOG-0270 to allow for IMRT to applied in treatment for patients with micrometastases in their sentinel node
  - b. GOG-0278 revise Section 3.14 to allow for PET imaging
- C. Other Business

## VIII. <u>Committee on Cancer of the Ovary</u> (Bookman/DiSilvestro)

Active Studies: 213

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

A. TerminationsB. AmendmentsC. Other Business

#### IX. Rare Tumor Committee (Gershenson)

Active Studies: 264, 281 Temporarily Closed: 283

Endorsed Protocols: E2607

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

A. TerminationsB. AmendmentsC. Other Business

#### X. Other New Business



# AGENDA NCORP PI & ADMINISTRATORS MEETING SATURDAY, JULY 18, 2015 8:00 – 10:00 AM DENVER, CO

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. Cancer Care Delivery Research Group	J. Lipscomb, PhD; David Cohn, MD
8:50 a.m.	IV. Cancer Prevention and Control Committee	L. Kachnic, MD; D. Alberts, MD
9:20 a.m.	VII. Polyp Surveillance Concept	R. Schoen, MD
9:35 a.m.	VIII. Q&A – Open discussion of NRG Oncolog	ду



#### NRG-CC003 Kickoff Meeting Friday, July 17, 2015 8:00-9:00am

# NRG-CC003: Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippocampal Avoidance (HA) for Small Cell Lung Cancer."

#### **Agenda**

Welcome and Introductions – Erica Field, MPH, MHA; NRG Project Administrator

Background - Minesh Mehta, MD; CC003 Co-Principal Investigator

Protocol Overview – Vinai Gondi, MD; CC003 Co-Principal Investigator

Credentialing and Central Review - Vinai Gondi, MD; CC003 Co-Principal Investigator

Cognitive Testing – Vinai Gondi, MD; CC003 Co-Principal Investigator

Correlative Imaging Plans – Joseph Bovi, MD CC003 Imaging Co-Chair

Comparative Effectiveness Plans -- Andre Konski, MD, MBA, CC003 Comparative Effectiveness Co-Chair

# NRG RADIOMICS/BIOINFORMATICS WORKING GROUP CENTER OF INNOVATION IN RADIATION ONCOLOGY (CIRO)

#### **AGENDA**

Friday, July 17, 2015 7:00am – 8:00am

Co-Chairs: Robert Jeraj, PhD and Ying Xiao, PhD

<u>Mission:</u> To facilitate the development and to develop personalized predictive models for radiation therapy guidance from specific characteristics of patients and treatments with integrated clinical trial databases, bridging clinical science, physics, biology, information technology and mathematics.

7:00 – 7:05	Welcome / Introduction Ying Xiao
7:05 – 7:15	Ancillary project review committee Mitch Machtay
7:15 – 7:30	NIH data commons Vik Bhadrasain/Jacek Capala
7:30 – 7:45	IROC IT workflow Ying Xiao
7:45 – 8:00	Other Business
8:00 a.m.	Adjournment



Advancing Research. Improving Lives.™



## NRG Oncology wishes to acknowledge the following exhibitors:

AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO)
CANCER TRIALS SUPPORT UNIT (CTSU)
CARIS LIFE SCIENCES
ECOG-ACRIN CANCER RESEARCH GROUP
FUJIREBIO DIAGNOSTICS, INC.
HELOMICS CORPORATION
LACLEDE, INC.
NCI CIRB
NOVOCURE
THE OSLER INSTITUTE
OXIGENE, INC.
PATHGROUP
TAIHO ONCOLOGY, INC

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

Plaza Exhibit Foyer, Plaza Building – Concourse Level

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 17, 2015 - 7:00 am - 5:00 pm Saturday, July 18, 2015 - 7:00 am - 5:00 pm

Some Exhibits may be open during the Welcome Reception from 6 – 8 pm on Friday, July 17<sup>th</sup>.

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.

#### **Cancer Trials Support Unit**

The Cancer Trials Support Unit (CTSU) is a service of the National Cancer Institute (NCI) designed to facilitate access to NCI-funded clinical trials for qualified clinical sites and to support the management and conduct of those clinical trials. Under guidance of the NCI, the CTSU provides centralized services to support the following goals and objectives:

- Facilitate investigator and research staff participation in selected NCI multi-center programs and their clinical trials.
- •Increase investigator and patient awareness and enrollment to cancer clinical trials.
- Provide standardized, integrated, and comprehensive support services to selected NCI multi-center programs.
- •Identify best practices and streamline or eliminate redundant processes and procedures.
- •Improve operational efficiency, enhance productivity and deliver products offering measurable business value to selected NCI multi-center programs.

#### **Caris Life Sciences**

Caris Life Sciences® is a leading biosciences company focused on fulfilling the promise of precision medicine through quality and innovation. Caris Molecular Intelligence®, one of the industry's leading tumor profiling services with more than 70,000 patients profiled, provides oncologists with the most potentially 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. The company is also developing Carisome® TOP™ technology, a revolutionary and proprietary blood-based profiling platform for diagnosis, prognosis, and theranosis of cancer

and other complex diseases. Headquartered in Irving, Texas, Caris Life Sciences offers services throughout Europe, the U.S., Australia and other international markets. To learn more, please visit <a href="https://www.CarisLifeSciences.com">www.CarisLifeSciences.com</a>.

#### **ECOG-ACRIN**

Learning Objective: Nurses/CRAs/Research Staff will be able to identify areas and apply strategies for the enrollment of patients onto a master screening protocol with multiple subprotocol treatment arms, that will require interdepartmental coordination and an organizational plan for successful trial participation.

#### Fujirebio Diagnostics, Inc.

Fujirebio Diagnostics, Inc. is a world leader in the production of in vitro diagnostics and the gold standard manufacturer of cancer biomarker assays worldwide. Available Biomarkers include: CA 125II™, CA19-9™, CA15-3®, CYFRA21-1™, HE4 and ROMA® (Risk of Malignancy Algorithm). ROMA® combines CA125 + HE4 to compute likelihood of ovarian malignancy.

#### **Helomics Corporation**

Helomics Corp. is a comprehensive personalized healthcare company, bringing the next generation of diagnostics to the oncology field. Our novel Live-Cell, molecular + cellular markers are designed to support treatment decisions by providing vital information based on the specific biological processes of each individuals' cancer.

#### Laclede, Inc.

Laclede Inc. is the manufacturer of Luvena Vaginal Health products specializing in vaginal dryness. Luvena products containing natural enzymes, are free from harmful ingredients such as parabens, glycerin & chlor-

## EXHIBITOR OBJECTIVES Continued

hexidine. The product line includes Luvena vaginal moisturizer, Luvena wipes, Luvena enhanced moisturizer & Luvena feminine wash.

#### **NCI CIRB**

The NCI's Central IRB (CIRB) is a free service for institutions participating in the NCI's National Clinical Trial Network, Experimental Therapeutics Clinical Trial Network, the NCI Community Oncology Research Program, and the Consortia for Early Phase Prevention Trials. Comprised of national experts in oncology, the four NCI CIRBs focus their reviews on adult late-phase trials, adult early-phase trials, pediatric trials, and cancer control and prevention trials.

#### **Novocure**

Novocure is a private Jersey Isle oncology company pioneering a novel therapy for solid tumors called TTFields. 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 company, please visit <a href="https://www.novocure.com">www.novocure.com</a>.

#### The Osler Institute

The Osler Institute prides itself with Annual Medical Board Review Courses that are designed for the purpose to help those pass their board exams as well as obtain CME credits or just refresh and update their knowledge base. The upcoming courses are specifically designed to enhance the residents with the knowledge that they need to prepare for the board certification exams. And in conjunction a three-day Mock Oral Exam Course is also available for those preparing for the Oral Exam. As a result, it provides a good review for your in-service exams as well as board qualification.

#### **PathGroup**

PathGroup is a premiere provider of anatomic, clinical and molecular pathology services. With more than 75 board-certified pathologists representing every subspecialty, a comprehensive test menu and industry leading technology, PathGroup is the practice partner of choice. PathGroup's approach is focused on driving better patient outcomes through innovative high-quality, high-service diagnostics, from clinical to genomic.

#### Taiho Oncology, Inc.

Taiho Oncology, Inc., a division of Taiho Pharmaceutical Co., Ltd. and Otsuka Holdings Co., Ltd., has built a world class clinical development organization that works urgently to develop innovative cancer treatments and is in the process of building commercial businesses in the USA and Europe. Taiho has an oral oncology pipeline consisting of both novel antimetabolic agents and selectively targeted agents. Advanced technology, dedicated researchers, and state of the art facilities are helping us to define the way the world treats cancer. It's our work; it's our passion; it's our legacy.

For more information about Taiho Oncology, please visit: <a href="www.taihooncology.com">www.taihooncology.com</a>



NRG Oncology would like to recognize and thank the commercial sponsors for Independent Medical Educational Support associated with this Semiannual Meeting.

Abbvie
Astellas Oncology
Amgen Oncology
AstraZeneca
Celgene
Lilly
Gilead
Genentech

# Save the Date!

# **NRG Oncology Semiannual Meeting**

January 21 - 24, 2016
Atlanta Marriott Marquis
Atlanta, GA



# **NRG Oncology Semiannual Meeting**

July 16 - 19, 2015 Sheraton Hotel, Denver, Colorado

# Save the Date for these upcoming NRG Oncology Semiannual Meetings!

January 21 - 24, 2016 Marriott Marquis Hotel Atlanta, GA

July 14 - 17, 2016 Sheraton Dallas Downtown Dallas, TX

January/February 2017 TBD

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

Visit the NRG Oncology Website at www.nrgoncology.org for daily updates.



NRG Oncology Four Penn Center 1600 John F. Kennedy Blvd., Suite 1020 Philadelphia, PA 19103 Website - www.nrgoncology.org

Advancing Research. Improving Lives.