

Protocol Support Committee Workshop

Clinical Trials Nurses/Clinical Research Associates Workshop- Educational Session

Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC

Session I: February 6, 2014 2:00 – 6:00 pm

Workshop Agenda

Topic/Time	Speakers
NRG Oncology Overview- 2:00 – 2:20	Tate Thigpen MD, NRG Vice Chair, NRG Chair Concepts Prioritization Advisory Committee
The New National Clinical Trial Networks' QA Service The Imaging and radiation Oncology Core Cooperative (IROC) 2:20 – 3:20	Jessica Lowenstein MS, DABR and Denise Manfredi BS, RT (T)
NCI CIRB Overview - 3:20 – 4:00	Laura Covington MS, CIP
Break – 4:00 – 4:15	
Migration to Medidata RAVE- 4:15 – 5:15	William Elgie MBA
Molecular Testing and Targeted Therapy- 5:15 – 6:00	Anthony M Magliocco MD, FRCPC, FCAP
QUESTIONS/DISCUSSION EVALUATION	

Learning Objectives

Following this activity, participants will be better able to:

- Discuss the structure and overall administrative function of the NRG Oncology Group
- Understand the CIRB model
- Define the requirements for enrolling in and using the CIRB
- Define the process for the review of local context considerations for sites using the CIRB's
- Understand the mission of IROC
- Learn about the structure, leadership and services provided by IROC
- Understand the levels of credentialing in the NCTN
- Discuss TRIAD (what and why) and learn how to use it
- Understand RAVE user role assignments
- Learn how to navigate the RAVE system
- Understand the multiple functions in RAVE
- Learn about the data entry system in RAVE
- Identify the learning opportunities available for the Medidata RAVE system
- Define molecular testing
- Explain how molecular testing can lead to new targeted therapeutic options
- Give examples of targeted therapeutic agents and their usage

Protocol Support Committee Workshop

Clinical Trial Nurse and Clinical Research Associate Workshop (Joint session 30 minutes, separate session 30 min)

Chair: Susan Nolte, PhD, CRNP
Co-Chairs: Nancy Knudsen RN, BSN, Terry Thomas MS, CCRC
CTN Co Chairs: Cindy Licavoli RN, BSN, MA, Bonnie Sauder, Nancy Fusco RN, BSN
CRA Co Chairs: Sally Brown RN, BSN, MGA, Joyce Neading, Sharon Stockman

Friday, February 7, 2014

9:00 – 10:00

Workshop Agenda

9:00 – 9:30 Protocol Support Committee (CTN and CRA)

1. Introduction of PSC, CTN and CRA subcommittee co-chairs and members
2. Outline of PSC structure and function
3. Description of CTN and CRA subcommittees
4. Future PSC initiatives - Quality Control, Education & Training, Mentorship, and Quality Control Working Groups
5. Working Group Membership

9:30 – 10:00 am – Clinical Trial Nurse (CTN) Subcommittee Agenda

1. PSC Co-Chairs discuss the structure and function of the NRG Protocol Support Committee (PSC)-30 min
 - a. Co-Chairs: Susan Nolte, PhD, CRNP (GOG Legacy); Nancy Knudsen, RN, BSN (NSABP Legacy); Terry Thomas, MS, CCRC (RTOG Legacy)
2. Introductions of Co-Chairs and Legacy appointed Committee Members-5 min
 - a. Co-Chairs: Nancy Fusco, RN, BSN, CCRP (GOG Legacy); Bonnie Sauder, RN, BS, CCRP, OCN (RTOG Legacy); Cindy Licavoli, RN, BSN, MA (NSABP Legacy)
3. Review CTN Subcommittee Responsibilities and Expectations of Committee Members-20 min
4. PSC Workshop-Breakout Sessions-5 min
 - a. Discuss opportunities and appointment process for committee members to working groups

9:30 – 10:00 am – Clinical Research Associates (CRA) Subcommittee Agenda

1. Introductions of CRA Subcommittee Co-Chairs
2. Introductions of CRA Subcommittee Members
3. Review CRA Subcommittee Charge and Function
4. Explain PSC Workshop Breakout Sessions (Working Groups)
5. Discuss future direction and tasks to be undertaken by CRA Subcommittee
6. Question / Answer

QUESTIONS/DISCUSSION
EVALUATION

Learning Objectives

- Discuss the structure and function of the NRG Protocol Support Committee
- Identify future PSC initiatives and implementation process

Protocol Support Committee Workshop

Clinical Trials Nurses/Clinical Research Associates Breakout Session

Friday, February 7, 2014

3:00 – 5:00

Workshop Agenda

Breakout session will include 4 thirty minute sessions devoted to PSC Working Groups.

1. Protocol Review
2. Education & Training
3. Quality Control
4. Mentorship

QUESTIONS/DISCUSSION
EVALUATION

Learning Objectives

Following this breakout session participants will:

- Describe the role and function of each working group
- Identify specific working group of interest for future participation

GOG Nursing Workshop – review of GOG Concepts/Protocols

Saturday, February 8, 2014

8:00 – 9:00

Workshop Agenda

Review of proposed GOG concepts and protocols:

CEM1401: Germline mutations in DNA repair genes and immune response in GOG-3003 (Elizabeth M Swisher)

CPC 1206: Pilot study of salpingectomy to reduce risk of high=grade serous carcinoma among premenopausal BRCA1/2 carriers

CPC1401: Randomized, double-blind placebo-controlled trial of Cannabidiol for the prevention of dose-dense Paclitaxel-induced peripheral neuropathy in women undergoing therapy for Platinum resistant, recurrent women's cancer : breast, cervix, endometrial and ovary: AN NRG Phase IIb trial.

CVM1401: Randomized Phase III Trial of Maintenance ADXS11-00 Immunotherapy in High Risk Cervical Cancer following chemotherapy and radiation (Monk)

CVM1402: Best supportive care with or without chemotherapy for extremely poor prognosis patients with recurrent cervical cancer (Leath)

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 (DS McMeekin)

DTM1402 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 (A Santin)

DTM1403 Randomized Phase II, Placebo-Controlled Trial of Nivolumab Monotherapy with Cross-Over and Run-In Randomized Phase II Trial of Nivolumab with and without Ipilimumab for Advanced Cervical Carcinoma Following Failure of Anti-VEGF Therapy (K Tewari)

DTM1404 A Phase II trial of Nivolumab in recurrent or persistent endometrial cancer (P Konstantinopoulos)

DTM1405 A Randomized Phase II study of paclitaxel/carboplatin +/- LY2157299 (a small molecule inhibitor selective for the kinase domain of type 1 TGF- β receptor) in patients with stage I-IV or recurrent Uterine Carcinosarcoma (DS McMeekin)

DTM1406 A phase II evaluation of nivolumab (NSC748726) in the treatment of recurrent or persistent carcinosarcoma of the uterus (GOG 230 series) (M Hensley)

DTM1407 A phase II study of the efficacy of poly (ADP-ribose) polymerase (PARP) -1 and -2 inhibitor rucaparib in the treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with and without germline or somatic mutations in genes affecting homologous recombination (B Norquist)

DTM1408 The Feasibility and Efficacy of adding the novel PD-1 monoclonal antibody Nivolumab to combination therapy with Bevacizumab, Cisplatin and Paclitaxel Among Women with Stage IVB and Recurrent Carcinoma of the Cervix (K Moore)

DTM1409 Randomized phase II study of single agent nivolumab versus combination nivolumab and ipilimumab for recurrent ovarian cancer (186 series) (U Matulonis)

DTM1410 Randomized Phase II of: 1) Nivolumab Monotherapy; 2) Nivolumab with Ipilimumab; and 3) Nivolumab with VTX-2337 for Recurrent Ovarian Cancer (170 series) (B Monk)

DTM1411 A Phase II Study of IMGN853 in Recurrent Endometrial Cancer (K Moore)

DTM1412 Phase 2 Study with a Safety lead-in of Nivolumab with Concurrent Chemoradiation for the Primary Treatment of Patients with Locally Advanced Cervical Cancer (K Moore)

DTM1413 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)

DTM1414 Randomized, stratified phase II trial of nivolumab and ipilimumab in patients with previously treated recurrent ovarian cancer (R Coleman)

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 (V Makker)

DTM1416 A phase II evaluation of nivolumab (NSC748726) in the treatment of recurrent or persistent endometrial carcinoma (GOG 229 series) (V Makker)

DTM1417 Nivolumab in newly diagnosed locally advanced cervical cancer (R Schilder)

OVM1401: Measurements of adiposity as clinical biomarkers for response to first-line bevacizumab-based chemotherapy in epithelial ovarian cancer: an ancillary data study of GOG 218 (Kathleen N Moore)

OVM1402: A seamless phase I/randomized phase II trial of BMN673, an orally-available, high potency PARP inhibitor, with and without cisplatin or carboplatin plus gemcitabine for the treatment of platinum-sensitive recurrence of ovarian, fallopian tube, or primary peritoneal carcinoma in select patients with high grade serous, endometrioid, undifferentiated, and carcinosarcoma histologies (GOG 213-R) (Leslie M Randall)

OVM1403: 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)

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)

RTM1401: A Randomized Phase II crossover study of Pimasartib plus SAR245409 versus SAR245409 following paclitaxel carboplatin induction chemotherapy in women with advanced stage clear cell carcinoma of the ovary, fallopian tube, or peritoneum (Farley)

RTM1402: A PHASE II EVALUATION of MAINTENANCE TREATMENT WITH AZD5363 IN STAGE III-IV CLEAR CELL CARCINOMA OF THE OVARY AS FIRST-LINE THERAPY IN THE TREATMENT (Mayu Yunokawa)

RTM1403: Randomized Phase II study of BKM120 (Buparlisib) or placebo as maintenance treatment for stage III/IV ovarian clear cell cancer (Danielle L Vicus)

UC1401: 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 (Jean A Hurteau)

UC1402: A phase II evaluation of Afatinib, an irreversible human epidermal growth factor receptor 2 (Her2/neu) tyrosine kinase inhibitor, in patients with persistent or recurrent HER2-positive endometrial carcinoma (Alessandro D Santin)

ADS1401: Surgery plus adjuvant radiotherapy versus surgery alone for stage II endometrial cancer

ADS1402: Laparoscopy versus laparotomy for comprehensive surgical staging of obese patients with uterine cancer: disease recurrence, survival, adverse events, and quality of life: a Gynecologic Oncology Group ancillary data study (Frederick R Ueland)

ADS1403: Patterns of Recurrence after Upfront Treatment with Bevacizumab in Women with Epithelial Ovarian Cancer (Elizabeth Lokich)

ADS1404: The Impact of Body Mass Index on Radiotherapy Protocol Deviations and Disease Recurrence in Women with Advanced Endometrial Cancer (Russell J Schilder)

ADS1405: The effect of cardiac glycosides on platinum response in ovarian cancer (Bobbie J Rimel)

ADS1406: Does the administration of bevacizumab influence the prognostic value of the primary platinum free interval? (Ashley R Stuckey)

ADS1407: The development of risk predictive models in locally advanced cervical cancer treated with chemoradiation (Jyoti S Mayadev)

ADS1408: The Effects of Capping Cisplatin in Patients with Cervical Cancer Who Are Treated With Curative Intent Chemoradiation (Floor J Backes)

ADS1409: Thrombocytosis as a prognostic factor in endometrial cancer (Joshua P Kesterson)

ADS1410: Minority Participation in Gynecologic Oncology Group (GOG) Studies: Insight into gynecologic oncology racial disparities. (R. Rocconi)

ADS1411: Risk factors for genitourinary and gastrointestinal adverse effects in a Phase III randomized trial of bevacizumab in treatment of recurrent, persistent, or advanced cervical cancer: a Gynecologic Oncology Group study (Lyndsay J Willmott)

ADS1412: Is there a difference in outcome between IV or intraperitoneal chemotherapy (IP) in stage III clear cell and mucinous carcinoma of the ovary (Robert L DeBernardo)

ADS1413: Advanced, recurrent, or persistent adenocarcinoma and adenosquamous carcinomas compared to squamous cell carcinoma of the uterine cervix in Gynecologic Oncology Group trials (Leigh G Seamon)

ADS1414: Weight change during chemotherapy with and without anti-VEGF therapy as a surrogate marker for survival in advanced stage epithelial ovarian cancer: A Gynecologic Oncology Group ancillary data study (Krishnansu S Tewari)

ADS1415: Treatment of Low Grade Ovarian Carcinoma: Does Combination Intravenous/Intraperitoneal improve patients outcomes when compared to standard Intravenous Chemotherapy (Jamie L Lesnock)

ADS1416: Is preoperative disease burden in patients with advanced stage epithelial ovarian cancer predictive of platinum resistance even in the patients who are considered to be optimal and microscopically resected (Thomas C Krivak)

ADS1417: Clinico-pathologic characteristics of patients with complete response treated on GOG protocol 240 (Robert E Bristow)

ADS1418 Predicting Overall Survival with Early Tumor Response: a more efficient Surrogate Endpoint in Ovarian Phase II Studies? (B Monk)

QUESTIONS/DISCUSSION
EVALUATION

Learning Objectives

- Discuss and make recommendations relating to GOG clinical studies from nursing perspective

Protocol Support Committee

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

Saturday, February 8, 2014

9:00 – 11:00

Workshop Agenda

1. Summary of PSC functions
2. Summary of CTN and CRA Subcommittees structure and function
3. Summary of Working Group structure, process for membership, and function

QUESTIONS/DISCUSSION
EVALUATION