81st GOG Semi-Annual Meeting

Gynecologic Oncology Group

July 15 - 18, 2010
Sheraton Hotel Boston
Boston, Massachusetts

Final Agenda Program

www.gog.org
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### Disclosure Information

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

Dear Colleagues,

On behalf of the Gynecologic Oncology Group (GOG), it is a pleasure to welcome you to attend the 81st GOG Semi-Annual Meeting in Boston, Massachusetts scheduled for July 15 - 18, 2010.

Our Group hosts two semi-annual meetings each year, with the goal to inform our participants about the most current state of clinical and basic research in gynecologic cancer. Our meeting’s purpose is to provide an exchange of information, establish criteria for evaluation of protocol compliance and review. Our workshops are convened by expert committees that address specific areas of inquiry.

This semi-annual meeting offers a full agenda that includes: an enlightening symposium, general and scientific sessions, educational workshops and committee meetings. A few highlighted events include the Summer Symposium entitled, “New Frontiers in Cervical and Corpus Cancers,” with noted Oncologists and Scientists serving as speakers and moderators. The speakers will focus their presentations on intermediate risk as well as advanced stage and recurrent cervical and corpus cancers. The faculty will also explore new approaches in the management of corpus sarcomas and a question and answer period will conclude the symposium with audience participation.

This meeting’s scientific session is entitled, “The GOG Specimen Bank and Translational Research.” These sessions will address clinical questions among the various disciplines involved in the treatment of gynecologic cancers, with the objectives of illustrating the importance of banked specimens in supporting hypothesis-driven translational research in the cooperative setting. You will find an overview of the meeting program and these highlighted events in the attached preliminary agenda. As you plan your schedule, please make a note to include these informative events in your itinerary.

You will find an overview of the meeting program and these highlighted events in the enclosed meeting agenda. As you plan your schedule, please make a note to include these informative events in your itinerary.

I want to thank you for your past support and commitment to our meetings.

Welcome to the GOG meeting in Boston, Massachusetts!

Sincerely,

Philip J. DiSaia, M.D.
GOG Mission

The Gynecologic Oncology Group (GOG) is a non-profit organization (national) with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of Gynecologic malignancies. The Group (gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, nurses, statisticians, basic scientists, quality of life experts, data managers and administrative personnel) is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. Continuous evaluation of our processes is utilized in order to constantly improve the quality of patient care.

GOG CME Mission

The purpose of the GOG CME program is to provide and promote an infrastructure dedicated to enhancing the knowledge base of GOG 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.

Educational Objectives

For the educational objectives, we list the following:

1. To inform the participants at the semi-annual meetings about the most current state of clinical and basic research in gynecologic oncology, but not exclusively as it relates to the clinical field by providing:
   ♦ To provide progress reports of recent completed GOG studies, cancer center activities, and work of other groups and efforts of individual investigators.
   ♦ To provide status updates of current trials, whether group or non-group trial in origin.
   ♦ To provide projections of future clinical programs to diagnose treat and/or prevent cancer.

2. To provide participants with peer review critique of progress (or lack of it) with the objective of self-improvement:
   ♦ To identify strengths and weaknesses of individual investigators and their institutions.
   ♦ To counsel investigators in corrective procedures to obtain better research and better-reported data.
   ♦ To set up detailed programs for quality and productivity from a basic foundation of education of the investigator in research objectives and procedures.

3. To provide an opportunity to learn research administration and financial management in a cooperative group setting.

4. To provide a lecture type forum of reports from experts from many fields that may relate to better research of patient management.
COMMITTEE/WORKSHOP INFORMATION

The Gynecologic Oncology Group now requires that you register for each Committee Meeting that you plan to attend. Please select all committee meetings on the enclosed registration form. The GOG has applied for Continuing Medical Education Credits (CMEs) for most of the meetings listed.

Important CME Information for Committee Members

CMEs can only be obtained by signing PINK sheets as you enter each session. They will be located at each entrance door. Sign-In Sheets cannot be signed after the session has finished. Committee members will not receive CMEs if they have only signed the committee sign-in sheets. They also must sign the CME sign-in sheets (pink).

Semi-Annual Committee/Workshops CME Credits

All PINK sign-in sheets must be signed, and an overall meeting evaluation must be filled out for each committee/workshop that you attended in order to receive CME credits. Sign-in sheets (PINK) are located outside each meeting room. Please visit the IT room to complete the evaluations online. Go to: http://www.gog.org/cme/evaluations.html. Please click CME evaluation

Please Note: To complete the online evaluation Form at any location other than the IT Room you must have Adobe 7.0 Professional.

Committee/workshop CME certificates WILL NOT be handed out onsite or in your meeting packets. You will receive your CME certificate approximately five weeks after the meeting upon completion of an evaluation form and verification of signatures on sign-in sheets.

Symposium/Scientific Session/CME Credits

A meeting evaluation form MUST be filled out in order to receive your CME credits. Evaluations will be available in the meeting room or at the CME evaluation desk. If you are registering onsite you can go to the CME registration desk to receive your certificate. All certificates for the Symposium / Scientific Session will be validated after the completion of the course.

For questions concerning CMEs please go to the CME desk at the GOG Semi-Annual Meeting or e-mail jreese@gog.org.

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the American College of Surgeons and the Gynecologic Oncology Group. The American College Surgeons is accredited by the ACCME to provide continuing medical education for physicians.

AMA PRA Category 1 Credits™

The American College of Surgeons designates this educational activity for a maximum of 23.5 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

American College of Surgeons
Division of Education
Listing of approved CME credits:

**AMA PRA Category 1 Credits**

Accredited by the American College of Surgeons *For Boston, MA - July 15 - 18, 2010*

<table>
<thead>
<tr>
<th>Session/Workshop</th>
<th>Thursday</th>
<th>Total Credits</th>
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<tbody>
<tr>
<td>Scientific Session, “The GOG Specimen Bank &amp; Translational Research”</td>
<td>2</td>
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<tr>
<td>Rare Tumor Workshop</td>
<td>1.5</td>
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<td>Vaccine Workshop</td>
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<th>Friday</th>
<th>Saturday</th>
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<td>Cervix Workshop</td>
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<tr>
<td>Corpus Workshop</td>
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<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Cancer Prevention &amp; Control Workshop</td>
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<tr>
<td>CPC-0199</td>
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<td>2</td>
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<tr>
<td>New Data Management Workshop (Orientation)</td>
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<td>Data Management Workshop</td>
<td>3</td>
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<tr>
<td>Developmental Therapeutics Workshop</td>
<td>2</td>
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<tr>
<td>Developmental Therapeutics and Phase I Workshops</td>
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<td>2</td>
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<tr>
<td>Experimental Medicine</td>
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</tr>
<tr>
<td>Experimental Medicine and CPC Workshops</td>
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<td>Gynecologic Oncology Workshop</td>
<td>2</td>
<td></td>
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<tr>
<td>Medical Oncology Workshop</td>
<td>1.5</td>
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<td>1.5</td>
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<tr>
<td>Ovarian Workshop</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Pathology Workshop</td>
<td>8</td>
<td>6</td>
<td>16</td>
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<td>Phase I Workshop</td>
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<tr>
<td>Protocol Development Workshop</td>
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<tr>
<td>Quality of Life Workshops</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Quality of Life and Cancer Prevention and Control Workshops</td>
<td>1</td>
<td></td>
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</tr>
<tr>
<td>Radiation Oncology Workshop</td>
<td>4</td>
<td></td>
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</tr>
<tr>
<td>Nursing <em>(Attendance Certificates Only)</em></td>
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</table>

All non-MD’s will receive a certificate of attendance.

The American College of Surgeons is accredited by the ACCME to provide continuing medical education (CME) for physicians.

The American College of Surgeons is accredited by the ACCME to provide continuing medical education (AMA PRA category 1 credits) for physicians. Physicians should only claim credit commensurate with the extent of their participation in the activity.
### Thursday, July 15, 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>7 am - 6 pm</td>
<td>Registration/Information Desk</td>
<td>Grand Ballroom Pre-Function Foyer/2nd Fl</td>
</tr>
<tr>
<td>7 am - 8 am</td>
<td>GOG Symposium/Meeting/Continental Breakfast</td>
<td>Grand Ballroom Pre-Function Foyer/2nd Fl</td>
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<tr>
<td>8 am - 3:15 pm</td>
<td>GOG Symposium <em>New Frontiers in Cervical and Corpus Cancers</em></td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
</tr>
<tr>
<td>8 am</td>
<td>Pathology Review Setup</td>
<td>Commonweath/3rd Fl</td>
</tr>
<tr>
<td>8 am - 5 pm</td>
<td>GYN Review <em>Closed Session</em></td>
<td>Boardroom/3rd Fl</td>
</tr>
<tr>
<td>9 am - 11 am</td>
<td>Chairman’s Working Group <em>Closed Session</em></td>
<td>Fairfax B/3rd Fl</td>
</tr>
<tr>
<td>11:30 am - 1 pm</td>
<td>Ancillary Data Subcommittee</td>
<td>Independence Ballroom West/2nd Fl</td>
</tr>
<tr>
<td>12:30 pm - 1:15 pm</td>
<td>GOG Symposium Lunch</td>
<td>Constitution Ballroom/2nd Fl</td>
</tr>
<tr>
<td>12 pm - 3 pm</td>
<td>Audit Training Workshop</td>
<td>Independence Ballroom East/2nd Fl</td>
</tr>
<tr>
<td>12 pm - 5 pm</td>
<td>Radiation Oncology Review <em>Closed Session</em></td>
<td>Gardner/3rd Fl</td>
</tr>
<tr>
<td>12 pm - 6 pm</td>
<td>Information Technology Resource Room</td>
<td>Fairfax A/3rd Fl</td>
</tr>
<tr>
<td>1 pm</td>
<td>Exhibits Setup</td>
<td>Grand Ballroom Pre-Function Foyer/2nd Fl</td>
</tr>
<tr>
<td>1:30 pm - 3:30 pm</td>
<td>Membership Committee <em>Closed Session</em></td>
<td>Fairfax B/3rd Fl</td>
</tr>
<tr>
<td>2 pm - 4 pm</td>
<td>Vaccine Subcommittee</td>
<td>Hampton/3rd Fl</td>
</tr>
<tr>
<td>3 pm - 4 pm</td>
<td>Publications Subcommittee</td>
<td>Exeter/3rd Fl</td>
</tr>
<tr>
<td>3 pm - 4:30 pm</td>
<td>Regulatory Question and Answer Session</td>
<td>Independence Ballroom East/2nd Fl</td>
</tr>
<tr>
<td>4 pm - 5:30 pm</td>
<td>Rare Tumor Workshop</td>
<td>Independence Ballroom West/2nd Fl</td>
</tr>
<tr>
<td>4 pm - 6 pm</td>
<td>Board of Directors <em>Closed Session</em></td>
<td>Fairfax B/3rd Fl</td>
</tr>
<tr>
<td>4 pm - 6 pm</td>
<td>Scientific Session <em>The GOG Specimen Bank and Translational Research</em></td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
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<tr>
<td>6:30 pm - 9 pm</td>
<td>CEM Meeting <em>Closed Session</em></td>
<td>Hampton/3rd Fl</td>
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<tr>
<td>5 pm - 6 pm</td>
<td>CER Working Group <em>Closed session</em></td>
<td>Conference Rm/3rd Fl</td>
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<tr>
<td>6:30 pm - 8:30 pm</td>
<td>GOG Welcome Reception</td>
<td>Constitution Ballroom/2nd Fl</td>
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### Friday, July 16, 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>7 am - 5 pm</td>
<td>Registration/Information Desk</td>
<td>Grand Ballroom Pre-Function Foyer/2nd Fl</td>
</tr>
<tr>
<td>7 am - 8 am</td>
<td>PDC Executive Session <em>Closed Session</em></td>
<td>Fairfax B/3rd Fl</td>
</tr>
<tr>
<td>7 am - 8 am</td>
<td>210 Subcommittee</td>
<td>Berkeley/3rd Fl</td>
</tr>
<tr>
<td>7 am - 10 am</td>
<td>Nursing Workshop</td>
<td>Back Bay Ballroom B/2nd Fl</td>
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<tr>
<td>7 am - 5 pm</td>
<td>Exhibits</td>
<td>Grand Ballroom Pre-Function Foyer/2nd Fl</td>
</tr>
<tr>
<td>7 am - 6 pm</td>
<td>Information Technology Resource Center</td>
<td>Fairfax A/3rd Fl</td>
</tr>
<tr>
<td>8 am - 9 am</td>
<td>Welcome to New Data Managers Workshop</td>
<td>Independence Ballroom/2nd Fl</td>
</tr>
<tr>
<td>8 am - 10 am</td>
<td>Ovarian Workshop</td>
<td>Back Bay Ballroom CD/2nd Fl</td>
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<tr>
<td>8 am - 10 am</td>
<td>Cervix Workshop</td>
<td>Back Bay Ballroom A/2nd Fl</td>
</tr>
<tr>
<td>8 am - 10 am</td>
<td>Corpus Workshop</td>
<td>Republic Ballroom/ 2nd Fl</td>
</tr>
<tr>
<td>9 am - 10 am</td>
<td>Data Management Workshop</td>
<td>Independence Ballroom/2nd Fl</td>
</tr>
<tr>
<td>8 am - 5 pm</td>
<td>GYN Review <em>Closed Session</em></td>
<td>Boardroom/3rd Fl</td>
</tr>
<tr>
<td>8 am - 5 pm</td>
<td>Pathology Workshop &amp; Review</td>
<td>Commonwealth/3rd Fl</td>
</tr>
<tr>
<td>10:30 am - 12 noon</td>
<td>Opening General Session</td>
<td>Grand Ballroom/ Liberty/ 2nd Fl</td>
</tr>
<tr>
<td>12 pm - 1 pm</td>
<td>IT Working Group for TR and Banking <em>Closed Session</em></td>
<td>Berkeley/3rd Fl</td>
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<tr>
<td>12:30 pm - 2 pm</td>
<td>Cancer Prevention &amp; Control Workshop</td>
<td>Back Bay Ballroom CD/2nd Fl</td>
</tr>
<tr>
<td>1 pm - 2:30 pm</td>
<td>Phase I Workshop</td>
<td>Republic Ballroom/ 2nd Fl</td>
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<tr>
<td>1 pm - 2:30 pm</td>
<td>Tissue Utilization Subcommittee</td>
<td>Back Bay Ballroom B/2nd Fl</td>
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<tr>
<td>1 pm - 5 pm</td>
<td>Radiation Oncology Workshop and Review</td>
<td>Gardner/3rd Fl</td>
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<td>1:30 pm - 3:30 pm</td>
<td>GYN Oncology Workshop</td>
<td>Back Bay Ballroom A/2nd Fl</td>
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<tr>
<td>1:30 pm - 3:30 pm</td>
<td>Data Management Workshop</td>
<td>Independence Ballroom/2nd Fl</td>
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</table>
**Friday, July 16, 2010**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>2 pm - 3 pm</td>
<td>Quality of Life and Cancer Prevention &amp; Control <strong>Combined Sessions</strong></td>
<td>Back Bay Ballroom CD/2nd Fl</td>
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<tr>
<td>2:30 pm - 4:30 pm</td>
<td>Developmental Therapeutics Workshop</td>
<td>Republic Ballroom/ 2nd Fl</td>
</tr>
<tr>
<td>3 pm - 5 pm</td>
<td>Quality of Life Workshop</td>
<td>Back Bay Ballroom B/2nd Fl</td>
</tr>
<tr>
<td>3 pm - 5 pm</td>
<td>Data Safety Monitoring Board (DSMB) (Formally DMC) <strong>Closed Session</strong></td>
<td>Hampton/3rd Fl</td>
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<tr>
<td>3:30 pm - 4:30 pm</td>
<td>Workshop on Experimental Medicine &amp; Cancer Prevention &amp; Control</td>
<td>Back Bay Ballroom CD/2nd Fl</td>
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<tr>
<td>4 pm - 5:30 pm</td>
<td>Committee on Information Technology</td>
<td>Back Bay Ballroom A/2nd Fl</td>
</tr>
<tr>
<td>4 pm - 6 pm</td>
<td>KGOG Meeting <strong>Closed Session</strong></td>
<td>Berkeley/3rd FL</td>
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<tr>
<td>4:30 pm - 5:30 pm</td>
<td>CCOP Meeting <strong>Closed Session</strong></td>
<td>Fairfax B/3rd Fl</td>
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<tr>
<td>4:30 pm - 6:30 pm</td>
<td>Workshop on Experimental Medicine</td>
<td>Back Bay Ballroom CD/2nd Fl</td>
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<tr>
<td>4:30 pm - 6 pm</td>
<td>Medical Oncology Workshop <em>(Meeting will begin immediately following the completion of the Dev. Therapeutics Workshop.)</em></td>
<td>Republic Ballroom/ 2nd Fl</td>
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<tr>
<td>5:30 pm - 6:30 pm</td>
<td>Pls Meeting – <strong>Closed Session</strong></td>
<td>Independence Ballroom/2nd Fl</td>
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**Saturday, July 17, 2010**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>7 am - 5 pm</td>
<td>Registration/Information Desk</td>
<td>Grand Ballroom Pre-Function Foyer 2nd Fl</td>
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<tr>
<td>7 am - 8 am</td>
<td>Elderly Working Group Meeting <strong>Closed Session</strong></td>
<td>Fairfax B/3rd Fl</td>
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<tr>
<td>7 am - 4 pm</td>
<td>Information Technology Resource Center</td>
<td>Fairfax A/3rd Fl</td>
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<tr>
<td>7 am - 8:30 am</td>
<td>Trophoblastic Subcommittee</td>
<td>Exeter/3rd Fl</td>
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<tr>
<td>7 am - 1 pm</td>
<td>Exhibits</td>
<td>Grand Ballroom Pre-Function Foyer 2nd Fl</td>
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<tr>
<td>7:30 am - 9 am</td>
<td>Safety Review Committee (SRC) <strong>Closed Session</strong></td>
<td>Hampton/3rd Fl</td>
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<td>7:30 am - 9:30 am</td>
<td>Workshop on Experimental Medicine</td>
<td>Republic Ballroom/ 2nd Fl</td>
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<tr>
<td>8 am - 10 am</td>
<td>Developmental Therapeutics &amp; Phase I Workshop</td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
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<td>8 am - 10 am</td>
<td>CPC 0199 Meeting</td>
<td>Back Bay Ballroom D/2nd Fl</td>
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<td>8 am - 5 pm</td>
<td>Pathology Workshop &amp; Review</td>
<td>Commonwealth/3rd Fl</td>
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<td>8 am - 5 pm</td>
<td>GYN Review <strong>Closed Session</strong></td>
<td>Boardroom/3rd Fl</td>
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<td>9 am - 10 am</td>
<td>Data Safety Monitoring Board (DSMB) <strong>Closed Session</strong></td>
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<td>9 am - 10 am</td>
<td>Membership Committee <strong>Closed Session</strong></td>
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<td>10 am - 12 pm</td>
<td>CPC Subcommittee Meetings <strong>Closed Session</strong></td>
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<tr>
<td>10 am - 12 pm</td>
<td>Cervix Workshop</td>
<td>Independence Ballroom/2nd Fl</td>
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<td>10 am - 12 pm</td>
<td>Ovarian Workshop</td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
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<td>10 am - 12 pm</td>
<td>Corpus Workshop</td>
<td>Republic Ballroom/ 2nd Fl</td>
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<td>10 am - 12 pm</td>
<td>GOG HRC <strong>Closed Session</strong></td>
<td>Hampton/3rd Fl</td>
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<tr>
<td>12 pm - 1 pm</td>
<td>SRC/DSMB/HRC/Pat Adv. Lunch <strong>Closed to committees only</strong></td>
<td>Berkeley/3rd FL</td>
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<tr>
<td>12: pm - 1 pm</td>
<td>Quality of Life Workshop</td>
<td>Independence Ballroom/2nd Fl</td>
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<tr>
<td>1 pm - 1:15 pm</td>
<td>Board of Directors <strong>Closed Session</strong></td>
<td>Hampton/3rd Fl</td>
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<tr>
<td>1 pm - 7 pm</td>
<td>Protocol Development Workshop</td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
</tr>
<tr>
<td>7 pm</td>
<td>ICT Dinner <strong>Closed (By Invitation Only)</strong></td>
<td>Hampton/3rd Fl</td>
</tr>
<tr>
<td>7 pm - 9 pm</td>
<td>Patient Advocate Meeting <strong>Closed Session</strong></td>
<td>Berkeley/3rd Fl</td>
</tr>
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**Sunday, July 18, 2010**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 am - 9 am</td>
<td>Operations Committee <strong>Open Session</strong></td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
</tr>
<tr>
<td>9 am - 10 am</td>
<td>Operations Committee <strong>Closed Session</strong></td>
<td>Grand Ballroom/ Liberty/2nd Fl</td>
</tr>
<tr>
<td>7 am</td>
<td>GYN Review <strong>Closed session</strong></td>
<td>Fairfax B/3rd Fl</td>
</tr>
</tbody>
</table>

*Closed Sessions are for committee members only*
Information Technology Resource Center

GOG Semi-Annual Meeting
Boston, MA
July 16-18, 2010

Sheraton Hotel
Fairfax A
Third Floor

Open
Thurs. Jul 15: 12-6pm
Fri. Jul 16: 7am-6pm
Sat. Jul 17: 7am-3pm

GOG Statistical & Data Center
Roswell Park Cancer Institute
Elm & Carlton Streets
Buffalo, NY 14263

Phone: 716-845-5702
Fax: 716-845-8393
http://www.gog.org

The Resource Center will feature:

Assistance will be available for any IT-related issues, specifically the following GOG Web applications:

- SDC Electronic Data Entry System (SEDES)
- Patient Registration
- GOG User Account Management (GUAM)
- Data Review
- Web-based T Form application
- GOG Web Menu/Member Access websites

Access to:

- The Internet
- Email
- Fax Machines
- Printers

To email from the Resource Center, make sure you have access to Web-based email such as Yahoo Mail, Hotmail, 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 can contact support@gogstats.org at the SDC prior to the meeting for more information.

Wireless Network Interface Cards (NICs) will be available on a first come-first served basis. If your laptop has a wireless NIC, bring it to the Resource Center to have it configured for the duration of the GOG Business Meeting.
Symposium - Sessions - Special Events
GOG 2010 SUMMER SYMPOSIUM

“New Frontiers in Cervical and Corpus Cancers”
Thursday, July 15, 2010
8:00 am - 3:15 pm

PROGRAM DESCRIPTION

The July 2010 Gynecologic Oncology Group educational symposium is entitled “New Frontiers in Cervical and Corpus Cancers”, with noted oncologists and scientists serving as speakers and moderators. The targeted audiences are members and non-members of the GOG research teams to include: Gynecologic Oncologists, Medical Oncologists and other MDs engaged in gynecologic oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, and other interested Allied Health professionals. The speakers will focus their presentations on intermediate risk as well as advanced stage and recurrent cervical and corpus cancers. The faculty will also explore new approaches in the management of corpus sarcomas, and a question and answer period will conclude the symposium with audience participation.

LEARNING OBJECTIVES

- Become familiar with new FIGO staging criteria and develop new management strategies for intermediate risk cervical and corpus cancers.
- Identify ways to optimize chemo radiation and systemic therapies for cervical and corpus cancers. Review translational research opportunities in these cancers.
- Develop optimal surgical management strategies for corpus sarcomas. Determine role of chemotherapy and targeted agents in sarcomas.

Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the American College of Surgeons and the Gynecologic Oncology Group. The American College of Surgeons is accredited by the ACCME to provide continuing medical education for physicians.

AMA PRA Category 1 Credits™

The American College of Surgeons designates this educational activity for a maximum of 6.25 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.
<table>
<thead>
<tr>
<th>TIME</th>
<th>TOPIC</th>
<th>Speaker/Moderator</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 am</td>
<td>REGISTRATION</td>
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</tr>
<tr>
<td>8:00 am</td>
<td>WELCOME</td>
<td>Welcome: Program Chairs</td>
</tr>
<tr>
<td>8:05-9:50 am</td>
<td>SESSION I: “Revisiting intermediate risk in cervical and corpus cancers”</td>
<td>Moderator: Bradley J. Monk, M.D.</td>
</tr>
<tr>
<td>8:05-8:35 am</td>
<td>Rationale for Modifying FIGO staging system in cervical and corpus cancer</td>
<td>David Mutch, M.D. Washington University School of Medicine</td>
</tr>
<tr>
<td>8:40-9:10 am</td>
<td>Expanding the role of systemic chemotherapy in surgically managed intermediate and high-risk stage cervical cancer</td>
<td>Sang Young Ryu, M.D., PhD Korea Cancer Center Hospital</td>
</tr>
<tr>
<td>9:15-9:45 am</td>
<td>Rationale for new approaches in the management of intermediate risk epithelial corpus cancers</td>
<td>D. Scott McMeekin, M.D. University of Oklahoma</td>
</tr>
<tr>
<td>9:50 – 10:05 am</td>
<td>BREAK</td>
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<tr>
<td>10:10 am – 12:30 pm</td>
<td>SESSION II: “Moving forward in advanced stage and recurrent cervical and corpus cancers”</td>
<td>Moderator: Bradley J. Monk, M.D.</td>
</tr>
<tr>
<td>10:10-10:40 am</td>
<td>Optimizing combination chemotherapy and radiation in treating locally advanced cervical cancer</td>
<td>Kathleen N. Moore, M.D. Oklahoma University Health Science Center</td>
</tr>
<tr>
<td>10:45 - 11:15 am</td>
<td>New systemic approaches to management of corpus cancer</td>
<td>Carol Aghajanian, M.D. Memorial Sloan-Kettering Cancer Center</td>
</tr>
<tr>
<td>11:20 - 11:50 am</td>
<td>Optimizing translational research opportunities in corpus cancers</td>
<td>George L. Mutter, M.D. Harvard Medical School</td>
</tr>
<tr>
<td>11:55am – 12:25 pm</td>
<td>Optimizing translational research opportunities in cervical cancers</td>
<td>Mark H. Einstein, M.D. Montefiore Medical Center</td>
</tr>
<tr>
<td>12:30-1:15 pm</td>
<td>BREAK (LUNCH)</td>
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<tr>
<td>1:20 – 3:00 pm</td>
<td>SESSION III: “New approaches in the management of corpus sarcomas”</td>
<td>Moderator – David Scott Miller, M.D.</td>
</tr>
<tr>
<td>1:20 - 1:50 pm</td>
<td>What are the optimal surgical approaches to corpus sarcomas?</td>
<td>Nick M. Spirto, M.D. Women’s Cancer Center</td>
</tr>
<tr>
<td>1:55 - 2:25 pm</td>
<td>New systemic strategies for the management of carcinosarcomas of the uterus</td>
<td>Matthew A. Powell, M.D. Washington University School of Medicine</td>
</tr>
<tr>
<td>2:30 - 3:00 pm</td>
<td>Role of anti-angiogenesis and other targeted agents in corpus leiomyosarcomas</td>
<td>Martee L. Hensley, M.D. Memorial Sloan-Kettering Cancer Center</td>
</tr>
<tr>
<td>3:00 - 3:15 pm</td>
<td>QUESTIONS AND ANSWERS</td>
<td></td>
</tr>
</tbody>
</table>

**Program Chairs:**

David Scott Miller, MD  
Univ. of Texas Southwestern Medical Center  
Dallas, TX

Bradley J. Monk, MD  
Creighton University School of Medicine at St. Joseph’s Hospital and Medical Center  
Phoenix, Arizona
Session Description
The Gynecologic Oncology Group July 2010 Scientific Session is titled “The GOG Specimen Bank and Translational Research”, with noted Oncologists and Scientists serving as speakers. This 2-hour session addresses clinical questions among the various disciplines involved in the treatment of gynecologic cancers, with the objectives of illustrating the importance of banked specimens in supporting hypothesis-driven translational research in the cooperative setting. The targeted audiences are members and non-members of GOG research teams to include: Gynecologic Oncologists, Medical Oncologists, Pathologists and other MDs engaged in gynecologic oncology research and/or clinical practice; Oncology Nurses, Nurse-practitioners, Data Managers and other interested Allied Health professionals. The speakers will focus their presentations on the use of repository specimens for translational research and a question and answer session will conclude the session with audience participation.

Learning Objectives
◊ To illustrate the importance of banked specimens in supporting hypothesis-driven translational research in the cooperative group setting
◊ To demonstrate the wide range of studies that benefit from use of banked specimens
◊ To identify emerging technologies that extend the utility of banked specimens

Presentation Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Program Chairs</th>
<th>Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:00 pm</td>
<td>Program Chairs</td>
<td>Welcome</td>
</tr>
<tr>
<td>4:05 - 4:25 pm</td>
<td>Paul Goodfellow, PhD</td>
<td>“Endometrial Cancer Tumor Studies: challenges and successes with bed side to bench research”</td>
</tr>
<tr>
<td>4:30 - 4:50 pm</td>
<td>G. Larry Maxwell, M.D.</td>
<td>“Identification of Biomarkers Associated with Poor Prognosis in Endometrial Cancer”</td>
</tr>
<tr>
<td>4:55 - 5:15 pm</td>
<td>David Huntsman, M.D.</td>
<td>“High Resolution Genomics of Ovarian Cancer: will it provide usable knowledge or more data?”</td>
</tr>
<tr>
<td>5:20 - 5:40 pm</td>
<td>Julie Gastier-Foster, PhD</td>
<td>“Beyond the Freezers: Technologies and Services Available at the GOG Bank”</td>
</tr>
<tr>
<td>5:45 - 6:00 pm</td>
<td>Program Chairs</td>
<td>Questions &amp; Answers / Wrap Up</td>
</tr>
</tbody>
</table>
Come out and meet the GOG Regulatory Affairs Department. This is your chance to discuss any Regulatory issues that you may have, in an open forum. You choose the topics, we give the answers.

Topics could include:
- Industry Studies
- Investigator Brochures
- NCI Site Codes & Federalwide Assurances
- AdEERS Reporting & Safety Reports
- Code of Federal Regulations
- CTSU

Thursday, July 15, 2010
3:00 – 4:30 pm
Independence Ballroom East / 2nd floor
GYNECOLOGIC ONCOLOGY GROUP

TAKE ME OUT TO THE BALL GAME!

WELCOME RECEPTION

THURSDAY, JULY 15™ 2010
6:30 PM – 8:30 PM

SHERATON CONSTITUTION BALLROOM

ENTERTAINMENT INCLUDES:
RED SOX GAME BROADCASTED LIVE
FOOD & DRINKS
PRIZES
MUSIC

Precision Therapeutics
will be giving away an Apple® Ipad!
### GOG OPENING GENERAL SESSION

**July 16, 2010 - 10:30 am - 12:00 pm**

<table>
<thead>
<tr>
<th>Opening</th>
<th>Dr. Philip DiSaia</th>
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<tbody>
<tr>
<td>Welcome</td>
<td>Dr. Michael Birrer</td>
</tr>
<tr>
<td>Membership Report</td>
<td>Dr. Charles Whitney</td>
</tr>
<tr>
<td>Chair Report</td>
<td>Dr. Philip DiSaia</td>
</tr>
<tr>
<td>Presentations/Awards</td>
<td>Dr. Philip DiSaia</td>
</tr>
<tr>
<td>Nominating Committee Report</td>
<td>Dr. Parviz Hanjani</td>
</tr>
<tr>
<td>Administrative Office Report</td>
<td>Ms. Laura Hanjani</td>
</tr>
<tr>
<td>Statistical &amp; Data Center Report</td>
<td>Dr. John Blessing</td>
</tr>
<tr>
<td>GOG-08199</td>
<td>Ms. Marion Piedmonte</td>
</tr>
<tr>
<td>IT Update</td>
<td>Mr. Bill Elgie</td>
</tr>
<tr>
<td>GOG-0252</td>
<td>Dr. Joan Walker</td>
</tr>
</tbody>
</table>

#### Guest Presentation

Robert E. Bristow, MD, MBA  
SGO Annual Meeting Program Committee Chair  
Title of presentation: *SGO Meeting and Abstract Submission Announcement*

<table>
<thead>
<tr>
<th>Audit &amp; Publications Update</th>
<th>Dr. Frederick Stehman</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI/CTEP Report</td>
<td>Dr. Ted Trimble</td>
</tr>
<tr>
<td>Protocol Update &amp; Meeting Orientation</td>
<td>Dr. J. Tate Thigpen</td>
</tr>
</tbody>
</table>
Workshop - Committee Agendas
Cancer Prevention and Control Workshop
Boston, MA

Chair: David S. Alberts, MD
Co-Chair: Joan Walker, MD

Session I: July 16, 2010 12:30 -2:00 pm
Session II: July 16, 2010 2:00 - 3:00 pm (with Quality of Life)
Session III: July 16, 2010 3:30 - 4:30 pm (with Experimental Medicine)
Session IV: July 17, 2010 8:00 -10:00 am (CPC 0199 Subcommittee)

Learning Objectives

Following this activity, participants will be better able to:
• Discuss proposed and ongoing GOG clinical trials on gynecologic cancer prevention and control in each of the primary gynecologic disease sites (endometrium, ovary, cervix, and vulva)
• Discuss proposed and ongoing GOG clinical trials on gynecologic cancer prevention and control in each of the four disciplines (disparities, chemoprevention, survivorship and biomarkers and early detection)
• Discuss multi-disciplinary aspects of ongoing and proposed clinical trials in each of the primary gynecologic disease sites (endometrium, ovary, cervix, and vulva)
• Discuss promising translational research objectives and priorities for future clinical trials
• Identify and prioritize areas of unmet need in cancer prevention research in each of the primary gynecologic disease sites (endometrium, ovary, cervix, and vulva)
• Apply standards and procedures required to design, submit, and conduct a research protocol for support by the GOG

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

SESSION I - Committee on Cancer Prevention and Control
A. Review of New Study Concepts
B. Review of Open Studies
C. Review of Protocols in Development

QUESTIONS/DISCUSSION

SESSION II - Joint meeting with QOL Mini-symposium on Neurotoxicity
A. Mini-symposium objectives:
  - Understand what was presented at NCI symptom management/QOL State of Science meeting on CIPN (Chemotherapy induced peripheral neuropathy)
  - Discuss ways GOG can participate in improving the state of Science for CIPN
  - Identify the chemotherapy agents most commonly associated with CIPN.
  - Describe the medications that have shown promise as prophylaxis or treatment of CIPN in animal models or clinical trials.
  - Identify approaches to CIPN prevention or treatment incorporated into current clinical trials.
  - Understand pathophysiology of neurotoxicity
- Understand approaches to prevention and therapy of neurotoxicity
- Know the basic methods for quantifying peripheral neuropathy and understand their relationship to one another and clinical relevance.

B. Speakers:
- **Paul Hutson**, Pharm D., BCOP University of Wisconsin School of Pharmacy and Carbone Cancer Center: *Review of the NCI symptom management/QOL State of the Science meeting on CIPN*  
  
(3/9/09)
- **Steven Plaxe**, M.D., University of California, San Diego, Rebecca & John Moores UCSD Cancer Center: *Neurotoxicity*
- **David Cella**, Ph.D. Center on Outcomes Research and Education, Evanston Northwestern Healthcare Research Institute & **Helen Huang**, MS GOG Statistical & Data Center Roswell Park Cancer Institute: *Measuring neurotoxicity with three shots on goal: CTCAE, patient report, and sensorimotor testing.*

QUESTIONS/DISCUSSION

**SESSION III** - Joint meeting with CEM *Mini-symposium on GOG 210*

A. Mini-symposium objectives:
- Understand the scope of the clinical impact of uterine papillary serous carcinoma
- Understand SNCG as a prognostic biomarker
- Understand the rationale for biomarker studies in type I versus type II endometrial cancers
- Identify the racial genetic admixture association with clinicopathologic variables and survival outcomes in a well described endometrial cancer cohort.
- Compare the concordance between racial genetic admixture and self designated race categorization.
- Provide an overview of serum and tissue based approaches to development of molecular profiles predictive of outcome including risk assessment of metastasis and recurrence
- Identify opportunities for future studies using newer technologies, innovative approaches and collaborative interactions
- Provide an overview of accrual, clinical characteristics, outcomes and specimen submissions for GOG 210
- Illustrate the types of epidemiologic data collected for the GOG 210 patients
- Summarize the current endometrial cancer and uterine carcinosarcoma studies using specimens and resources from GOG 210
- Discuss strategies for leveraging GOG 210 resources and studies to stimulate, advance and facilitate additional multidisciplinary collaborations to further improve risk assessment and outcome for women with endometrial cancer or uterine carcinosarcoma

B. Speakers:
- **Wendy Brewster**, M.D., UNC Chapel Hill: *Introduction*
- **William Creasman**, M.D., Medical University of South Carolina: *Overview of GOG 210*
- **Barbara Buttin**, M.D., Northwestern University: *Role of Synuclein-γ (SNCG) in the Carcinogenesis of Uterine Papillary Serous Carcinoma*
- **Dr. Rodney Rocconi**, M.D., University of South Alabama, Mitchell Cancer Institute: *The Relationship of Racial Genetic Admixture with Endometrial Cancer Outcomes*
- **Larry Maxwell**, M.D., Walter Reed Army Medical Center: *Proteomic and genomic profiling in endometrial cancer: a review of DOD studies in collaboration with GOG*
- **Kathleen Darcy**, Ph.D., GOG Statistical & Data Center Roswell Park Cancer Institute: *GOG 210 Status: Opportunities for Multidisciplinary Collaborations to Establish New Standards of Care and improve patient outcome*

QUESTIONS/DISCUSSION

EVALUATION

20
SESSION IV (GOG 199 Subcommittee)

Protocols and Concepts for Review

Friday, July 16th, 12:30 PM-3:00 PM
Cancer Prevention and Control Committee

New Study Concepts

CPC1004: Prospective Study of Risk-Reducing Bilateral Salpingectomy (RRBS) Among Women at Increased Genetic Risk of Ovarian Cancer (GOG-199R) (Douglas A Levine)
  • **Primary Objective**: To determine the prospective incidence of ovarian cancer or primary peritoneal cancer among women who are known BRCA1/2 mutation carriers, who do not wish to undergo risk-reducing salpingo-oophorectomy (RRSO), and who have undergone RRBS and to compare the cancer rate to women who are known BRCA1/2 mutation carriers and had elected screening under GOG-199.
  • **Secondary Objective**: To assess prospectively the prevalence of clinically occult fallopian tube cancer (FTC) among women undergoing RRBS and to seek evidence of precursor lesions in the excised fallopian tubes. To determine the feasibility of RRBS is women at increased genetic risk for ovarian cancer. To determine the incidence of regret in relation to RRBS in women who would otherwise retain fertility potential.

CPC1007: Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)
CPC1008: DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)
AD51018: Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)
QLM1003: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)
UC1008: Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-Positive Endometrial Carcinoma (Jennifer F De Los Santos)
QLM1003: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

Active Studies

GOG-0207: As of 06.22.09 GOG-0207 is temporarily closed to accrual. A Randomized Double-Blind Phase II Trial of Celecoxib, a COX-2 Inhibitor, in the Treatment of Patients with Cervical Intraepithelial Neoplasia 2/3 or 3 (CIN II/III or III) (J. Rader)

GOG-0215: A Phase II Randomized Study of the Effect of Zoledronic Acid Versus Observation on Bone Mineral Density of the Lumbar Spine in Women Who Elect to Undergo Surgery that Results in Removal of Both Ovaries (D. Alberts)

GOG-0224: As of 04.27.09 GOG-0224 is temporarily closed to accrual A Randomized, Controlled Phase II Evaluation of Megestrol in Different Doses and Sequence in the Treatment of Endometrial Intraepithelial Neoplasia (EIN) from a Referred Cohort of Atypical Endometrial Hyperplasia (AEH) or EIN (M. Method)

GOG-0237: Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papillomavirus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC) (S-Y Liao).

GOG-08199 (CPC-816) - Prospective Study of Risk-Reducing Salpingo-Oophorectomy (RRSO) and Longitudinal CA-125 Screening Among Women At Increased Genetic Risk of Ovarian Cancer: Extended Follow-up of Select GOG-0199 Study Participants (M. Greene)
Protocols in Development

GOG-0247: Patient and Physician Factors Associated with Entry onto Clinical Trials and Completion of Treatment for Women With Invasive Carcinoma of the Cervix. (S. Brooks)

GOG-0244: Prospective evaluation of lower extremity lymphedema in women undergoing radical surgery for gynecologic malignancy. (R. Barakat)

CPC0812 - A Phase II Trial Utilizing Bioimpedance to Measure Lower Extremity Lymphedema associated with the Treatment of a Vulvar Cancer (J. Carlson)
This study seeks to evaluate the sensitivity of bioimpedance technology as compared to volumetric measurements to detect lower extremity lymphedema in patients who are undergoing an inguinal lymphadenectomy in the management of a vulvar cancer. Additionally it would attempt to develop an objective, standard method for detecting lymphedema for future GOG trials and monitor for preoperative, intraoperative and postoperative interventions that are associated with lower extremity lymphedema.

GOG-0257 (CPC0705): A Randomized, Double-Blind, Placebo Controlled Trial Using Acetyl-L-Carnitine (ALCAR) for the Prevention of Chemotherapy-Induced Peripheral Neuropathy in Patients with Recurrent Ovarian, Primary Peritoneal or Fallopian Tube Cancer. (D. Kushner)

GOG-0225 - Can Diet and Physical Activity Modulate Ovarian Cancer Progression Free Survival? (D. Alberts). This study is designed to increase progression-free survival among women previously treated for Stage III-IV ovarian and primary peritoneal cancer and randomly assigned to a lifestyle intervention (low fat/high fruit & vegetable (including cruciferous) diet and daily physical activity). The primary objective of this study is to determine if a lifestyle intervention will significantly increase progression free survival among women who are disease-free after successfully completing primary, and potentially consolidation/maintenance therapy for Stage III-IV ovarian or primary peritoneal cancer

CPC-0903 - Phase IV clinical study of alvimopan vs placebo for the resolution of post-operative ileus in patients undergoing laparotomy for primary ovarian cytoreduction (R. Coleman)
This study seeks to improve the rate of bowel function return (GI-2) relative to placebo in ovarian cancer patients undergoing primary debulking. (GI-2: represents the time to achieve tolerance of solid food and first bowel movement, whichever occurred last.) Secondarily to evaluate the length of hospital stay, safety and tolerance of alvimopan in this population, incidence of prolonged postoperative ileus, incidence of insertion or reinsertion of an NGT and to document the incidence of re-hospitalization for postoperative ileus

CPC-0904 (formerly CPC-0814) - Standard vs. Extended Aprepitant therapy for prevention of nausea and emesis associated with intraperitoneal chemotherapy. (S. Plaxe)
The primary objective of the planned phase III study will be to compare the frequency and severity of chemotherapy induced nausea and vomiting in women receiving intraperitoneal cisplatin or carboplatin for ovarian cancer when treated with six day vs. three day regimens of aprepitant in combination with a 5-HT3 receptor antagonist and dexamethasone. The phase III study also plans to compare the quality of life in women receiving intraperitoneal cisplatin or carboplatin for ovarian cancer when treated with six day vs. three day regimens of aprepitant in combination with a 5-HT3 receptor antagonist and dexamethasone

Open Studies
GOG-0256 (CPC 703): A Prospective Study of Cognitive Function During Chemotherapy for the Front Line Treatment of Advanced Ovarian Cancer (L.Hess)

Friday, July 16th, 2:00 PM-2:50 PM
Joint CPC/Quality of Life Committee Session
Mini-symposium on Neurotoxicity

Objectives:
- Understand what was presented at NCI symptom management/QOL State of Science meeting on CIPN (Chemotherapy induced peripheral neuropathy)
- Discuss ways GOG can participate in improving the state of Science for CIPN
- Identify the chemotherapy agents most commonly associated with CIPN.
- Describe the medications that have shown promise as prophylaxis or treatment of CIPN in animal models or clinical trials.
- Identify approaches to CIPN prevention or treatment incorporated into current clinical trials.
- Understand pathophysiology of neurotoxicity
- Understand approaches to prevention and therapy of neurotoxicity
- Know the basic methods for quantifying peripheral neuropathy and understand their relationship to one another and clinical relevance.

Speakers:
- Paul Hutson, Pharm D., BCOP University of Wisconsin School of Pharmacy and Carbone Cancer Center: *Review of the NCI symptom management/QOL State of Science meeting on CIPN (3/9/09)*

Steven Plaxe, M.D., University of California, San Diego, Rebecca & John Moores UCSD Cancer Center: *Neurotoxicity*

David Cella, Ph.D. Center on Outcomes Research and Education, Evanston Northwestern Healthcare Research Institute & Helen Huang, MS, GOG Statistical & Data Center Roswell Park Cancer Institute: *Measuring neurotoxicity with three shots on goal: CTCAE, patient report, and sensorimotor testing.*

2:50 PM-3:30 PM  Cancer Prevention and Control Committee Meeting

Review of Protocols in Development

- **CPC0616-** Randomized Study of Six vs. Three Day Regimens of Aprepitant in Combination with a 5-HT3 Receptor Antagonist and Dexamethasone for Prevention of Acute and Delayed Chemotherapy Induced Vomiting in Women with Ovarian Cancer Receiving Intraperitoneal Cisplatin (S. Plaxe)
  *This study will compare the frequency of complete control of chemotherapy induced vomiting in women receiving intraperitoneal cisplatin for ovarian cancer when treated with five day vs. three day regimens of aprepitant in combination with a 5-HT3 receptor antagonist and dexamethasone. Secondary objectives include a comparison of the quality of life in women receiving intraperitoneal cisplatin for ovarian cancer when treated with five day vs. three day regimens of aprepitant in combination with a 5-HT3 receptor antagonist and dexamethasone.*

- **CPC0412 –** Change in Mammographic Density (CMD) Among Women at High Genetic Risk of Breast and Ovarian Cancers and who Undergo Risk-Reducing Salpingo-oophorectomy (RRSO) and Ovarian Cancer Screening (L. Korde)
  *This study is designed to assess the difference in change in MD between women who undergo risk-reducing salpingo-oophorectomy (RRSO) and those who do not have risk reducing surgery. In addition to assess the relation between baseline MD and BRCA1/2 mutation status, and other established breast cancer risk factors, (eg. age, parity, age at first live birth, menopausal status, BMI, history of breast feeding). This study will also attempt to estimate the relation between baseline mammographic density and incidence of breast cancer.*

- **CPC0706 -** A New Proposed Analysis Based on GOG-199: Epidemiology of a Latent Serous Cancer Precursor in Women at Increased Genetic Risk of Ovarian Cancer (C. Crum)
  *This study is designed to identify the epidemiologic covariates that correlate with the presence of a putative precursor (p53 signatures) to pelvic serous cancer in the distal fallopian tube of high-risk women*
with (BRCA+) and without (BRCA-) BRCA1/2 mutations and to document transitions from p53 signatures to malignancy (tubal intraepithelial carcinoma) in this population.

- **GOG-0199** - Prospective Study of Risk-Reducing Salpingo-Oophorectomy and Longitudinal CA-125 Screening Among Women at Increased Genetic Risk of Ovarian Cancer (M. Greene)

**Friday, July 16th 3:30-4:30**
**Joint meeting with Committee on Experimental Medicine**
**Mini-symposium on GOG-0210**

**Objectives:**
- Understand the scope of the clinical impact of uterine papillary serous carcinoma
- Understand SNCG as a prognostic biomarker
- Understand the rationale for biomarker studies in type I versus type II endometrial cancers
- Identify the racial genetic admixture association with clinico-pathologic variables and survival outcomes in a well described endometrial cancer cohort.
- Compare the concordance between racial genetic admixture and self designated race categorization.
- Provide an overview of serum and tissue based approaches to development of molecular profiles predictive of outcome including risk assessment of metastasis and recurrence.
- Identify opportunities for future studies using newer technologies, innovative approaches and collaborative interactions.
- Provide an overview of accrual, clinical characteristics, outcomes and specimen submissions for GOG 210
- Illustrate the types of epidemiologic data collected for the GOG 210 patients
- Summarize the current endometrial cancer and uterine carcinosarcoma studies using specimens and resources from GOG 210
- Discuss strategies for leveraging GOG 210 resources and studies to stimulate, advance and facilitate additional multidisciplinary collaborations to further improve risk assessment and outcome for women with endometrial cancer or uterine carcinosarcoma

**Speakers:**
- Wendy Brewster, M.D., UNC Chapel Hill: *Introduction*
- William Creasman, M.D., Medical University of South Carolina: *Overview of GOG 210*
- Barbara Buttin, M.D., Northwestern University: *Role of Synuclein-γ (SNCG) in the Carcinogenesis of Uterine Papillary Serous Carcinoma*
- Dr. Rodney Rocconi, M.D., University of South Alabama, Mitchell Cancer Institute: *The Relationship of Racial Genetic Admixture with Endometrial Cancer Outcomes*
- Larry Maxwell, M.D., Walter Reed Army Medical Center: *Proteomic and genomic profiling in endometrial cancer: a review of DOD studies in collaboration with GOG*
- Kathleen Darcy, Ph.D., GOG Statistical & Data Center Roswell Park Cancer Institute: *GOG-0210 Status: Opportunities for Multidisciplinary Collaborations to Establish New Standards of Care and Improve Patient Outcome*
GOG-0199 Subcommittee Meeting

Ongoing 199 Spin-offs

**CPC0706:** A New Proposed Analysis Based on GOG-199: Epidemiology of a Latent Serous Cancer Precursor in Women at Increased Genetic Risk of Ovarian Cancer (C. Crum)

**CPC0711:** Predictors of CA125 Levels at Baseline in Ovarian Cancer Early Detection Studies - A Planned Pooled Analysis of Data from the GOG-199 and ROCA Screening Studies (S. Skates)

**GOG-8010** (CPC 0807): BRCA2-Related Breast Cancer Risk and Protective Alleles by Genome-Wide Association and Copy Number Analysis (M. Greene)

**CPC0816:** Extended Follow up of High Ovarian Cancer Risk cohort from GOG 0199 (M. Greene)

**CPC0817:** Proposed analysis of Data already collected under GOG0199: Surgical Pathology finding among GOG0199 Participants who Underwent Risk-Reducing Salpingo-Oophorectomy at study entry (M. Greene)

**CPC0905:** Genetic Modifiers of BRCA-Related Cancer Risk in BRCA1/BRCA2 Mutation Carriers - CIMBA 7: A GOG-199 ANCILLARY STUDY (M. Greene)

**CPC0802:** Genetic Variants in Telomerase Genes as Candidate Modifiers of BRCA Mutation-associated Breast Cancer Risk (M. Greene)

**GOG-8009** (CPC 0806): Genome-Wide Association Study (GWAS) for Modifiers of Breast Cancer Risk in BRCA1 Mutation Carriers (M. Greene)
Learning Objectives

Following this activity, participants will be better able to:

• Outline barriers and potential solutions to improve International cooperation in cervical and vulvar cancer research
• Discuss emerging and ongoing GOG clinical trials on the prevention, diagnosis, and treatment of cervical and vulvar cancers
• Discuss promising translational research objectives and priorities for future clinical trials
• Apply standards and procedures required to design, submit, and conduct a research protocol for support by the GOG

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda and Protocols and Concepts for Review

A. General
1. Introduction of current and new members, 08:00 – 08:10
   Excused Absences:
   Members rotated off:
   New Members:

2. Update on Phase I and II trials (John Farley) 08:10-08:20

3. Update on GCIG and International Collaboration (Wui-Jin Koh) 08:20-08:45

4. Cervical Cancer Task Force update (Anthony Russell) 08:45-09:00

5. Sentinel Lymph Nodes and Vulvar Cancer: Charles Levenback and Brian Slomovitz 09:00-09:30

B. Closed Studies
   1. Protocols 101, 120, 205, 222, 141, 173, 179, 204, 206, 9806; Termination of Protocols:191

C. Active Studies 9:30-10:00
1. GOG 0233/ACRON 6671 (CVM0013): Utility of Preoperative FDG-PET/CT and Ferumoxtran-10 MRI Scanning Prior to Primary Chemoradiation Therapy to Detect Retroperitoneal Lymph Node Metastasis in Patients With Locoregionally Advanced (IB2, IIA, ≥4 CM, IIB-IVA) Carcinoma of the Cervix (Michael Gold).
   a) Opened September 2007; Accrual Goal 325
   XX patients accrued to date

2. GOG 240: A randomized phase III trial of cisplatin plus paclitaxel with and without bevacizumab versus the non-platinum doublet, topotecan plus paclitaxel, with and without bevacizumab, in stage IVB, recurrent or persistent carcinoma of the cervix. (Krishnansu Tewari).
   a) Opened April 2009; Accrual Goal 450
   XX patients accrued to date

3. GOG 0724: 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; Accrual Goal 400
   XX patients accrued to date

D. Pending Activation 10:00-10:15

1. GOG 263: 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

2. Groningen International Study on Sentinel nodes in Vulvar cancer (GROINSS-V) II, An observational study (Brian Slomovitz, Charles Levenbach)
   a) Approved in Concept July 2009
   b) CTF NA
   c) GCSC NA
   d) Activation pending

E. Proposed Studies (Prior Meetings) 10:15-10:30

1. CVM0503: Phase III Study of Weekly Cisplatin +/- Cetuximab as Concurrent and Adjuvant Therapy for Patients with Cervical Carcinoma Metastatic to Para-aortic Nodes (John Farley)
2. GOG-0263 (CVM0801): Randomized Phase III Clinical Trial of Adjuvant Chemoradiation vs. Chemoradiation in Intermediate Risk, Stage I/IIA, Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Sang-Young Ryu)
3. CVM0903: (GROningen International Study on Sentinel nodes in Vulvar cancer) [GROINSS-V] II An Observational Study (Brian Slomovitz)
4. CVM1001: Non Radical Surgical Therapy for Stage IA1-IB1 (≤2cm) Cervical Cancer (A. Covens)
5. CVM1002: A Phase II Trial of Erlotinib, Weekly Cisplatin, and Radiation Therapy For the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva (Neil S. Horowitz)
6. CVM1003: A Phase II Trial of Bevacizumab, Weekly Cisplatin, and Radiation Therapy for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva (Neil S. Horowitz)
7. CVM1004: 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) (Kathleen Moore)
   a) Approved in Concept July 2009 (modified October 2009, Modified January 2010)
b) CTF discussed September 2009

c) GCSC April 20, 2010, review received April 29, Harmonization call
   May 18, GCIG discussion June 3

d) Activation pending

F. New Concepts from other committees  10:30-11:30

1. **ADS1019**: A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)

2. **DTM1014**: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

3. **DTM1015**: A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

4. **PIS1002**: Extended Field Radiation Therapy with Concomitant Paclitaxel and Cisplatin Chemotherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Women with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Cecelia H Boardman)

5. **PIS1005**: A Phase I Trial of AMG 459 and Gemcitabine in patients with Metastatic Cervical Cancer (Susana M Campos)

6. **QLM1003**: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

G. Reports from Other Committees and Groups /Discussion of Concepts to Other Committees  11:30-11:50

a) Publications Subcommittee (Monk)

b) Developmental Therapeutics and phase I (Dizon) DTM1002 Leath; DTM 0941Khleif

c) Tissue Utilization Committee (Monk)

b) Quality of Life Committee (Jhingran)

c) Ancillary Data Committee: (Edelson, Michael) ADS 1008 Plaxe

d) Committee on Experimental Medicine: (K Tewari)

e) Cancer Prevention and Control: (Trimble) CPC1002 McCourt; CPC1005 Krivak

f) Rare Tumor Committee: (Schorge)

g) Vaccine Subcommittee: (Einstein)

h) Pathology Committee: (Michael)

i) Radiation Committee: (Jacobson)

j) SPORE Committee: (C. Trimble)

k) Nursing: (Eldermire)

l) Medical Oncology: (Verschraegen)

m) Patient/Community: Tamika Felder

H. Wrap up and questions 11:50-12:00
Chair – Sharon Stockman

Friday, July 16, 2010

8:00 a.m. – 9:00 a.m.   **New Data Manager Workshop**

- Welcome
- History of GOG
- GOG Website
- Group Structure
- Clinical Trials
- Data Management Procedures
- Data Management Resources
- Translational Research
- Meeting Format

*Learning Objectives:*

1) Participants will learn the history of the GOG
2) Participants will become familiar with the GOG website, learn how to gain access, and understand its various functions
3) Participants will learn the structure of the GOG, including the various committees and their functions, membership criteria, and parent/affiliate institution relationships
4) Participants will understand the scope of Phase I, II and III clinical trials
5) Participants will have a basic understanding of the role and responsibilities of data management
6) Participants will learn what resources are available to help them perform their duties as a GOG data manager
7) Participants will understand the role of translational research in the GOG clinical trials
8) Participants will understand how the GOG meeting functions, which meetings are relevant to data managers, and how to maximize their time and learning opportunities at this meeting

**Friday, July 16, 2010**

9:00 a.m. – 10:00 a.m.   **Data Management Workshop**

- Meeting Overview
- DM1-DM2 Meeting Review
Learning Objectives:
1) Participants will understand the purpose and importance of the meeting materials and agenda
2) Participants will understand the objectives and accomplishments of the previous DM1-DM2 meetings
3) Participants will learn of helpful regulatory tools and procedures
4) Participants will learn of helpful data management tools and procedures
5) Participants will learn of helpful office organization tools and procedures
6) Participants will learn of helpful patient recruitment tools and procedures
7) Participants will be provided an opportunity to share comments, provide suggestions, and ask questions

Friday, July 16, 2010

1:30 p.m. – 3:30 p.m. Data Management Workshop
> Welcome to Boston
> Group Chair Report
> Protocol GOG-0086P
  Don Dizon, MD
> Protocol GOG-0237
  Shu-Yuan Liao, MD
> Oncology Patient Enrollment Network (OPEN)
  Lucille Patrichuk
  Jenny Hopkins
> Data Management Updates
> Statistical and Data Center Report
> Regulatory Updates
> Administrative Office Report
> Translational Research/GOG Tissue Bank
  Nilsa Ramirez, MD
> Information Technology
> Other Business

Learning Objectives:
1) Participants will understand the importance of their role in the overall function of the group
2) Participants will learn the background and rationale for
Protocol GOG-0086P, the trial design, patient eligibility, treatment regimens, and the importance of accrual to this randomized Phase II trial

3) Participants will learn the objectives of Protocol GOG-0237, the procedures required for patient enrollment, and the importance of institution participation in this Cancer Prevention and Control trial

4) Participants will understand how to enroll patients on clinical trials through OPEN and learn what protocols are currently available through this system

5) Participants will understand appropriate data reporting procedures and learn about new or revised data forms

6) Participants will learn of new information or policy changes in the Statistical and Data Center relevant to data management

7) Participants will understand appropriate regulatory approval procedures

8) Participants will learn of any new information or policy changes in the Administrative Office relevant to data management

9) Participants will understand the importance of tissue specimen quality for use in translational research and understand how to improve the quality of specimens submitted to the GOG Tissue Bank

10) Participants will learn of recent changes and new functions available on the GOG Website
AGENDA – JULY 2010
Developmental Therapeutics Workshop
(Including Vaccine Subcommittee)

Chair: Carol Aghajanian, MD
Co-Chair: Paula Fracasso, MD, PhD

Dates and Times of Meetings:

<table>
<thead>
<tr>
<th>Subcommittee</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Subcommittee</td>
<td>THU 15-Jul-2010</td>
<td>2:00 PM – 4:00 PM</td>
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<tr>
<td>Developmental Therapeutics</td>
<td>FRI 16-Jul-2010</td>
<td>2:30 PM – 4:30 PM</td>
</tr>
<tr>
<td>Developmental Therapeutics</td>
<td>SAT 17-Jul-2010</td>
<td>8:00 AM – 10:00 AM</td>
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Speakers and Topics:
(Note: Detailed Vaccine and Phase II list appended at end)

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Friday 16-July-2010

General Business, Developmental Therapeutics Committee
2:30 PM – 2:40 PM Presentation, Carol Aghajanian, MD, New protocol development processes and time lines
2:40 PM – 2:50 PM Presentation, Pamela Harris, MD, IDB/CTEP/NCI, CTEP Drug Development Pipeline
2:50 PM – 3:00 PM Presentation, Charles Kunos, MD, PhD, Director of Gynecologic and Pediatric Radiation Oncology, Ireland Cancer Center, University Hospitals of Cleveland, Developing new targeted therapies in combination with chemoradiation for cervical cancer

Review of Phase II Studies (Active, Under Development, and New Concepts):
3:00 PM – 3:45 PM Ovarian Cancer (Robert Burger)
GOG0126 Ovarian Cancer, Platinum-Resistant, Cytotoxic
GOG0186 Ovarian Cancer, Multiple Priors
  ➢ Single arm studies
  ➢ Randomized phase II studies
GOG0170 Ovarian Cancer, Targeted Therapies
  • Suspended
  • Studies under development
  • New Phase II concepts

3:45 PM – 4:15 PM Endometrial Cancer (D. Scott McMeekin)
GOG0086 Endometrial Cancer, No Prior Therapy
GOG0129 Endometrial Cancer, Prior Therapy, Cytotoxic
GOG0229 Endometrial Cancer, Prior Therapy, Targeted Therapies
Learning Objectives
- Participants will become familiar with the current status of phase I, phase II, and vaccine studies that are under development or activated for accrual.
- New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents (as appropriate).
- Integration and prioritization of studies will be reviewed with reference to disease-site committees and the Committee on Experimental Medicine.
- Recommendations for action by the Protocol Development Committee will be summarized.

Detailed List of Studies (Under Development and Proposed)

Vaccine Studies (Active and Under Development):
**CERVICAL CANCER**
- DTM0941 (DTM0817) A randomized phase II study of E2 peptide vaccine + GM-CSF + montanide versus GM-CSF + montanide in HLA A2 positive patients with HPV16 associated early cervical lesions (LSIL or ASCUS) (S. Khleif). Concept JAN08. NCI Division of Cancer Prevention (DCP) approved pending response 3.5.10 (protocol due by the end of March 2011). 2:1 randomization. 200 patients.

**OVARIAN CANCER**
• GOG-0255 A phase II randomized, double-blind trial of a polyvalent vaccine-KLH conjugate (NSC 748933) + 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). Protocol UD.

New Vaccine Concepts

Ovarian Cancer Phase II:
  126 Series (1 prior; platinum resistant)
• 0126T Phase II evaluation of belinostat and carboplatin in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (D. Dizon). Active for accrual.
• 0260/DTM0805 (0126) Phase II evaluation of elesclomol and weekly paclitaxel in the treatment of recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (B. Monk). Concept JAN08. Protocol CTEP approved 04.15.09.
• DTM0836 (0126) Phase II evaluation of intraperitoneal EGEN-001 (IL-12 plasmid formulated with PEG-PEI-Cholesterol lipopolymer) administered in combination with pegylated liposomal doxorubicin (Doxil) in recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (R. Alvarez). Concept OCT08. Protocol UD. Safety lead in being considered (see phase I section).
  186 Series (1-3 priors) – Randomized Phase II studies – Taxane
• 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). Concept JAN09. CTEP LOI 4.24.09. Approved 3.15.10.
• DTM0927 (0186) A randomized phase II study of MK-2206, a novel, allosteric pan-AKT inhibitor in combination with docetaxel versus docetaxel in patients with persistent or recurrent ovarian, fallopian tube or primary peritoneal cancer (R. Coleman). Concept JUL09.
• DTM1003 (0186) A randomized phase IIIB evaluation of pazopanib versus weekly paclitaxel plus pazopanib versus weekly paclitaxel in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (D. Richardson). Concept JAN10. OCTF review 5.21.10.
  186 Series (1-3 priors) – Randomized Phase II studies - Bevacizumab
• 186-G A randomized phase II evaluation of bevacizumab plus everolimus (RAD001) vs. bevacizumab plus placebo in treatment of recurrent or persistent epithelial ovarian, fallopian tube or primary peritoneal cancer (W. Tew). LOI GCSC/CTEP approved 12.01.08. Protocol CTEP approved 04.06.09.
  186 series (1-3 priors)
  170 series (1-2 priors)
• 0170N A6 (M. Gold). Suspended.
• 0170P AMG102 (L. Martin). Concept JAN08. Protocol CTEP approved 12.4.09.
DTM0911 (0170) AZD8055 (dual mTORC1 and mTORC2 inhibitor) (K. Behbakht). Concept JAN09. On hold pending completion of phase I study and CTEP mass solicitation.

DTM0913 (0170) ARQ-197 (M. McHale). Concept JAN09. On hold pending CTEP mass solicitation.

DTM0917/PIS0904 (0170) TRC105 (anti-CD105 monoclonal antibody) (R. Burger). Concept JAN09

DTM0919 (0170) EZN-2968 (L. Martin). Concept APR09

New Ovarian Concepts

DTM1016 (0170) A phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (D. O’Malley)

DTM1017 (0170) A phase II evaluation of BEZ235, a dual Inhibitor of PI3K And mTOR, in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (B. Monk)

DTM1018 (0186) A phase II evaluation of notch inhibitor MK 0725 plus docetaxel in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (J. Chan)

DTM1021 (0126) Phase II evaluation of cabazitaxel in the treatment of recurrent or persistent platinum resistant ovarian, fallopian tube, or primary peritoneal cancer (J. Chan)

PIS1007 A phase I/randomized phase II study of VTX-2337 in combination with pegylated liposomal doxorubicin (Doxil) as second-line treatment for patients with advanced recurrent ovarian cancer (G. Coukos)

Response to RFP for randomized phase II or III trials for platinum-resistant recurrence:

OVM1019: A phase II study targeting BRCANESS in ovarian cancer tissue to determine whether there is an alteration in the response rate to weekly paclitaxel alone or in combination with olaparib (R. Coleman).

Randomized Phase II adaptive design. Patients will first be assessed for BRCAness in their referent tumor (archived paraaffin tissue blocks). Those with a BRCAness profile will be randomized to:

A: Paclitaxel 80 mg/m² days 1, 8, 15 on 28 day schedule with Olaparib 400 mg po BID or
B: Paclitaxel 80 mg/m² days 1, 8, 15 on 28 day schedule

Patients with a “wild type” profile will receive:

Paclitaxel 80 mg/m² days 1, 8, 15 on 28 day schedule

Phase III proposals:

- OVM1018 Phase III, randomized open-label study of NKTR-102 versus pegylated liposomal doxorubicin as second-line therapy in recurrent platinum resistant ovarian cancer (R. Coleman)

Response to RFP for randomized phase II or III trials for 1st platinum-sensitive recurrence:

DTM1019 A randomized phase II study of dasatinib, a SRC inhibitor, in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin in patients with recurrent platinum-sensitive ovarian, fallopian tube or primary peritoneal cancer (A. Secord)

OVM1015 A randomized phase II, multi-center, open-label study of the efficacy and safety of BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with
platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (O. Dorigo) No phase I data for the proposed 3 drug combination.

Phase III proposals:

- OVM1011 A randomized phase III trial of carboplatin and pegylated doxorubicin versus dose-dense paclitaxel and carboplatin in platinum sensitive recurrent ovarian and primary peritoneal cancer (S. Rose)
- OVM1012 A randomized phase III trial of chemotherapy doublet with or without ABT888 in platinum sensitive recurrent ovarian and primary peritoneal cancer (B. Monk) No phase I data for PLD/carboplatin/ABT-888
- OVM1013 OVATYON Phase III multicenter, randomized study of trabectedin plus pegylated liposomal doxorubicin (PLD) versus carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (B. Monk)
- OVM1017 A phase III trial comparing paclitaxel, carboplatin, bevacizumab with or without sorafenib in patients with recurrent, platinum sensitive ovarian carcinoma (C. Leath) No phase I data for this 4 drug combination
- OVM1021 A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain bevacizumab stratified by prior bevacizumab exposure (D. O’Malley)
- OVM1022 A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy (D. O’Malley)
- OVM1023 A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without CTEP-supplied PARP inhibitor ABT-888 in platinum sensitive recurrent ovarian cancer (D. Armstrong) No phase I data
- OVM1024 A phase III trial of carboplatin and dose dense paclitaxel plus placebo versus carboplatin and paclitaxel plus concurrent and extended AMG-386, in women with newly diagnosed, previously untreated, stage III or IV, epithelial ovarian, primary peritoneal or fallopian tube cancer (R. Wenham) ? change to 213R
- OVM1025 A phase III randomized controlled clinical trial of carboplatin and paclitaxel in combination with bevacizumab with or without ABT-888 versus carboplatin and pegylated liposomal doxorubicin in combination with bevacizumab with or without ABT-888 followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian, primary peritoneal and fallopian tube cancer (L. Landrum)

Cervical Cancer Phase II:

127 Series

- 127V Phase II trial of weekly abraxane in the treatment of recurrent and/or metastatic squamous cell cancers of the cervix (D. Alberts). Second stage accrual in progress.
- 127W (DTM0940) Phase II trial of ABT-888 and topotecan (C. Kunos). Concept JUL09. CTEP LOI 12.31.09 – approved 5.3.10. 6 patient (with prior pelvic RT) safety lead in. See phase I section.

76 Series

- 76GG A limited access phase II trial of pemetrexed in combination with cisplatin in the treatment of advanced, persistent or recurrent carcinoma of the cervix (D. Miller). Second stage accrual in progress.
• DTM0933 (0076) A phase I/II study of cisplatin, paclitaxel with the PARP-inhibitor ABT-888 in primary stage IVB or recurrent and persistent carcinoma of the cervix (R. Salani). Concept JUL09. CTEP LOI 12.23.09 – approved 6.9.10. See phase I section.

• DTM0935 (0076) Phase II open-label trial of Abraxane plus cisplatin in women with metastatic and/or recurrent cervical cancer (D. Alberts). Concept JUL09. LOI submitted to Abraxis 08.13.09.

227 Series

• O265 (DTM0622/CVM0601) (0227) A phase II study of Lovaxin-C (L. Monocytogenes expressing human papilloma virus type 16 E7/Listeriolysin-O fusion protein) in the treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix (W. Huh). Safety lead in. Protocol UD (see vaccine and phase I sections).

• DTM0822 (0227) A phase II evaluation of brivanib (BMS-582664) in the treatment of persistent or recurrent squamous cell carcinoma of the cervix (J. Chan). Concept JUL08. LOI approved by BMS 12.19.08.


• DTM1011 (0227) A phase II evaluation of GDC-0449 in the treatment of persistent or recurrent carcinoma of the cervix (L. Duska). Concept JAN10. Administrative hold by CTEP.

New Cervical Concepts

• DTM1014 (0227) A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (C. Boardman)

• DTM1015 (0227) A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (U. Matulonis)

Endometrial Cancer Phase II:

86 Series

• 86-P A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab, paclitaxel/carboplatin/temsirolimus or ixabepilone/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, stage IVB, or recurrent endometrial cancer (C. Aghajanian). Active for accrual.

129 Series

• DTM0908 (0129) A phase II evaluation of EC-0225 in the treatment of recurrent or persistent endometrial carcinoma (R. Wendel Naumann). Concept JAN09.

229 Series

• 229-H AZD6244 (R. Coleman). Suspended after first stage.

• 229-I Brivanib (M. Powell). Suspended after first stage.

• 229-J Cediranib (AZD2171) (D. Bender/K. Leslie). First stage accrual in progress.


• DTM0906 (0229) Phase II evaluation of the triple tyrosine kinase inhibitor, BIBF 1120, in the treatment of metastatic or advanced endometrial cancer (D. Dizon - Chair/S. Campos – Co-Chair). Concept JAN09. Protocol CTEP approved 5.27.10.

• DTM0920 (0229) A phase II evaluation of A6 in the treatment of persistent or recurrent endometrial carcinoma (M. Gold). Concept JUL09.

• DTM0939 (0229) A phase II evaluation of GDC-0980, a PI3K/mTOR inhibitor, in the treatment of persistent or recurrent endometrial cancer (U. Matulonis). Concept JUL09.
New Endometrial Concepts

- **DTM1013** (0086) Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (L. Duska)
- **UC1014** A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (J. Brown)
- **DTM1020** A randomized phase II study of everolimus and GSK1120212 (oral MEK 1/2 inhibitor) versus everolimus alone in women with advanced, persistent or recurrent endometrial cancer (248R) (A. Myers)

Gynecologic Sarcoma Phase II:

**LEIOMYOSARCOMA**

- 87M Trabectedin (B. Monk).  **Suspended**
- **DTM0909** (0131) A phase II evaluation of EC-0225 in the treatment of recurrent or persistent leiomyosarcoma of the uterus (R. Wendel Naumann).  **Concept JAN09.**
- **DTM0944** (0131) A phase II evaluation of ixabepilone in the treatment of recurrent or persistent leiomyosarcoma of the uterus (L. Duska/D. Dizon).  **Concept OCT09. CTEP LOI 12.31.09 – approved 5.12.10.**

New Leiomyosarcoma Concepts

- **DTM1012** (0131) A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (M. Hensley)

**CARCINOSARCOMA**

- 130-F A phase II evaluation of ixabepilone in the treatment of recurrent or persistent carcinosarcoma of the uterus (C. McCourt/D. Dizon).  **Concept JUL09. CTEP LOI 10.21.09 – approved 1.29.10.**
- **DTM0932** (0230) A phase II trial of pazopanib in the management of patients with recurrent uterine carcinosarcomas (S. Campos).  **Concept JUL09. CTEP LOI 09.18.09 – approved 12.18.09.**

New Carcinosarcoma Concepts

**Studies from Other Committees for Review**

A.  **ADS1016**: Correlation of patient reported neurotoxicity with health-care provider's assessment of neurotoxicity using data collected as part of GOG 9919 (Amy D Tiersten)
Phase I Workshop
Boston, MA

Chair: Carol Aghajanian, MD
Co-Chair: Paula Fracasso, MD, PhD

Friday 16-July-2010 1:00 PM – 2:30 PM

Phase I Subcommittee
1:00 PM – 1:15 PM  Introduction, Membership and Policies (Paula Fracasso)
1:15 PM – 2:00 PM  Review of Ongoing Phase I Studies (Paula Fracasso)
2:00 PM – 2:30 PM  New Phase I Concepts and Studies under Development (Paula Fracasso)

Learning Objectives
• Participants will become familiar with the current status of phase I studies that are under development or activated for accrual.
• New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents (as appropriate).
• Integration and prioritization of studies will be reviewed with reference to disease-site committees and the Committee on Experimental Medicine.
• Recommendations for action by the Protocol Development Committee will be summarized.

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Phase I and Chemoradiation Pilots (Active and Under Development):
ENDOMETRIAL
• 9920 A phase I study of IV plus intraperitoneal (IP) chemotherapy in endometrial cancer patients at high risk for peritoneal failure (IV TAP x 2; IV Dox/IV→IP cisplatin/IP paclitaxel x 4) (S. McMeekin). Active for accrual.

OVARIAN – NO PRIOR THERAPY
• 9916 PART A: IV paclitaxel, IP carboplatin and IP paclitaxel; PART B: IV docetaxel, IP carboplatin and IP paclitaxel; PART C: IV paclitaxel, IP carboplatin, IV bevacizumab and IP paclitaxel in patients with previously untreated ovarian, fallopian tube or primary peritoneal carcinoma (J. Walker) On hold
• 9917 PART A: IV paclitaxel and IP carboplatin; PART B: IV paclitaxel, IP carboplatin and IV bevacizumab (M. Morgan) On hold
• 9921 A phase I study of IV paclitaxel (3 hour) - IP cisplatin on day 1 and IP paclitaxel on day 8 (D. Dizon). On hold
• 9923 A phase I study of IV paclitaxel (2 cohorts – 3 hour and weekly), IV carboplatin, IV bevacizumab, and oral ABT-888 (PARP inhibitor) in patients with previously untreated ovarian, fallopian tube or primary peritoneal cancer (K. Bell-McGuinn). Active for accrual.
OVARIAN – PRIOR THERAPY
- PIS0604/DTM0527 ipilimumab (CTLA4)-bevacizumab (R. Burger). Concept JUL05. CTEP LOI to be prepared (await availability of ipilimumab).
- 9924 A phase I pharmacokinetic study of intraperitoneal bortezomib and carboplatin in patients with persistent or recurrent ovarian, fallopian tube or primary peritoneal cancer (D. Dizon/S. Howell). Active for accrual.
- DTM0836 (0126) Phase II evaluation of intraperitoneal EGEN-001 (IL-12 plasmid formulated with PEG-PEI-Cholesterol lipopolymer) administered in combination with pegylated liposomal doxorubicin (Doxil) in recurrent or persistent platinum-resistant ovarian, fallopian tube or primary peritoneal cancer (R. Alvarez). Concept OCT08. Protocol UD. Safety lead in being considered (see phase II section).

CERVICAL CANCER
Chemo-RT pilots
- 9913 A phase I study of pelvic radiation therapy with concomitant weekly cisplatin and topotecan chemotherapy in patients with cervical carcinoma without extra-pelvic metastasis (P. Rose). Active for accrual.

127 Series
- 127W (DTM0940) Phase II trial of ABT-888 and topotecan (C. Kunos). Concept JUL09. CTEP LOI 12.31.09 – approved 5.3.10. 6 patient (with prior pelvic RT) safety lead in. See phase II section.

76 Series
- DTM0933 (0076) A phase I/II study of cisplatin, paclitaxel with the PARP-inhibitor ABT-888 in primary stage IVB or recurrent and persistent carcinoma of the cervix (R. Salani). Concept JUL09. CTEP LOI 12.23.09 – approved 6.9.10. See phase II section.

Vaccine/227 series

New Phase I and Pilot Concepts
Cervical Cancer
- PIS1002 Extended field radiation therapy with concomitant paclitaxel and cisplatin chemotherapy followed by paclitaxel and carboplatin chemotherapy in women with cervical carcinoma metastatic to the para-aortic lymph nodes (C. Boardman)
- PIS1005 A phase I trial of AMG 479 and gemcitabine in patients with metastatic cervical cancer (S Campos)

Ovarian
- PIS1003 A phase I clinical trial of platinum, paclitaxel, pegylated liposomal doxorubicin, bevacizumab and ABT-888 in ovarian, primary peritoneal, and fallopian tube cancer, followed by consolidation with bevacizumab and weekly paclitaxel (L. Landrum)
• **PIS1004** A phase I clinical trial of carboplatin, pegylated liposomal doxorubicin, bevacizumab and ABT-888 in platinum-sensitive, recurrent ovarian, primary peritoneal and fallopian tube cancer (L. Landrum)

• **PIS1007** A phase I/randomized phase II study of VTX-2337 in combination with pegylated liposomal doxorubicin (Doxil) as second-line treatment for patients with advanced recurrent ovarian cancer (G. Coukos)

**Carcinosarcoma**

• **PIS1006** Phase I study of intravenous Ifosfamide and paclitaxel chemotherapy followed by radiation with intravenous cisplatin and consolidation therapy with intravenous paclitaxel and carboplatin for uterine sarcoma (A. Evans)

QUESTIONS / DISCUSSION

EVALUATION
Experimental Medicine Workshop
Boston, MA

Chair: Michael Birrer, MD, PhD
Co-Chair: Thomas Hamilton, MD
Co-Chair: William Beck, MD

Session I: Thursday, July 15, 2010 6:30 – 10:00 pm (Closed Retreat)
Session II: Friday, July 16, 2010 3:30 – 6:30 pm (3:30 – 4:30 with CPC Control Committee)
Session III: Saturday, July 17, 2010 7:30-9:30 am

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

- Discuss the results of recently completed GOG clinical studies
- Discuss the status and progress of ongoing GOG clinical trials
- Discuss the developing research priorities of the GOG
- Assure strict quality control of GOG clinical trials

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

**SESSION I (Closed)**
CEM Retreat
Discussion of 5 year vision for committee

**SESSION II - Joint meeting with CPC**
Review of concepts and protocol
Core lab reports
Translational Research Projects
Grant Applications

**SESSION III**
A. Scientific Presentations
B. Internal Bank Presentations
C. Joint meeting with CDT (9-9:30)

QUESTIONS/DISCUSSION

EVALUATION

Protocols and Concepts for Review

**A. Proposed protocols**

1. CEM0109: (GOG-8006) Development of a Serum Proteomic Profile for Cervical Cancer with Prognostic Value (Samir Khleif)
2. CEM0208: (GOG-0245) A Molecular Profiling Study for Ovarian Cancer Diagnosis and Prognosis in Women Undergoing Surgery for a Pelvic Mass (Doris Benbrook)
3. CEM0604: Tripath Oncology Biomarker Panel for Ovarian Cancer Screening Using Serum from Patients Participating in GOG-0220 (Andrew Berchuck)
4. CEM0703 (formerly PIS0704): A Limited Institution Study of the Local and Systemic Effects of Intraperitoneal Chemotherapy in the Treatment of Previously-Untreated, Invasive Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma (Robert Edwards and Kunle Odunsi)
5. CEM0704 (formerly UC0709): Measurement of hCG-related Markers to Aid Diagnoses of Patients with Persistent Low Levels of hCG (James Hoffman)  GOG-0242 amendment
6. CEM0802: Determination of the EGFR Expression Pathways in Patients with Cervical Cancer Treated with Chemoradiation (Claire F. Verschaeren)

7. CEM0803: ERCC1 Expression as a Predictor of Progression Free and Overall Survival in Patients with Epithelial Ovarian Cancer Treated on GOG Protocols 172 and 182 (Thomas C. Krivak)

8. GOG-8001 (CEM0805): GOG-0177 SHARE Study: Steroid Hormone and Receptors in Endometrial Carcinoma. (Kimberly Leslie)

9. CEM0807: Topoisomerase 2-alpha (TOPO2A) Genomic Alterations and Immunohistochemical Expression as Well as Chromosome 17 Polysomy in Advanced or Recurrent Endometrial Carcinoma Treated with Anthracycline-Based Therapy. (Tatyana A. Grushko)

10. CEM0902: Validating the Prognostic Role of ATR Mutation in Patients with High and Intermediate Risk Endometrioid Endometrial Cancer [same cases as Goodfellow R21 study]. (Israel Zigelboim)

11. CEM0904: Evaluation of Specific Bevacizumab-Associated Single Nucleotide Polymorphisms and Whole Genome Single Nucleotide Polymorphisms in Patients with Advanced Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma Treated with Platinum and Taxane Based Combination Chemotherapy with or without Bevacizumab (Thomas C. Krivak)

12. CEM1001: BRC1/2 Restoration and Platinum Response in GOG-0213 (Elizabeth Swisher)

13. CEM1004: Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)

14. CEM1005: Evaluation of BRCA1 and 2 expression in papillary serous endometrial carcinoma (Thomas C Krivak)

15. CEM1006: Micro RNA Expression Patterns in Endometrial Cancer Tumors and Biological Specimens (Kimberly K Leslie)

B. Studies from Other Committees for Review

1. CPC1004: A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)

2. CPC1007: Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)

3. CPC1009: PPV and specificity of screening women and elevated risk in ROCA and GOG-0199 (Steven Skates)

4. CPC1010: Novel Markers trial: Screening Summary (Joan L Walker)

5. CPC1011: Evaluating the early Detection Potential of Established and Novel Ovarian Cancer Biomarkers (Charles Drescher)

6. DTM1012: A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

7. DTM1013: Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

8. DTM1014: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

9. DTM1015: A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

10. DTM1016: Phase II study of lorvoduzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

11. DTM1017: A PHASE II EVALUATION OF BEZ235, A DUAL INHIBITOR OF PI3K AND MTOR, IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER (170 SERIES) (Bradley J Monk)

12. OVM1010: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor A6 or Bevacizumab or VargatefTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian
Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

14. OVM1011: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)

15. OVM1012: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

16. OVM1013: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

17. OVM1014: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

18. OVM1015: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP-BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (Oliver Dorigo)

19. OVM1016: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

20. OVM1017: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)


22. OVM1019: A PHASE II STUDY TARGETING BRCA NESS IN OVARIAN CANCER TISSUE TO DETERMINE WHETHER THERE IS AN ALTERATION IN THE RESPONSE RATE TO WEEKLY PACLITAXEL ALONE OR IN COMBINATION WITH OLAPARIB (Robert L Coleman)

23. OVM1020: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

24. OVM1021: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

25. OVM1022: (GOG213R/212R-Recurrent) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

26. OVM1023: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)

27. RTM1006: Molecular changes in large cell neuroendocrine carcinoma of the uterus (Shashikant B Lele)

28. UC1009: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

29. UC1010: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera)
30. UC1011: Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond J Osborne)
31. UC1012 Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)
32. UC1013: Defining the Role of Microsatellite Instability in Endometrial Cancer (Israel Zighelboim)
33. UC1015: Randomized phase III trial of lymphadectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

QUESTIONS / DISCUSSION

EVALUATION
Chair: Nicola Spirtos, MD  
Co-Chair: Charles W. Whitney, MD

Friday, July 16, 2010 1:30 – 3:30 PM

Learning objectives
- To inform the committee members and the audience of the GOG surgical standards and quality control methods.
- Review the GOG Surgical Procedures Manual
- Review submitted concepts for future trials.
- Review charts for eligibility and surgical quality control

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Agenda

1) Call to order

2) Introduction of new Members

3) Status of chart reviews were held in November, December and at this meeting,

4) Site Committee Reports

Cervix

No new proposals

Ovary

OVM1012: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

OVM1015: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP-BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (Oliver Dorigo)

OVM1016: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)
**OVM1020:** (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy. (David M O’Malley)

**OVM1022:** (GOG213R/212R–Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

**Uterine Corpus**

**UC1010:** A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I–III (Christina Bandera)

**UC1012:** Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

**UC1015:** Randomized phase III trial of lymphadectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

**Developmental therapeutics**
No new proposals

**Cancer Prevention and Control**

**CPC1008:** DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)

**Quality of Life**
No new proposals

**Experimental Medicine**
No new proposals

**Rare Tumor**

**RTM1006:** Molecular changes in large cell neuroendocrine carcinoma of the uterus (Shashikant B Lele)

1) Review of Surgical Procedures Manual

2) New Business

3) Adjournment
Medical Oncology Workshop
Boston, MA

Chair: Franco Muggia, MD
Co-Chair: Paul Sabbatini, MD

Friday, July 16, 2010  4:30 – 6:00 pm

Learning Objectives

Following this activity, participants will be better able to:

- Discuss general medical oncology issues related to conduct of research
- Understand the diagnosis and treatment of dermatologic issues associated with novel anti-cancer agents in GOG trials
- Consider prophylactic strategies to decrease carboplatin hypersensitivity reactions
- Review the merits of drug dosing based on creatinine clearance versus serum creatinine level

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Workshop Agenda

A) CME Presentation: Dermatologic Effects of Anti-neoplastic Agents: An update  
(30 minutes)

Susan Burgin, MD
Assistant Professor of Dermatology
Harvard Medical School
Attending Dermatologist
Department of Dermatology
Beth Israel Deaconess Medical Center

B) Review of January 2010 meeting

C) Presentation: “Prophylactic Conversion to Extended Schedule Carboplatin and Impact on Hypersensitivity”  
(15 minutes)

Paul Sabbatini, M.D.
Associate Attending
Memorial Sloan-Kettering Cancer Center
New York, NY

D) Review of Ancillary Data Project regarding Creatinine Clearance and Toxicity Events

E) Review of selected assigned concepts and protocols
ADS1019: A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)

CEM1004: Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)

DTM1012: A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

DTM1013: Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

DTM1014: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

DTM1015: A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

DTM1016: Phase II study of lornotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

DTM1017: A PHASE II EVALUATION OF BEZ235, A DUAL INHIBITOR OF PI3K AND MTOR, IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER (170 SERIES) (Bradley J Monk)

DTM1018: A Phase II evaluation of Notch inhibitor MK 0752 plus docetaxel in the treatment of persistent or recurrent epithelial ovarian primary peritoneal of fallopian tube cancer (0186 series) (John K Chan)

OVM1010: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor Â6 or Bevacizumab or VargatefTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

OVM1011: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)

OVM1012: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

OVM1013: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

OVM1014: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

OVM1015: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP- BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (Oliver Dorigo)
OVM1016: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

OVM1017: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)

OVM1018: Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)

OVM1019: A PHASE II STUDY TARGETING BRCANESS IN OVARIAN CANCER TISSUE TO DETERMINE WHETHER THERE IS AN ALTERATION IN THE RESPONSE RATE TO WEEKLY PACLITAXEL ALONE OR IN COMBINATION WITH OLAPARIB (Robert L Coleman)

OVM1020: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

OVM1021: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

OVM1022: (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

OVM1023: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)

PIS1002: Extended Field Radiation Therapy with Concomitant Paclitaxel and Cisplatin Chemotherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Women with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Cecelia H Boardman)

PIS1003: A Phase I Clinical Trial of Platinum, Paclitaxel, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, Followed By Consolidation with Bevacizumab and Weekly Paclitaxel. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

PIS1004: A PHASE I CLINICAL TRIAL OF CARBOPLATIN, PEGYLATED LIPOSOMAL DOXORUBICIN, BEVACIZUMAB AND ABT-888 IN PLATINUM-SENSITIVE, RECURRENT OVARIAN, PERITONEAL PRIMARY AND FALLOPIAN TUBE CANCER. NCI-SUPPLIED AGENTS: BEVACIZUMAB, ABT-888 (Lisa Landrum)

PIS1005: A Phase I Trial of AMG 459 and Gemcitabine in patients with Metastatic Cervical Cancer (Susana M Campos)

PIS1006: Phase I Study of Intravenous Ifosfamide and Paclitaxel Chemotherapy followed by Radiation with Intravenous Cisplatin and Consolidation Therapy with Intravenous Paclitaxel and Carboplatin for Uterine Carcinosarcoma (Anthony C Evans)
PIS1007: A Phase I / randomized Phase II Study of VTX-2337 in Combination with Pegylated Liposomal Doxorubicin (Doxil) as Second-Line Treatment for Patients with Advanced Recurrent Ovarian Cancer (George Coukos)

UC1008: Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-Positive Endometrial Carcinoma (Jennifer F De Los Santos)

UC1009: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

UC1011: Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond J Osborne)

UC1014: A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (Jubilee Brown)

UC1015: Randomized phase III trial of lymphadectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

QUESTIONS / DISCUSSION

EVALUATION
Nursing Workshop
Boston, MA

Chair: Susan Nolte, PhD

Session: July 16, 2010  7:00 – 10:00 am
July 17, 2010  7:00 – 10:00 am (IMR sponsored Symposia – Independent of GOG meeting)

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

• Discuss and make recommendations relating to GOG clinical studies from nursing perspective
• Discuss GOG 0259; patient recruitment, study plan, data requirements
• Identify strategies for recruitment to GOG 0259

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

Friday, July 16, 2010  7:00 am - 9:00 am

A. Subcommittee Reports
   1. Nursing Research (Suann Mitchell) – Discussion of research critiques
   2. Nursing Education (Ginny Martin) - Future educational programs
   4. Patient Education (Kathy Apollo)

B. Update on GOG-259, “Nurse delivered WRITE symptoms vs. self-directed WRITE symptoms vs care as usual for optimal symptom management for women with recurrent ovarian, primary peritoneal, and fallopian tube cancer (Heidi Donovan PhD and panel). Review of study plan, data requirements, and eligibility. A Panel of nurses from Magee Women’s, University of Oklahoma, Washington University, Wayne State, and Northern Indiana CCOP will discuss successful strategies for patient recruitment. Barriers to recruitment will be identified.

C. Review of proposed GOG concepts and protocols (Approximately 40 will be reviewed)

QUESTIONS/DISCUSSION
EVALUATION

Review of proposed GOG concepts and protocols

CEM1004 Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)

CEM1005 Evaluation of BRCA1 and 2 expression in papillary serous endometrial carcinoma (Thomas C Krivak)

CEM1006 Micro RNA Expression Patterns in Endometrial Cancer Tumors and Biological Specimens (Kimberly K Leslie)
CPC1004 A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)

CPC1007 Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)

CPC1008 DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)

CPC1009: PPV and specificity of screening women and elevated risk in ROCA and GOG-0199 (Steven Skates)

CPC1010: Novel Markers trial: Screening Summary (Joan L Walker)

DTM1012 A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

DTM1013 Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

DTM1014 A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

DTM1015 A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

DTM1016 Phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

DTM1017 A PHASE II EVALUATION OF BEZ235, A DUAL INHIBITOR OF PI3K AND MTOR, IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER (170 SERIES) (Bradley J Monk)

DTM1018 A Phase II evaluation of Notch inhibitor MK 0752 plus docetaxel in the treatment of persistent or recurrent epithelial ovarian primary peritoneal of fallopian tube cancer (0186 series) (John K Chan)

DTM1019: A randomized phase II study of dasatinib, a SRC inhibitor, in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin in patients with recurrent platinum-sensitive ovarian or primary peritoneal cancer. (Angeles Alvarez Secord)

DTM1020: A Randomized Phase II Study of Everolimus and GSK1120212 (oral MEK 1-2 inhibitor) Versus Everolimus alone in women with advanced, persistent or recurrent endometrial cancer (0248R) (C Aghajanian)

DTM1021: Phase II Evaluation of Cabazitaxel in the Treatment of Recurrent or Persistent Platinum Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (John K Chan)

OVM1010 A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor Â6 or Bevacizumab or VargatefTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

OVM1011 A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)
OVM1012 A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

OVM1013 Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

OVM1014 A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

OVM1015 A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP- BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (Oliver Dorigo)

OVM1016 A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

OVM1017 A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)

OVM1018 Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)

OVM1019 A PHASE II STUDY TARGETING BRCAANESS IN OVARIAN CANCER TISSUE TO DETERMINE WHETHER THERE IS AN ALTERATION IN THE RESPONSE RATE TO WEEKLY PACLITAXEL ALONE OR IN COMBINATION WITH OLAPARIB (Robert L Coleman)

OVM1020 (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

OVM1021 (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

OVM1022 (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

OVM1023 A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)

PIS1002 Extended Field Radiation Therapy with Concomitant Paclitaxel and Cisplatin Chemotherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Women with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Cecelia H Boardman)
PIS1003: A Phase I Clinical Trial of Platinum, Paclitaxel, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Previously Untreated Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, Followed By Consolidation with Bevacizumab and Weekly Paclitaxel. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

PIS1004: A Phase I Clinical Trial of Carboplatin, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Recurrent Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

PIS1005: A Phase I Trial of AMG 459 and Gemcitabine in patients with Metastatic Cervical Cancer (Susana M Campos)

PIS1006: Phase I Study of Intravenous Ifosfamide and Paclitaxel Chemotherapy followed by Radiation with Intravenous Cisplatin and Consolidation Therapy with Intravenous Paclitaxel and Carboplatin for Uterine Carcinosarcoma (Anthony C Evans)

PIS1007: A Phase I / randomized Phase II Study of VTX-2337 in Combination with Pegylated Liposomal Doxorubicin (Doxil) as Second-Line Treatment for Patients with Advanced Recurrent Ovarian Cancer (George Coukos)

QLM1003: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

UC1008: Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-Positive Endometrial Carcinoma (Jennifer F De Los Santos)

UC1009: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

UC1010: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera)

UC1011: Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond J Osborne)

UC1012: Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

UC1013: Defining the Role of Microsatellite Instability in Endometrial Cancer (Israel Zighelboim)

UC1014: A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (Jubilee Brown)

UC1015: Randomized phase III trial of lymphadectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

*Saturday, July 17, 2010 / 7:00-10:00am: IMR Sponsored Symposia– Independent of GOG meeting

Symposia “Optimizing patient outcomes in epithelial ovarian cancer: therapeutic options, nursing interventions, and patient management strategies. Sponsored by Institute for Medical Education and Research (IMER) This program is not part of the official GOG semi-annual meeting. CME is provided by IMER.
Chair: Larry Copeland, MD  
Co-Chair: Fred Stehman, MD

JULY 18, 2010 – (OPEN) 7:00-9:00am Grand Ballroom/Liberty/2nd Fl

AGENDA

I. General Business

A. Call to order (Copeland)  
B. Approval of minutes of January 2010 (Copeland)

II. Committee on Experimental Medicine (Birrer)

A. Active Studies: 136, 221, 235, 8005, 8008, 8009, 8010, 8011, 8012, 8014  
B. Temporarily Closed:  
C. Closed Studies: 211, 220  
D. Terminations  
E. Amendments  
F. Other Business

III. Developmental Therapeutics Committee (Aghajanian)

Phase II

A. Active Studies: 76GG, 86P, 126T, 127V, 229J  
B. Temporarily Closed: 87M, 170N, 229I, 229H  
C. Closed Studies: 76DD, 87B, 87C, 126M, 126R, 129Q, 130E, 146O, 146Q, 170D, 170F,  
230C, 232B, 232C  
D. Terminations
E. Amendments
F. Other Business

1) Request to removal pathologist listing from ovarian and cervical DTM trials as a path review is not required.

2) Change language for the following in DTM trials (will apply to Ovary, Endometrium and Cervix); it is consistently three years throughout:

- 3.22 Patient with a history of other invasive malignancies, with the exception of non-melanoma skin cancer and other specific malignancies as noted in Sections 3.23 and 3.24, are excluded if there is any evidence of other malignancy being present within the last five three years. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.

- 3.23 Patients who have received prior radiotherapy to any portion of the abdominal cavity or pelvis OTHER THAN for the treatment of endometrial cancer within the last five three years are excluded. Prior radiation for localized cancer of the breast, head and neck, or skin is permitted, provided that it was completed more than three years prior to registration, and the patient remains free of recurrent or metastatic disease.

- 3.24 Patients who have received prior chemotherapy for any abdominal or pelvic tumor OTHER THAN for the treatment of endometrial cancer within the last five three years are excluded. Patients may have received prior adjuvant chemotherapy for localized breast cancer, provided that it was completed more than three years prior to registration, and that the patient remains free of recurrent or metastatic disease.

Phase I
A. Active Studies: 9913, 9916, 9917, 9918, 9920, 9921, 9923, 9924
B. Closed Studies: 8906, 9001, 9204, 9801, 9903, 9915, 9919
C. Terminations
D. Amendments
E. Other Business

IV. Cancer Prevention and Control Committee (Alberts/Walker)
A. Active Studies: 214, 237, 256, 8199
B. Temporarily Closed: 207, 224
C. Closed Studies: 199, 215
Operations Committee Agenda (open)
July 18, 2010

D. Terminations
E. Amendments
F. Other Business

V. Quality of Life Committee (Wenzel)
A. Active Studies: 212, 213, 240, 249, 252, 258, 259
B. Temporarily Closed:
C. Closed Studies: 111, 147, 152, 172, 184, 199, 204, 209, 218, 222, 9902, LAP2
D. Terminations
E. Amendments
F. Other Business

VI. Committee on Cancer of the Uterine Corpus (Miller)
A. Active Studies: 210, 238, 242, 248, 249, 250, 258, 261
B. Temporarily Closed:
C. Closed Studies: 174, 184, 188, 209, LAP2
D. Terminations
E. Amendments
E. Other Business

VII. Committee on Cancer of the Cervix and Vulva (Monk)
A. Active Studies: 233, 240, 263, 724
B. Closed Studies: 171, 173, 204, 205, 206, 219, 222, 9806
C. Terminations
D. Amendments
E. Other Business

VIII. Committee on Cancer of the Ovary (Bookman)
A. Active Studies: 212, 213, 252
B. Imminent Activation: 262
C. Temporarily Closed:
D. Closed Studies: 104, 152, 157, 158, 172, 175, 178, 182, 198, 218, 9302, 9303
E. Terminations
F. Amendments
Operations Committee Agenda (open)
July 18, 2010

a) GOG-0252

G. Other Business

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

A. Active Studies: 187, 254, 264
B. Temporary Closed: 251
C. Closed Studies 239
D. Terminations
E. Amendments
F. Other Business

X. **Ancillary Data Subcommittee** *(Waggoner)*

XI. **Committee on Information Technology** *(Bookman)*

1) **Action from January 2010 meeting:**
   a) Online Dose Calculation to be added to the public side of the GOG website. Status?

XII. **Gynecologic Oncology Committee** *(Spirtos)*

XIII. **Medical Oncology Committee** *(Muggia)*

XIV. **Nursing Committee** *(Nolte)*

XV. **Pathology Committee** *(Rodgers)*

XVI. **Publications Committee** *(Stehman)*

XVII. **Radiation Oncology Committee** *(Petersen)*

XVIII. **Tissue Utilization Subcommittee** *(Cibull)*

XIX. Other Business

1) **Action from January 2010 meeting**
   a) Indications for not terminating large phase III trials.
Chair: Robert Mannel, MD
Co-Chair: Gini Fleming, MD

Session I: July 16, 2010  8:00 – 10:00 am
Session II: July 17, 2010  10:00 am – 12 pm

Learning Objectives

Following this activity, participants will be better able to:

- Discuss the status and significance of new and ongoing GOG clinical trials on the prevention, diagnosis, and treatment of ovarian cancers
- Discuss promising translational research objectives and priorities for future clinical trials
- Apply standards and procedures required to design, submit, and conduct a research protocol for support by the GOG
- Assure strict quality control of GOG clinical trials

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

A. General
   Introduction of new members and review of workshop agenda

B. Review of Closed Studies

C. Review of Active Studies

D. Proposed Concepts
   1. Primary review
   2. Secondary review

E. Studies from other committees

F. New Business
   1. Report from Phase I (Fracasso)
   2. Report from DTM (Burger)
   3. Report from QOL
   4. Report from CEM (Birrer)

QUESTIONS / DISCUSSION

EVALUATION

Protocols and Concepts for Review
B. Review of Closed Studies

Protocols 45, 72, 78, 90, 140, 152, 157, 158, 162, 172, 175, 178, 182, 198, 218, 9302, 9303

C. Review of Active Studies

2. **GOG-0187** Phase II Study of Paclitaxel for Ovarian Stromal Tumors as Second-Line Therapy (Howard D Homesley)

3. **GOG-0212** A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or CT-2103 (IND # 70177) versus no treatment until documented relapse in women with advanced ovarian or primary peritoneal cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Maurie Markman)

4. **GOG-0214** Phase II Double Blind Randomized Trial Evaluating the Biologic Effect of Levonorgestrel on the Ovarian Epithelium in Women at High Risk for Ovarian Cancer (Gustavo Rodriguez)

5. **GOG-0215** A phase II randomized study of the effect of zoledronic acid versus observation on bone mineral density of the lumbar spine in women who elect to undergo surgery that results in removal of both ovaries (David s Alberts)

7. **GOG-0235** A Prospective, Longitudinal Study of YKL-40 in Patients with FIGO Stage III or IV Invasive Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer Undergoing Primary Chemotherapy (Katherine Bell-McGuinn)

8. **GOG-8005** Validation of Tumor-Infiltrating T Cells as a Biomarker for Advanced Epithelial Ovarian Cancer (George Coukos)

D. Proposed Concepts Review/ Protocols under Development

**Primary Review**

OVM0502: Primary, Neoadjuvant, and Adjuvant Chemotherapy in Elderly Women with Ovarian, Peritoneal Primary or Tubal Cancer (Vivian von Gruenigen)

GOG-0266 (OVM0701): Validation of a Tumor Burden Index for Analysis of Cytoreductive Effort in Women Undergoing Surgery for a Suspected Primary Gynecologic Cancer (Jay Carlson)

GOG-0262 (OVM0813): A Three-arm Randomized Phase III Trial Comparing 1) Dose Dense Weekly Paclitaxel Combined with Carboplatin vs. 2) Dose Dense Weekly Paclitaxel + Bevacizumab, Combined with Carboplatin vs. 3) Every-Three-Weeks Paclitaxel + Bevacizumab, Combined with Carboplatin in the Treatment of Primary Suboptimal Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (John K Chan)

OVM0818: A Phase III Trial of VEGF-Trap Versus Placebo and Doxil vs Docetaxel in Platinum Resistant Ovarian Cancer. (Angeles Alvarez-Secord)

OVM0902: A Phase III Study of Carboplatin/Paclitaxel/Bevacizumab and Placebo versus Carboplatin/Paclitaxel/Bevacizumab and ABT-888 in Newly Diagnosed Patients with Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (Katherine M Bell-McGuinn)
OVM1002: Phase II Trial of Sub-Optimally Debulked Ovarian/Peritoneal/Tubal Cancer: Standard Chemotherapy vs. Target Directed Individual Therapy (Kathleen Moore)

OVM1004: A Three Arm Phase III Study Investigating the Appropriate Dose and Duration of Bevacizumab in Suboptimally Debulked Stage III and Stage IV Epithelial Ovarian, Peritoneal and Tubal Cancer (Bradley Monk)

OVM1005: A phase III randomized trial of primary debulking surgery versus neoadjuvant chemotherapy and interval debulking for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)

Secondary Review

OVM1010: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor â€” or Bevacizumab or VargateFTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

OVM1011: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)

OVM1012 A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

OVM1013: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

OVM1014: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

OVM1015: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP-BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy (Oliver Dorigo)

OVM1016: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

OVM1017: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)

OVM1018: Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)
OVM1019: A Phase II Study Targeting BRCANESS In Ovarian Cancer Tissue To Determine Whether There Is An Alteration In The Response Rate To Weekly Paclitaxel Alone Or In Combination With Olaparib (Robert L Coleman)

OVM1020: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

OVM1021: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

OVM1022: (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

OVM1023: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)

E. Studies from Other Committees for Review:

ADS1002 Survival following recurrence based on time to recurrence following platinum and taxane in advanced ovarian carcinoma: An analysis of prognostic factors utilizing individual patient data (Peter G Rose)

ADS1017 Retrospective Analysis of the Tolerability, Complication Rate, and Survival of Elderly Patients Receiving Intraperitoneal Chemotherapy (Peter A Argenta)

ADS1018 Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)

ADS1019 A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)

ADS1021 A comparative effectiveness study of cancer risk management for women at elevated genetic risk of ovarian cancer (Laura J Havrilesky)

ADS1022 AN ANALYSIS OF CLINICOPATHOLOGIC VARIABLES IN LOW-GRADE SEROUS OVARIAN CARCINOMA PATIENTS ENROLLED IN GOG 182 (Amanda Nickles-Fader)

ADS1023 Hypertension as a predictor of bevacizumab activity in patients with epithelial ovarian, primary peritoneal ovarian or fallopian tube carcinoma. (Pedro T Ramirez)

CEM1004 Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)
DTM1016 Phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

DTM1017 A Phase II Evaluation Of BEZ235, A Dual Inhibitor of PI3K and MTOR, in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Cancer (170 Series) (Bradley J Monk)

PIS1003 A Phase I Clinical Trial of Platinum, Paclitaxel, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, Followed By Consolidation with Bevacizumab and Weekly Paclitaxel. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

PIS1004 A PHASE I CLINICAL TRIAL OF CARBOPLATIN, PEGYLATED LIPOSOMAL DOXORUBICIN, BEVACIZUMAB AND ABT-888 IN PLATINUM-SENSITIVE, RECURRENT OVARIAN, PERITONEAL PRIMARY AND FALLOPIAN TUBE CANCER. NCI-SUPPLIED AGENTS: BEVACIZUMAB, ABT-888 (Lisa Landrum)

PIS1007 A Phase I / randomized Phase II Study of VTX-2337 in Combination with Pegylated Liposomal Doxorubicin (Doxil) as Second-Line Treatment for Patients with Advanced Recurrent Ovarian Cancer (George Coukos)

F. New Business
Learning Objectives

Following this activity, participants will be better able to:

- Apply standardized criteria for evaluation of gynecologic neoplasms
- Discuss current diagnostic criteria for gynecologic neoplasms as cited in the GOG Pathology Manual
- Utilize staging criteria as cited in the GOG Pathology Manual
- Utilize current quality assurance methods to review cases submitted for protocols
- Discuss active and proposed protocols for gynecologic neoplasms
- Become familiar with Aperio Digital slide review technology

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required): or onsite in the IT Resource Room

Workshop Agenda

A. Review slides and eligibility for current active protocols (8-12, 2-5 both days)
   Each case is reviewed by a two-pathologist team, with input from a referee pathologist as needed.

B. Business Meeting/ (12-2 both days)
   - HIPAA Requirements
   - Reports from Cervix, Corpus, and Ovarian Committees
   - Report from Committee on Experimental Medicine
   - Report from Tissue Utilization Subcommittee
   - Presentation by Ron Soslow: Ovarian Tumor nomenclature and recommendations of Ovarian Tumor Nomenclature Committee (7/16, 1 hr)
   - Presentation by Louis Dubeau: Ovarian Carcinoma Nomenclature (7/16, 1 hr)
   - Discussion of Ovarian Carcinoma Nomenclature (Ovarian Tumor Nomenclature Committee)

C. Review of new concepts and protocols

D. Demonstration/training in use of Aperio Digital Slide Review (by IT committee members, 8-12 both days)

QUESTIONS / DISCUSSION

EVALUATION
CURRENTLY ACTIVE PROTOCOLS (phase II and phase III)

GOG0076A Master Protocol for Phase II Drug Studies in the Treatment of Advanced or Recurrent squamous cell carcinoma of the Cervix (James Arseneau)

GOG-0076GG A Limited Access Phase II Trial of Pemetrexed (Alimta, LY231514) in Combination with Cisplatin in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix. (David S Miller)

GOG-0086P A Three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab(NSC #704865, IND #7921), paclitaxel/carboplatin/temsirolimus (NSC #683864, IND#61010), and ixabepilone (NSC#710428 IND # 59699)/carboplatin/bevacizumab as initial chemotherapy for measurable stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (86 series). (Carol Aghajanian)

GOG-0127V A Phase II Evaluation of ABI-007 (IND #55,974)in the Treatment of Persistent or Recurrent Squamous or Non Squamous Cell Carcinoma of the Cervix (David S Alberts)

GOG-0136 Acquisition of Human Gynecologic Specimens and Serum to be Serum to be used in Studying the Causes, Diagnosis, Prevention and Treatment of Cancer(Michael Cibull)

GOG-0170N A Phase II Evaluation of a Urokinase-Derived Peptide (A6) (IND# 64,298)in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma (170 series) (Michael A Gold)

GOG-0187 Phase II Study of Paclitaxel for Ovarian Stromal Tumors as Second-Line Therapy (Howard D Homesley)

GOG-0210 A Molecular Staging Study of Endometrial Carcinoma (William T Creasman)

GOG-0212 A randomized phase III trial of maintenance chemotherapy comparing 12 monthly cycles of single agent paclitaxel or ct-2103 (IMD# 70177) versus no treatment until documented relapse in women with advanced ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum/taxane chemotherapy (Maurie Markman)

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. NCI-supplied agents: bevacizumab (NSC#704865, IND #7921) (Robert Coleman)

GOG-0214 Phase II Double Blind Randomized Trial Evaluating the Biologic Effect of Levonorgestrel on the Ovarian Epithelium in Women at High Risk for Ovarian Cancer (Gustavo Rodriguez)

GOG-0215 A phase II randomized study of the effect of zoledronic acid versus observation on
bone mineral density of the lumbar spine in women who elect to undergo surgery that results in removal of both ovaries (David S. Alberts)

GOG-0221 Glycoprotein and Glycan Profiling in Patients with Locally Advanced Cervical Cancer (Stage IB2, IIA > 4 cm, IIB to IVA) Undergoing Pelvic and Para-aortic (Abdominal) Lymphadenectomy (Michael Gold)

GOG-0229H A phase II Evaluation of AZD6244 (NSC#741078, CTEP IND #77782) in the Treatment of recurrent or persistent endometrial cancer (229-Series) (Robert L Coleman)

GOG-0229I 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)

GOG-0233 Utility of preoperative FDG PET/CT and Ferumoxtran-10 MRI scanning prior to primary chemoradiation therapy to detect retroperitoneal lymph node metastasis in patients with loco regionally advanced (IB2, IIA ≥ 4 cm, IIB-IVA) carcinoma of the cervix (Michael Gold)

GOG-0235 A Prospective, Longitudinal Study of YKL-40 in Patients with FIGO Stage III or IV Invasive Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer Undergoing Primary Chemotherapy (Katherine Bell-McGuinn)

GOG-0237 Comparative Analysis of CA-IX, p16, Proliferative Markers and Human Papilloma Virus (HPV) in the Diagnosis of Significant Cervical Lesions in Patients with a Cytologic Diagnosis of Atypical Glandular Cells (AGC) (Shu-Yuan Liao)

GOG-0238 A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-only Recurrence of Carcinoma of the Uterine Corpus (Higinia R Cardenes)

GOG-0239 A Randomized Phase II Trial of AZD6244 (NSC 741078, IND #77782) in Women with Recurrent Low-Grade Serous Carcinoma of the Ovary (John H Farley)

GOG-0240 (0240) A Randomized Phase III Trial of Cisplatin Plus Paclitaxel With and Without NCI-Supplied Bevacizumab vs. the Non-Platinum Doublet, Topotecan Plus Paclitaxel, With and Without NCI-Supplied Bevacizumab, in Stage IVB, Recurrent or Persistent Carcinoma f the Cervix (K. Tewari) (Krishnansu Tewari)

GOG-0248 A Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy Plus Temsirolimus in Women with Advanced, Persistent, or Recurrent Endometrial Carcinoma (Gini Fleming)

GOG-0249 A Phase III Trial of Pelvic Radiation Therapy Versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Carcinoma (D. Scott McMeekin)

GOG-0251 A Phase II Trial of Bevacizumab (rhuMAB VEGF)(NSC# 704865, IND# 7921) for Recurrent Sex Cord-Stromal Tumors of the Ovary (Jubilee Brown)
GOG-0252 Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma (Joan L Walker)

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 (Daniele Matei)

GOG-0261 A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus (Matthew A Powell)

GOG-8008 Genetic Modifiers of BRCA-related Breast Cancer Risk in BRCA1/BRCA2 Mutation Carriers - CIMBA 5 (Mark H Greene)

GOG-8009 Genome-Wide Association Study (GWAS) for Modifiers of Breast Cancer Risk in BRCA1 Mutation Carriers (Mark H Greene)

GOG-8010 BRCA2-related Breast Cancer Risk and Protective Alleles by Genome-Wide Association and Copy Number Analysis (Mark H Greene)

GOG-8011 GOG-0177 SHARE Study: Steroid Hormone and Receptors in Endometrial Carcinoma. (Kimberly Leslie)

GOG-9913 A Phase I Study of Pelvic or Pelvic and Extended Radiation Therapy with Concomitant Weekly Cisplatin and Topotecan Chemotherapy in Patients with Cervical Carcinoma with or without Paraortic Nodal Metastasis (Peter Rose)

GOG-9916 A phase I trial of intravenous paclitaxel, intraperitoneal carboplatin and intraperitoneal paclitaxel or intravenous docetaxel, intraperitoneal carboplatin and intraperitoneal paclitaxel or intravenous paclitaxel, intraperitoneal carboplatin, intraperitoneal paclitaxel and CTEP-supplied agent: bevacizumab (NSC 704865, IND 7921) in patients with previously untreated ovarian, fallopian tube or primary peritoneal carcinoma (Joan Walker)

GOG-9917 A dose-escalating phase I study with an expanded cohort to assess the feasibility of intraperitoneal carboplatin (NSC #214240) and intravenous paclitaxel(NSC #673089) in patients with previously untreated epithelial ovarian, primary peritoneal, or fallopian tube carcinoma (Mark A Morgan)

NEW CONCEPTS AND PROTOCOLS

CEM1004 Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)

CEM1005 Evaluation of BRCA1 and 2 expression in papillary serous endometrial carcinoma (Thomas C Krivak)

CEM1006 Micro RNA Expression Patterns in Endometrial Cancer Tumors and Biological Specimens (Kimberly K Leslie)
CPC1004 A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)

CPC1007 Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)

CPC1008 DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)

DTM1012 A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

DTM1013 Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

DTM1014 A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

DTM1015 A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

DTM1016 Phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

DTM1017 A PHASE II EVALUATION OF BEZ235, A DUAL INHIBITOR OF PI3K AND MTOR, IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER (170 SERIES) (Bradley J Monk)

DTM1018 A Phase II evaluation of Notch inhibitor MK 0752 plus docetaxel in the treatment of persistent or recurrent epithelial ovarian primary peritoneal of fallopian tube cancer (0186 series) (John K Chan)

OVM1010 A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor Â6 or Bevacizumab or VargateffTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

OVM1011 A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)

OVM1012 A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)
OVM1013 Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

OVM1014 A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

OVM1015 A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP- BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (Oliver Dorigo)

OVM1016 A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

OVM1017 A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)

OVM1018 Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)

OVM1019 A PHASE II STUDY TARGETING BRCANESS IN OVARIAN CANCER TISSUE TO DETERMINE WHETHER THERE IS AN ALTERATION IN THE RESPONSE RATE TO WEEKLY PACLITAXEL ALONE OR IN COMBINATION WITH OLAPARIB (Robert L Coleman)

OVM1020 (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

OVM1021 (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

OVM1022 (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)
OVM1023 A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND#77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)

PIS1002 Extended Field Radiation Therapy with Concomitant Paclitaxel and Cisplatin Chemotherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Women with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Cecelia H Boardman)

PIS1003 A Phase I Clinical Trial of Platinum, Paclitaxel, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, Followed By Consolidation with Bevacizumab and Weekly Paclitaxel. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

PIS1004 A PHASE I CLINICAL TRIAL OF CARBOPLATIN, PEGYLATED LIPOSOMAL DOXORUBICIN, BEVACIZUMAB AND ABT-888 IN PLATINUM-SENSITIVE, RECURRENT OVARIAN, PERITONEAL PRIMARY AND FALLOPIAN TUBE CANCER. NCI-SUPPLIED AGENTS: BEVACIZUMAB, ABT-888 (Lisa Landrum)

PIS1005 A Phase I Trial of AMG 459 and Gemcitabine in patients with Metastatic Cervical Cancer (Susana M Campos)

PIS1006 Phase I Study of Intravenous Ifosfamide and Paclitaxel Chemotherapy followed by Radiation with Intravenous Cisplatin and Consolidation Therapy with Intravenous Paclitaxel and Carboplatin for Uterine Carcinosarcoma (Anthony C Evans)

PIS1007 A Phase I / randomized Phase II Study of VTX-2337 in Combination with Pegylated Liposomal Doxorubicin (Doxil) as Second-Line Treatment for Patients with Advanced Recurrent Ovarian Cancer (George Coukos)

QLM1003 Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

RTM1006 Molecular changes in large cell neuro endocrine carcinoma of the uterus (Shashikant B Lele)

UC1008 Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-Positive Endometrial Carcinoma (Jennifer F De Los Santos)

UC1009 A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

UC1010 A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera)

UC1011 Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond J Osborne)
UC1012 Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

UC1013 Defining the Role of Microsatellite Instability in Endometrial Cancer (Israel Zighelboim)

UC1014 A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (Jubilee Brown)

UC1015 Randomized phase III trial of lymphadectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)
PROTOCOL DEVELOPMENT WORKSHOP
Boston, MA

Chair: J. Tate Thigpen, MD
Co-chair: Ronald Alvarez, MD

July 17, 2010 / 1:00pm - 7:00pm

DETAILED AGENDA

Learning Objectives:
Following this activity, participants will be better able to:
  - Discuss the status and significance of new and ongoing GOG clinical trials on the prevention, diagnosis, and treatment of all gynecologic cancers.
  - Discuss promising translational research objectives and priorities for future clinical trials.
  - Apply standards and procedures required to design, submit, and conduct a research protocol for support by GOG.
  - Assure strict quality control of GOG clinical trials.

DETAILED AGENDA
Bolded concepts are new at this meeting

I. Committee on Experimental Medicine (Birrer)
   A. Proposed protocols

1. CEM0109: (GOG-8006) Development of a Serum Proteomic Profile for Cervical Cancer with Prognostic Value (Samir Khleif)
2. CEM0208: (GOG-0245) A Molecular Profiling Study for Ovarian Cancer Diagnosis and Prognosis in Women Undergoing Surgery for a Pelvic Mass (Doris Benbrook)
3. CEM0604: Tripath Oncology Biomarker Panel for Ovarian Cancer Screening Using Serum from Patients Participating in GOG-0220 (Andrew Berchuck)
4. CEM0703 (formerly PIS0704): A Limited Institution Study of the Local and Systemic Effects of Intraperitoneal Chemotherapy in the Treatment of Previously-Untreated, Invasive Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma (Robert Edwards and Kunle Odunsi)
5. CEM0704 (formerly UC0709): Measurement of hCG-related Markers to Aid Diagnoses of Patients with Persistent Low Levels of hCG (James Hoffman) GOG-0242 amendment
6. CEM0802: Determination of the EGFR Expression Pathways in Patients with Cervical Cancer Treated with Chemoradiation (Claire F. Verschraegen)
7. GOG-8013 (CEM0807): Topoisomerase 2-alpha (TOPO2A) Genomic Alterations and Immunohistochemical Expression as Well as Chromosome 17 Polysomy in Advanced or Recurrent Endometrial Carcinoma Treated with Anthracycline-Based Therapy. (Tatyana A.Grushko)
8. CEM0902: Validating the Prognostic Role of ATR Mutation in Patients with High and Intermediate Risk Endometrioid Endometrial Cancer [same cases as Goodfellow R21 study]. (Israel Zighelboim)
9. CEM0904: Evaluation of Specific Bevacizumab-Associated Single Nucleotide Polymorphisms and Whole Genome Single Nucleotide Polymorphisms in Patients with Advanced Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma Treated with
Platinum and Taxane Based Combination Chemotherapy with or without Bevacizumab (Thomas C. Krivak)

10. CEM1001: BRC1/2 Restoration and Platinum response in GOG-0213 Tabled

11. CEM1004: Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)

12. CEM1005: Evaluation of BRCA1 and 2 expression in papillary serous endometrial carcinoma (Thomas C Krivak)

13. CEM1006: Micro RNA Expression Patterns in Endometrial Cancer Tumors and Biological Specimens (Kimberly K Leslie)

B. Studies from Other Committees for Review

1. CPC1004: A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)

2. CPC1007: Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)

3. DTM1012 A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

4. DTM1013: Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

5. DTM1014: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

6. DTM1015: A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

7. DTM1016: Phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

8. DTM1017: A Phase II Evaluation Of BEZ235, A Dual Inhibitor Of PI3K And MTOR, In The Treatment Of Persistent Or Recurrent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Cancer (170 Series) (Bradley J Monk)

9. DTM1018: A Phase II evaluation of Notch inhibitor MK 0752 plus docetaxel in the treatment of persistent or recurrent epithelial ovarian primary peritoneal of fallopian tube cancer (0186 series) (John K Chan)

10. DTM1019: A randomized phase II study of dasatinib, a SRC inhibitor, in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin in patients with recurrent platinum-sensitive ovarian or primary peritoneal cancer. (Angeles Alvarez Secord)

11. DTM1020: A randomized phase II study of Everolimus and GSK1120212 versus Everolimus alone in women with advanced, persistent or recurrent endometrial cancer (0248R) (C. Aghajanian)

12. OVM1010: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor A6 or Bevacizumab or VargatefTM [BIBF1120]) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

13. OVM1011: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)
14. **OVM1012**: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)
15. **OVM1013**: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)
16. **OVM1014**: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)
17. **OVM1015**: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP-BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy (Oliver Dorigo)
18. **OVM1016**: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debunking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)
19. **OVM1017**: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)
20. **OVM1018**: Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)
21. **OVM1019**: A Phase II Study Targeting BRCANESS In Ovarian Cancer Tissue To Determine Whether There Is An Alteration In The Response Rate To Weekly Paclitaxel Alone Or In Combination With Olaparib (Robert L Coleman)
22. **OVM1020**: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)
23. **OVM1021**: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)
24. **OVM1022**: (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)
25. **OVM1023**: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)
26. **OVM1024**: A Phase III Trial Of Carboplatin And Dose Dense Paclitaxel Plus Placebo Versus Carboplatin And Paclitaxel Plus Concurrent And Extended AMG 386, In Women With Newly Diagnosed, Previously Untreated, Stage III Or IV, Epithelial Ovarian, Primary Peritoneal Or Fallopian Tube Cancer (Robert M Wenham)
27. **RTM1006**: Molecular changes in large cell neuro endocrine carcinoma of the uterus (Shashikant B Lele)
28. **UC1009**: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)
29. **UC1010**: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera)

30. **UC1011**: Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond J Osborne)

31. **UC1012**: Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

32. **UC1013**: Defining the Role of Microsatellite Instability in Endometrial Cancer (Israel Zighelboim)

33. **UC1015**: Randomized phase III trial of lymphadenectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

C. Other business

II. **Developmental Therapeutics Committee**

A. **Phase II (Aghajanian)**

1. Proposed studies

   Ovary:

   a. DTM0719: A Randomized Phase II Evaluation of Single Agent Bevacizumab (NSC #704865) and Combination Bevacizumab with Sorafenib (BAY 43-9006) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma (John K Chan) **Tabled**

   b. GOG-0186G (DTM0801): A Phase II Randomized, Double-Blind Evaluation of Oral Everolimus (RAD001) plus Bevacizumab vs. Oral Placebo plus Bevacizumab in the Treatment of Recurrent or Persistent Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.(0186 series) (William Tew)

   c. GOG-0260 (DTM0805): A Phase II Evaluation of Elesclomol and Weekly Paclitaxel in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (Bradley J Monk)

   d. GOG-0170P (DTM0814): A Phase II Evaluation of AMG 102 in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma (0170 Series) (Lainie Martin)

   e. GOG-0126T (DTM0832): A Phase II Trial of Belinostat and Carboplatin in the Treatment of Platinum-Resistant or Platinum-Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer (Don S. Dizon)

   f. DTM0835: A Phase II Evaluation of intraperitoneal EGEN-001 (IL-12 plasmid formulated with PEG-PEI-Cholesterol lipopolymer) in the Treatment of Persistent or Recurrent Ovarian, Fallopian Tube or Primary Peritoneal Cancer. (0170-series) (Ronald Alvarez)

   g. DTM0836: A Phase II Evaluation of intraperitoneal EGEN-001 (IL-12 plasmid formulated with PEG-PEI-Cholesterol lipopolymer) administered in combination with pegylated liposomal doxorubicin (Doxil) in the Treatment of Persistent or Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer. (Ronald Alvarez)

   h. DTM0901 A Phase IIB Randomized Trial of Weekly Paclitaxel with or without Oncolytic Reovirus (REOLYSIN) in Patients with Persistent or Recurrent,
Platinum-Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer (David Cohn)
i. DTM0904: A Phase II Evaluation of Weekly Paclitaxel and Fosbretabulin in the Treatment of Persistent or Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer (186 Series) (Bradley J Monk)
j. DTM0905-A Randomized Phase II Evaluation of Single-Agent Bevacizumab and Combination Bevacizumab with Fosbretabulin in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer (186 Series) (Bradley J Monk)
k. DTM0911: A Phase II Evaluation of AZD 8055 (dual oral mTORC1 and mTORC2 inhibitor) in the Treatment of Persistent of Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma (Kian Behbakht)
l. DTM0913: A Phase II Evaluation of ARQ-197 in the Treatment of Recurrent or Persistent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (170 series) (Michael T Mchale)
m. DTM0917: A Phase II Evaluation of TRC105 (ANTI-CD105 Monoclonal Antibody) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer (0170-series) (Robert A Burger)
n. DTM0919: A Phase II Evaluation of EZN-2968, a Locked Nucleic Acid Antisense Oligonucleotide Against HIF 1α, in the Treatment of Persistent or Recurrent Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma (0170-series) (Lainie Martin)
o. DTM0927: A Phase II study of MK-2206, a novel, allosteric pan-AKT inhibitor in combination with docetaxel in the Treatment of Persistent or Recurrent Ovarian, Fallopian Tube or Primary Peritoneal Cancer (186-Series) (Robert L Coleman)
p. DTM0929: A Phase II Evaluation of the Potent, Highly Selective Poly(ADP-RIBOSE) Polymerase (PARP) -1 AND -2 Inhibitor MK-4827 in the Treatment of Persistent or Recurrent High-Grade Serous Ovarian Cancer (Bradley J Monk)
q. DTM1003: A Phase II Trial of Pazopanib, an oral antiangiogenic agent, in the treatment of persistent or recurrent epithelial ovarian, fallopian tube or primary peritoneal carcinoma (Debra L. Richardson)
r. **DTM1016**: A Phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)
s. **DTM1017**: A Phase II Evaluation of BEZ235, A Dual Inhibitor of PI3K And MTOR, In The Treatment Of Persistent Or Recurrent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Cancer (170 Series) (Bradley J Monk)
t. **DTM1018**: A Phase I II Evaluation of Notch inhibitor MK 0725 plus docetaxel in the Treatment Of Persistent Or Recurrent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Cancer (186 Series) (John K Chan)
u. **DTM1019**: A randomized phase II study of dasatinib, a SRC inhibitor, in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin in patients with recurrent platinum-sensitive ovarian or primary peritoneal cancer. (Angeles Alvarez Secord)
v. **DTM1021**: Phase II Evaluation of Cabazitaxel in the Treatment of Recurrent or Persistent Platinum Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (John K Chan)

Uterine Corpus:
w. DTM0812: A Phase II Evaluation of Cediranib (RECENTIN; AZD2171) in the Treatment of Recurrent or Persistent Endometrial Cancer (229 series) (Kimberly Leslie)
x. DTM0906: A Phase II evaluation of BIBF 1120 (IND# ), in the Treatment of Recurrent or Persistent Endometrial Cancer (Don S Dizon)
y. DTM0908: A Phase II Evaluation of EC-0225 in the Treatment of Recurrent or Persistent Endometrial Carcinoma (129 series) (R. Wendel Naumann)
z. DTM0909: A Phase II Evaluation of EC-0225 in the treatment of recurrent or persistent leiomyosarcoma of the uterus (131 series) (R. Wendel Naumann)
aa. DTM0910: A Phase II Trial of AMG 386, a Selective Angiopoietin 1/2 Neutralizing Peptibody, in Patients with Persistent/Recurrent Carcinoma of the Endometrium (229 Series) (Kathleen N Moore)
bb. DTM0920: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Endometrial Carcinoma (229-series) (Michael A Gold)
c. GOG-0230D (DTM0932): A Phase II trial of Pazopanib in the Treatment of Patients with Recurrent or Persistent Carcinosarcoma of the Uterus (Susana M Campos)

d. DTM0937: A Phase II evaluation of Ixabepilone (IND #59699, NSC #710428) in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus (McCourt)

e. DTM0939: A Phase II evaluation of GDC-0941 in the treatment of persistent or recurrent endometrial carcinoma (229 series) (Carol Aghajanian)

ff. DTM0944: A Phase II evaluation of Ixabepilone (IND #59699, NSC #710428) in the Treatment of Recurrent or Persistent leiomyosarcoma of the Uterus. (Don Dizon)

g. DTM1004: A Phase II Evaluation of Temsirolimus (CCI-779, NSC 683864) and IGF-1 Receptor Antibody IMC-A12 (NSC 742460) in the Treatment of Recurrent or Persistent Endometrial Carcinoma (GOG 229 Series) (Vicky Makker)

hh. DTM1006: Phase II study of Pazopanib, a potent inhibitor of VEGFR1,2,3, PDGFR and cKit, in women with recurrent endometrial cancer (GOG 229-series) (Robert L. Coleman)

ii. DTM1008: A Phase II Evaluation of ADZ8055, and mTORI and 2 Inhibitor, in Advanced or Recurrent Endometrial Cancer (229 queue) (Kimberly K. Leslie)

jj. DTM1012: A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

kk. DTM1013: Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

ll. DTM1020: A Randomized Phase II Study of Everolimus and GSK1120212 (oral MEK 1-2 inhibitor) Versus Everolimus alone in women with advanced, persistent or recurrent endometrial cancer (0248R) ( C Aghajanian)

Cervix:

mm. DTM0822: A Phase II Evaluation of Brivanib (IND#) in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (BMS Study CA182-048). (John K Chan)

nn. DTM0933: A Limited Access Phase II Trial of Cisplatin, Paclitaxel and CTEP Supplied Agent ABT-888 (IND#, NSC#) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix (76 Series) (Ritu Salani)

oo. DTM0935: A Limited Access Phase II Trial of Abraxane plus Cisplatin in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix (76 series) (David S Alberts)
pp. DTM1002: A Phase II Evaluation of OSI-906 (IGF-1R) in the Treatment of Persistent or Recurrent Carcinoma of the Cervix (227 Series) (Charles A Leath)

qq. DTM1014: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)

rr. DTM1015: A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)

Vaccine:

ss. GOG-0265 (DTM0622/CVM 0601): A Phase II Study of Lovaxin-C in the Treatment of Persistent or Recurrent Squamous or Non-Squamous Cell Carcinoma of the Cervix (Warner K Huh)

tt. DTM0941 (formerly DTM0817): A Randomized Phase II Study of E2 Peptide vaccine + GM-CSF + Montanide Versus GM-CSF + Montanide in HLA A2 positive patients with HPV16 associated early Cervical lesions (LSIL or ASCUS) (Khleif)

uu. GOG-0255: A Randomized Phase II Trial in Patients with Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer with a Polyvalent Vaccine-KLH Conjugate + QS-21 versus QS-21 (Paul Sabbatini).

2. Other phase II business

B. Studies from Other Committees for Review

a. ADS1016: Correlation of patient reported neurotoxicity with health-care provider’s assessment of neurotoxicity using data collected as part of GOG 9919 (Amy D Tiersten)

b. OVM1015: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP- BEZ235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy in patients with platinum sensitive, recurrent ovarian, fallopian or primary peritoneal cancer (Oliver Dorigo)

c. OVM1019: A Phase II Study Targeting BRCANESS In Ovarian Cancer Tissue To Determine Whether There Is An Alteration In The Response Rate To Weekly Paclitaxel Alone Or In Combination With Olaparib (Robert L Coleman)

d. UC1014: A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (Jubilee Brown)

C. Phase I (Fracasso)

1. Proposed studies

Ovary:

a. PIS0604: Limited Access Phase I/II trial of Bevacizumab (rhuMAB VEGF) (NSC# 704865, IND #7921) plus Ipilimumab CTLA4 in the treatment of Persistent or Recurrent Epithelial Ovarian or Primary peritoneal carcinoma (Burger)

b. PIS1003: A Phase I Clinical Trial of Platinum, Paclitaxel, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Previously Untreated Ovarian,
7. CPC0706: A New Proposed Analysis Based on GOG-199: Epidemiology of a Latent Serous Cancer Precursor in Women at Increased Genetic Risk of Ovarian Cancer (Christopher P Crum)
8. CPC0812: A Phase II Trial Utilizing Bioimpedance to Measure Lower Extremity Lymphedema associated with the Treatment of a Vulvar Cancer (Jay Carlson)
9. GOG-8199 (CPC0816): Extended Follow up of High Ovarian Cancer Risk cohort from GOG 0199 (Mark Greene)
10. CPC0817: Proposed Analysis of Data Already Collected under GOG 0199: Surgical Pathology findings among GOG 0199 Participants who Underwent Risk-Reducing Salpingo-Oophorectomy at Study entry (Mark Greene)
11. CPC0903: (formerly OVM0903) Phase IV clinical study of alvimopan vs placebo for the resolution of post-operative ileus in patients undergoing laparotomy for primary ovarian cytoreduction (Robert L Coleman)
12. CPC0904: Pilot Study of Aprepitant Therapy for Prevention of Nausea and Emesis Associated with Intraperitoneal Chemotherapy (Steven Plaxe)
13. CPC0905: Genetic Modifiers of BRCA-Related Cancer Risk in BRCA1/BRCA2 Mutation Carriers-CIMBA: A GOG-0199 Ancillary Study. (Mark Greene)
15. CPC1004: A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)
16. CPC1007: Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)
17. CPC1008: DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)
18. CPC1009: PPV and specificity of screening women and elevated risk in ROCA and GOG-0199 (Steven Skates)
19. CPC1010: Novel Markers trial: Screening Summary (Joan L Walker)
20. CPC1011: Evaluating the early Detection Potential of Established and Novel Ovarian Cancer Biomarkers (Charles Drescher)

B. Studies from Other Committees for Review:

1. ADS1018: Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)
2. QLM1003: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)
3. UC1008: Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-Positive Endometrial Carcinoma (Jennifer F De Los Santos)

C. Other business

IV. Quality of Life Committee (Wenzel)

A. Proposed studies
1. GOG-0267 (QLM0301): Quality of Life and Care Needs in Advanced Ovarian, Fallopian Tube, and Peritoneal Cancer Patients (von Gruenigen)
2. QLM0902: Late toxicities from chemoradiation, a constellation of under-recognized morbidities related to current therapy. (Joan Walker)
3. QLM1001: Cost-Utility Analysis of the Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma (GOG 0252) (Lisa M Hess)
4. QLM1003: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

B. Studies from Other Committees for Review:

1. CPC0812: A Phase II Trial Utilizing Bioimpedance to Measure Lower Extremity Lymphedema associated with the Treatment of a Vulvar Cancer (Jay Carlson)
2. CPC0904: Pilot Study of Aprepitant Therapy for Prevention of Nausea and Emesis Associated with Intraperitoneal Chemotherapy (Steven Plaxe)
3. OVM0813: GOG-0262 A Three-arm Randomized Phase III Trial Comparing 1) Dose Dense Weekly Paclitaxel Combined with Carboplatin vs. 2) Dose Dense Weekly Paclitaxel + Bevacizumab, Combined with Carboplatin vs. 3) Every-Three-Weeks Paclitaxel + Bevacizumab, Combined with Carboplatin in the Treatment of Primary Suboptimal Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (John K Chan)
4. OVM0818: A Phase III Trial of VEGF-Trap Versus Placebo and Docil vs Docetaxel in Platinum Resistant Ovarian Cancer. (Angeles Alvarez-Secord)
5. OVM0902: A Phase III Study of Carboplatin/Paclitaxel/Bevacizumab and Placebo versus Carboplatin/Paclitaxel/Bevacizumab and ABT-888 in Newly Diagnosed Patients with Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (Katherine M Bell-McGuinn)
6. UC0901: A randomized Phase III trial of eight-day parenteral methotrexate and folinic acid versus bi-weekly dactinomycin as a primary management for persistent low risk gestational trophoblastic neoplasia (GTN). (Raymond J Osborne)
7. UC0904: A Prospective Randomized Trial of Hysterectomy and Bilateral Salpingo-Oophorectomy with and without Aortic and Pelvic Lymphadenectomy in Patients with Stage IA (Grade 1, 2, 3) and IB (Grade 1 and 2) Endometrial Cancer. (Nicola M. Spirtos) will include QOL component
9. CPC1004: A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)
10. CPC1007: Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)
11. CPC1008: DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)
12. DTM1017: A PHASE II EVALUATION OF BEZ235, A DUAL INHIBITOR OF PI3K AND MTOR, IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER (170 SERIES) (Bradley J Monk)
13. CVM1001: Non Radical Surgical Therapy IA1-IB1 (≤2cm) Cervical Cancer (A. Covens)
14. OVM1004: A Three Arm Phase III Study Investigating the Appropriate Dose and Duration of Bevacizumab in Suboptimally Debulked Stage III and Stage IV Epithelial Ovarian, Peritoneal and Tubal Cancer (Bradley Monk)
15. OVM1005: A phase III randomized trial of primary debulking surgery versus neoadjuvant chemotherapy and interval debulking for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)
16. OVM1007: A phase III randomized trial of primary debulking surgery with bevacizumab consolidation versus neoadjuvant chemotherapy and interval debulking with bevacizumab consolidation for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)
17. OVM1010: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor Â6 or Bevacizumab or VargatefTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)
18. OVM1011: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)
19. OVM1012: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)
20. OVM1013: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)
21. OVM1014: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)
22. OVM1016: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)
23. OVM1017: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)
25. OVM1020: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)
26. OVM1021: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)
27. OVM1022: (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)
28. OVM1023: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)
29. OVM1024: A Phase III Trial Of Carboplatin And Dose Dense Paclitaxel Plus Placebo Versus Carboplatin And Paclitaxel Plus Concurrent And Extended AMG-386, In Women
With Newly Diagnosed, Previously Untreated, Stage III OR IV, Epithelial Ovarian, Primary Peritoneal Or Fallopian Tube Cancer (Robert M Wenham)

30. UC1007: A Phase II trial of BN83495 in the treatment of patients with recurrent, persistent or metastatic ER positive and ER negative endometrial cancer. (David S. Miller)

31. **UC1009**: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

32. **UC1010**: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera)

33. **UC1012**: Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

34. **UC1015**: Randomized phase III trial of lymphadenectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

35. **ADS1018**: Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)

36. **ADS1020**: Factors associated with toxicity in women with gynecologic cancers (Bradley J Monk)

C. Other business

V. **Committee on Cancer of the Uterine Corpus** (Miller)

A. Proposed studies

1. **UC0904**: A Prospective Randomized Trial of Hysterectomy and Bilateral Salpingo-Oophorectomy with and without Aortic and Pelvic Lymphadenectomy in Patients with Stage IA (Grade 1, 2, 3) and IB (Grade 1 and 2) Endometrial Cancer. (Nicola M. Spirtos)

2. **UC1005**: A sequential phase II/III randomized trial comparing three widely used regimens for the management of low risk gestational trophoblastic neoplasia (John Tidy)

3. **UC1007**: A Phase II trial of BN83495 in the treatment of patients with recurrent, persistent or metastatic ER positive and ER negative endometrial cancer. (David S. Miller)

4. **UC1008**: Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-Positive Endometrial Carcinoma (Jennifer F De Los Santos)

5. **UC1009**: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

6. **UC1010**: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera)

7. **UC1011**: Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond Osbourne)

8. **UC1012**: Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

9. **UC1013**: Defining the Role of Microsatellite Instability in Endometrial Cancer (Israel Zighelboim)

10. **UC1014**: A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (Jubilee Brown)

11. **UC1015**: Randomized phase III trial of lymphadenectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)
B. Studies from Other Committees for Review:

1. **ADS1019** A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)

2. **CEM1005** Evaluation of BRCA1 and 2 expression in papillary serous endometrial carcinoma (Thomas C Krivak)

3. **CEM1006** Micro RNA Expression Patterns in Endometrial Cancer Tumors and Biological Specimens (Kimberly K Leslie)

4. **DTM1012** A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley)

5. **DTM1013** Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska)

6. **DTM1020**: A Randomized Phase II Study of Everolimus and GSK1120212 (oral MEK 1-2 inhibitor) Versus Everolimus alone in women with advanced, persistent or recurrent endometrial cancer (0248R) (C Aghajanian)

7. **PIS1006** Phase I Study of Intravenous Ifosfamide and Paclitaxel Chemotherapy followed by Radiation with Intravenous Cisplatin and Consolidation Therapy with Intravenous Paclitaxel and Carboplatin for Uterine Carcinosarcoma (Anthony C Evans)

8. **RTM1006** Molecular changes in large cell neuroendocrine carcinoma of the uterus (Shashikant B Lele)

VI. **Committee on Cancer of the Ovary** (Mannel)

A. Proposed studies

1. **OVM0502**: Primary, Neoadjuvant, and Adjuvant Chemotherapy in Elderly Women with Ovarian, Peritoneal Primary or Tubal Cancer (Vivian von Gruenigen)

2. **GOG-0266 (OVM0701)**: Validation of a Tumor Burden Index for Analysis of Cytoreductive Effort in Women Undergoing Surgery for a Suspected Primary Gynecologic Cancer (Jay Carlson)

3. **GOG-0262 (OVM0813)**: A Three-arm Randomized Phase III Trial Comparing 1) Dose Dense Weekly Paclitaxel Combined with Carboplatin vs. 2) Dose Dense Weekly Paclitaxel + Bevacizumab, Combined with Carboplatin vs. 3) Every-Three-Weeks Paclitaxel + Bevacizumab, Combined with Carboplatin in the Treatment of Primary Suboptimal Stage II or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (John K Chan)

4. **OVM0818**: A Phase III Trial of VEGF-Trap Versus Placebo and Doxil vs Docetaxel in Platinum Resistant Ovarian Cancer. (Angeles Alvarez-Secord)

5. **OVM0902**: A Phase III Study of Carboplatin/Paclitaxel/Bevacizumab and Placebo versus Carboplatin/Paclitaxel/Bevacizumab and ABT-888 in Newly Diagnosed Patients with Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (Katherine M Bell-McGuinn)

6. **OVM1002**: Phase II Trial of Sub-Optimally Debulked Ovarian/Peritoneal/Tubal Cancer: Standard Chemotherapy vs. Target Directed Individual Therapy (Kathleen Moore)

7. **OVM1004**: A Three Arm Phase III Study Investigating the Appropriate Dose and Duration of Bevacizumab in Suboptimally Debulked Stage III and Stage IV Epithelial Ovarian, Peritoneal and Tubal Cancer (Bradley Monk)

8. **OVM1005**: A phase III randomized trial of primary debulking surgery versus neoadjuvant chemotherapy and interval debulking for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)
9. **OVM1010**: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor A6 or Bevacizumab or VargateFMT (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

10. **OVM1011**: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)

11. **OVM1012**: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

12. **OVM1013**: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

13. **OVM1014**: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

14. **OVM1015**: A randomized phase II, multi-center, open-label study of the efficacy and safety of NVP-BEZ2235, a dual kinase inhibitor of phosphatidylinositol-3-kinase (PI3K) and mammalian target of rapamycin (mTOR) in combination with carboplatin and taxane chemotherapy (Oliver Dorigo)

15. **OVM1016**: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

16. **OVM1017**: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)

17. **OVM1018**: Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)

18. **OVM1019**: A Phase II Study Targeting BRCANESS In Ovarian Cancer Tissue To Determine Whether There Is An Alteration In The Response Rate To Weekly Paclitaxel Alone Or In Combination With Olaparib (Robert L Coleman)

19. **OVM1020**: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

20. **OVM1021**: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

21. **OVM1022**: (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

22. **OVM1023**: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)

23. **OVM1024**: A Phase III Trial Of Carboplatin And Dose Dense Paclitaxel Plus Placebo Versus Carboplatin And Paclitaxel Plus Concurrent And Extended AMG-386, In Women
B. Studies from Other Committees for Review:

1. **ADS1002**: Survival following recurrence based on time to recurrence following platinum and taxane in advanced ovarian carcinoma: An analysis of prognostic factors utilizing individual patient data (Peter G Rose)

2. **ADS1017**: Retrospective Analysis of the Tolerability, Complication Rate, and Survival of Elderly Patients Receiving Intraperitoneal Chemotherapy (Peter A Argenta)

3. **ADS1018**: Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)

4. **ADS1019**: A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)

5. **ADS1021**: A comparative effectiveness study of cancer risk management for women at elevated genetic risk of ovarian cancer (Laura J Havrilesky)

6. **ADS1022**: AN ANALYSIS OF CLINICOPATHOLOGIC VARIABLES IN LOW-GRADe SEROUS OVARIAN CARCINOMA PATIENTS ENROLLED IN GOG 182 (Amanda Nickles-Fader)

7. **ADS1023**: Hypertension as a predictor of bevacizumab activity in patients with epithelial ovarian, primary peritoneal ovarian or fallopian tube carcinoma. (Pedro T Ramirez)

8. **CEM1004**: Evaluation of BRCA1/BRCA2 expression in patients undergoing IV/IP chemotherapy compared to IV chemotherapy: An analysis of GOG 0252 (Thomas C Krivak)

9. **DTM1016**: Phase II study of lorvotuzumab mertansine (BB-10901; IMGN901), a CD56 binding monoclonal antibody-drug conjugate in women with recurrent ovarian, fallopian tube and peritoneal primary ovarian cancer (GOG 170/126-series) (David M O’Malley)

10. **DTM1017**: A Phase II Evaluation Of BEZ235, A Dual Inhibitor Of PI3K And MTOR, In The Treatment Of Persistent Or Recurrent Epithelial Ovarian, Fallopian Tube Or Primary Peritoneal Cancer (170 Series) (Bradley J Monk)

11. **DTM1019**: A randomized phase II study of dasatinib, a SRC inhibitor, in combination with paclitaxel and carboplatin versus paclitaxel and carboplatin in patients with recurrent platinum-sensitive ovarian or primary peritoneal cancer. (Angeles Alvarez Secord)

12. **DTM1021**: Phase II Evaluation of Cabazitaxel in the Treatment of Recurrent or Persistent Platinum Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (John K Chan)

13. **PIS1003**: A Phase I Clinical Trial of Platinum, Paclitaxel, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Previously Untreated Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, Followed By Consolidation with Bevacizumab and Weekly Paclitaxel. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

14. **PIS1004**: A Phase I Clinical Trial of Carboplatin, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Recurrent Ovarian, Primary Peritoneal, and Fallopian Tube Cancer. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)

15. **PIS1007**: A Phase I / randomized Phase II Study of VTX-2337 in Combination with Pegylated Liposomal Doxorubicin (Doxil) as Second-Line Treatment for Patients with Advanced Recurrent Ovarian Cancer (George Coukos)

C. Other business

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

A. Proposed studies
1. CVM0503: Phase III Study of Weekly Cisplatin +/- Cetuximab as Concurrent and Adjuvant Therapy for Patients with Cervical Carcinoma Metastatic to Para-aortic Nodes (John Farley)
2. GOG-0263 (CVM0801): Randomized Phase III Clinical Trial of Adjuvant Chemoradiation vs. Chemoradiation in Intermediate Risk, Stage I/IIA, Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy (Sang-Young Ryu)
3. CVM0903: (GROningen International Study on Sentinel nodes in Vulvar cancer) [GROINSS-V] II An Observational Study (Brian Slomovitz)
4. CVM1001: Non Radical Surgical Therapy for Stage IA1-IB1 (≤2cm) Cervical Cancer (A. Covens)
5. CVM1002: A Phase II Trial of Erlotinib, Weekly Cisplatin, and Radiation Therapy For the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva (Neil S. Horowitz)
6. CVM1003: A Phase II Trial of Bevacizumab, Weekly Cisplatin, and Radiation Therapy for the Treatment of Locally-Advanced Squamous Cell Carcinoma of the Vulva (Neil S. Horowitz)
7. CVM1004: 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) (Kathleen Moore)

B. Studies from Other Committees for Review:
4. ADS1019: A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)
5. DTM1014: A Phase II Evaluation of A6 in the Treatment of Persistent or Recurrent Cervical Carcinoma (Cecelia H Boardman)
6. DTM1015: A Phase II study of GSK-458 in Stage IVB, Recurrent or Persistent Cervical Cancer. (Ursula A Matulonis)
7. PI51002: Extended Field Radiation Therapy with Concomitant Paclitaxel and Cisplatin Chemotherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Women with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Cecelia H Boardman)
8. PI51005: A Phase I Trial of AMG 459 and Gemcitabine in patients with Metastatic Cervical Cancer (Susana M Campos)
9. QLM1003: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

C. Other business

VIII. Rare Tumor Committee (Gershenson)

A. Proposed studies
1. GOG-0241 (RTM0412): A CGIG Intergroup Multicentre Phase III Trial of Open Label Carboplatin and Paclitaxel +/- Bevacizumab Compared with Oxaliplatin and Capecitabine +/- Bevacizumab as First Line Chemotherapy in Patients with Mucinous Epithelial Ovarian Cancer (MEOC) (David Gershenson)
2. GOG-0254 (RTM0607): A Phase II Evaluation of SU11248 (Sunitinib Malate) in the Treatment of Persistent or Recurrent Clear Cell Ovarian Carcinoma (John K. Chan)
3. RTM0905: A Phase II Study of dasatinib in the Treatment of Vulvovaginal Melanoma Harboring Somatic Alterations of c-KIT (Mario M. Leitao, Jr.)
4. GOG-0268 (RTM0907): A Phase II Evaluation of Sunitinib Malate (Stutent & SU11248, NCI-Supplied agent, NSC#736511, IND #74019) in Combination with Carboplatin and
Primary Peritoneal, and Fallopian Tube Cancer, Followed By Consolidation with Bevacizumab and Weekly Paclitaxel. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)
c. **PIS1004**: A Phase I Clinical Trial of Carboplatin, Pegylated Liposomal Doxorubicin, Bevacizumab and ABT-888 in Recurrent, Ovarian, Primary Peritoneal, and Fallopian Tube Cancer. NCI Supplied Agents: Bevacizumab, ABT-888 (Lisa Landrum)
d. **PIS1007**: A Phase I / randomized Phase II Study of VTX-2337 in Combination with Pegylated Liposomal Doxorubicin (Doxil) as Second-Line Treatment for Patients with Advanced Recurrent Ovarian Cancer (George Coukos)

Uterine Corpus:

a. **PIS1006**: Phase I Study of Intravenous Ifosfamide and Paclitaxel Chemotherapy followed by Radiation with Intravenous Cisplatin and Consolidation Therapy with Intravenous Paclitaxel and Carboplatin for Uterine Carcinosarcoma (Anthony C Evans)

Cervix:

a. **PIS1002**: Extended Field Radiation Therapy with Concomitant Paclitaxel and Cisplatin Chemotherapy Followed by Paclitaxel and Carboplatin Chemotherapy in Women with Cervical Carcinoma Metastatic to Para-Aortic Lymph Nodes (Cecilia H Boardman)
b. **PIS1005**: A Phase I trials of AMG 479 and Gemcitabine in patients with Metastatic Cervical Cancer (Suzanna Campos)

2. Other phase I business

### III. **Cancer Prevention and Control Committee** (Alberts)

#### A. Proposed studies

1. CPC0404 (GOG-0225): Can Diet and Physical Activity Modulate Ovarian and Primary Peritoneal Cancer Progression Free Survival? (David S Alberts)
2. CPC0412: Change in Mammographic Density (CMD) Among Women at High Genetic Risk of Breast and Ovarian Cancers and who Undergo Risk Reducing Salpingo-oophorectomy (RRSO) and Ovarian Cancer Screening (Larissa Korde)
3. GOG-0247 (CPC0506): Patient, Physician and Nurse Factors Associated with Entry onto Clinical Trials and Completion of Treatment for Women with Primary or Recurrent Invasive Carcinoma of the Uterine Corpus or Utero-cervix, All Stages . (Sandra E Brooks)
4. CPC0609 (GOG-0244): The Lymphedema and Gynecologic Cancer (LEG) Study: Incidence, Risk Factors and Impact (Richard Barakat)
5. CPC0616: Randomized Study of Five Day Regimens of Divided Dose vs. Once Daily Dose of Aprepitant in Combination with Palonosetron and Dexamethasone for Prevention of Acute and Delayed Chemotherapy Induced Vomiting in Women with Ovarian Cancer Receiving Intraperitoneal Cisplatin. (Steven Plaxe)
6. GOG-0257 (CPC0705): A Randomized, Double Blind, Placebo Controlled Trial Using Acetyl-L-Carnitine (ALCAR) for the Prevention of Chemotherapy-Induced Peripheral Neuropathy in Patients with Recurrent Ovarian, Primary Peritoneal or Fallopian Tube Cancer (David M Kushner)
Paclitaxel as First-line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary. (John H. Farley)

5. RTM1001: A Phase II Trial of Bevacizumab in Women with Recurrent Low-grade Serous Carcinoma of the Ovary and Peritoneum (John H. Farley)

6. RTM1002: A Phase II trial of IMC-A12 for women with recurrent low grade serous carcinoma of the ovary or peritoneum. (David Gershenson)

7. RTM1003: A Phase II trial of MK-2206 for women with recurrent low grade serous carcinoma of the ovary or peritoneum. (David Gershenson)

8. RTM1005: Phase II study of Pazopanib, a potent inhibitor of VEGFR1,2,3, PDGFR and cKIT, in women with recurrent low grade serous ovarian or peritoneal cancer (GOG 239-R) (Robert L. Coleman)

9. RTM1006: Molecular changes in large cell neuro endocrine carcinoma of the uterus (Shashikant B Lele)

10. RTM1007 A Phase II trial if anastrozole in patients with sex cord stromal tumors of the ovary (M Leitao)

D. Studies from Other Committees for Review

1. ADS1022: An Analysis Of Clinicopathologic Variables In Low-Grade Serous Ovarian Carcinoma Patients Enrolled In GOG 182 (Amanda Nickles-Fader)

B. Other business

IX. Ancillary Data Subcommittee (Waggoner)

A. Proposed Studies

2. ADS1002: Survival following recurrence based on time to recurrence following platinum and taxane in advanced ovarian carcinoma: An analysis of prognostic factors utilizing individual patient data (Peter G Rose)

3. ADS1016: Correlation of patient reported neurotoxicity with health-care provider’s assessment of neurotoxicity using data collected as part of GOG 9919 (Amy D Tiersten)

4. ADS1017: Retrospective Analysis of the Tolerability, Complication Rate, and Survival of Elderly Patients Receiving Intraperitoneal Chemotherapy (Peter A Argenta)

5. ADS1018: Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)

6. ADS1019: A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini)

7. ADS1020: Factors associated with toxicity in women with gynecologic cancers (Bradley J Monk)

8. ADS1021: A comparative effectiveness study of cancer risk management for women at elevated genetic risk of ovarian cancer (Laura J Havrilesky)

9. ADS1022: An Analysis Of Clinicopathologic Variables In Low-Grade Serous Ovarian Carcinoma Patients Enrolled In GOG 182 (Amanda Nickles-Fader)

10. ADS1023: Hypertension as a predictor of bevacizumab activity in patients with epithelial ovarian, primary peritoneal ovarian or fallopian tube carcinoma. (Pedro T Ramirez)

QUESTIONS / DISCUSSION
Quality of Life Workshop
Boston, MA

Chair: Lari Wenzel, PhD
Co-Chair: Jeffrey Bell, MD

Session I: Friday, July 16, 2010 2:00 – 2:50 pm Joint meeting with CPC/QOL session
Session II: Friday, July 16, 2010 3:00 – 5:00 pm
Session III: Saturday, July 17, 2010 12:00 – 1:00 pm

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

- Discuss emerging and ongoing GOG clinical trials, with respect to quality of life issues
- Discuss promising translational research objectives and priorities for future clinical trials
- Apply standards and procedures required to design, submit, and conduct a research protocol for support by the GOG

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

SESSION I: 2:00 – 2:50 PM
Joint CPC/Quality of Life Committee Session (In CPC room)

A. Mini Symposium on Chemotherapy-induced Peripheral Neuropathy

B. Review of Approved Studies in Development

QUESTIONS/DISCUSSION
EVALUATION

SESSION II: 3:00 -5:00 PM
A. General Business/Scientific Presentation
   - Call to order
   - Approval of minutes of January 2010
   - New member introduction

B. Closed studies and Manuscript Status Protocol 97, 111, 122, 152, 169, 172, 177, 184, 191, 192, 199, 201, 204, 9902, LAP2, 0222

C. Active Studies
   Protocols 212, 213, 0249, 252, 259
Report from Ad Hoc Compliance Task Force

D. Previously Proposed studies from QLM

1. **QLM0301**: Quality of Life and Care Needs in Advanced Ovarian, Fallopian Tube, and Peritoneal Cancer Patients (von Gruenigen)

2. **QLM0902**: Late toxicities from chemoradiation, a constellation of under-recognized morbidities related to current therapy. (Joan Walker) (see CVM0905)

3. **QLM1001**: Cost-Utility Analysis of the Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma (GOG 0252) (Lisa M Hess) *Presentation*

4. **QLM1003**: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

E. New Proposed studies from QLM

**QLM1003**: Late Toxicity Following Treatment for Cervical Cancer (Karen M Gil)

F. Previously Proposed studies from Other Committees

*From Prior Meetings:*

1. **CPC0812**: A Phase II Trial Utilizing Bioimpedance to Measure Lower Extremity Lymphedema associated with the Treatment of a Vulvar Cancer (Jay Carlson)

2. **CPC0904**: Pilot Study of Aprepitant Therapy for Prevention of Nausea and Emesis Associated with Intraperitoneal Chemotherapy (Steven Plaxe)

3. **OVM0813**: GOG-0262 A Three-arm Randomized Phase III Trial Comparing 1) Dose Dense Weekly Paclitaxel Combined with Carboplatin vs. 2) Dose Dense Weekly Paclitaxel + Bevacizumab, Combined with Carboplatin vs. 3) Every-Three-Weeks Paclitaxel + Bevacizumab, Combined with Carboplatin in the Treatment of Primary Suboptimal Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (John K Chan)

4. **OVM0818**: A Phase III Trial of VEGF-Trap Versus Placebo and Doxil vs Docetaxel in Platinum Resistant Ovarian Cancer. (Angeles Alvarez-Secord)

5. **OVM0902**: A Phase III Study of Carboplatin/Paclitaxel/Bevacizumab and Placebo versus Carboplatin/Paclitaxel/Bevacizumab and ABT-888 in Newly Diagnosed Patients with Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (Katherine M Bell-McGuinn)

6. **UC0901**: A randomized Phase III trial of eight-day parenteral methotrexate and folinic acid versus bi-weekly daclomycin as a primary management for persistent low risk gestational trophoblastic neoplasia (GTN). (Raymond J Osborne)
7. **UCO904:** A Prospective Randomized Trial of Hysterectomy and Bilateral Salpingo-Oophorectomy with and without Aortic and Pelvic Lymphadenectomy in Patients with Stage IA (Grade 1, 2, 3) and IB (Grade 1 and 2) Endometrial Cancer. (Nicola M. Spirtos) will include QOL component

8. **CPC1001:** Genetic Modifiers of BRCA-Related Cancer Risk in BRCA1/BRCA2 Mutation Carriers – CIMBA Collaboration: A GOG-199 Ancillary Study – CIMBA-9 and Subsequent Studies (Mark H. Greene)

9. **CVM1001:** Non Radical Surgical Therapy IA1-IB1 (≤2cm) Cervical Cancer (A. Covens)

10. **OVM1004:** A Three Arm Phase III Study Investigating the Appropriate Dose and Duration of Bevacizumab in Suboptimally Debulked Stage III and Stage IV Epithelial Ovarian, Peritoneal and Tubal Cancer (Bradley Monk)

11. **OVM1005:** A phase III randomized trial of primary debulking surgery versus neoadjuvant chemotherapy and interval debulking for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)

12. **OVM1007:** A phase III randomized trial of primary debulking surgery with bevacizumab consolidation versus neoadjuvant chemotherapy and interval debulking with bevacizumab consolidation for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)

13. **UC1007:** A Phase II trial of BN83495 in the treatment of patients with recurrent, persistent or metastatic ER positive and ER negative endometrial cancer. (David S. Miller)

**G. New Proposed Studies from Other Committees**

**CPC1004:** A FEASIBILITY STUDY OF RISK-REDUCING BILATERAL SALPINGECTOMY (RRBS) AMONG WOMEN AT INCREASED GENETIC RISK OF OVARIAN CANCER WHO HAVE REFUSED RISK-REDUCING BILATERAL SALPINGO-OOPHORECTOMY (GOG-199R) (Douglas A Levine)

**CPC1007:** Prevalence of BRCA1 and BRCA2 mutations among participants enrolled in GOG-199, with a special focus on BRCA1/2 large genomic rearrangements (Mark H Greene)

**CPC1008:** DVT prophylaxis comparing preoperative vs. postoperative low molecular weight heparin in patients undergoing major abdominal or pelvic surgery (Jeanne M Schilder)

**DTM1017:** A PHASE II EVALUATION OF BEZ235, A DUAL INHIBITOR OF PI3K AND MTOR, IN THE TREATMENT OF PERSISTENT OR RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER (170 SERIES) (Bradley J Monk)

**CVM1001:** Non Radical Surgical Therapy IA1-IB1 (≤2cm) Cervical Cancer (A. Covens)

**OVM1004:** A Three Arm Phase III Study Investigating the Appropriate Dose and Duration of Bevacizumab in Suboptimally Debulked Stage III and Stage IV Epithelial Ovarian, Peritoneal and Tubal Cancer (Bradley Monk)

**SESSION III: Noon – 1:00 pm Saturday**

A. Review of New Concepts/Developing Protocols
B. Other business
OVM1005: A phase III randomized trial of primary debulking surgery versus neoadjuvant chemotherapy and interval debulking for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)

OVM1007: A phase III randomized trial of primary debulking surgery with bevacizumab consolidation versus neoadjuvant chemotherapy and interval debulking with bevacizumab consolidation for patients with stage III ovarian, tubal, and peritoneal carcinoma (Dennis S. Chi)

OVM1010: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus a Biological Agent (Subcutaneous Urokinase Plasminogen Inhibitor Â6 or Bevacizumab or VargatefTM (BIBF1120)) In Patients With Small Volume Disease (Biochemical Recurrence) Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jean A Hurteau)

OVM1011: A Randomized Phase III Trial of Carboplatin and Pegylated Doxorubicin (PLD) Versus Dose-Dense Paclitaxel and Carboplatin in Platinum Sensitive Recurrent Ovarian and Primary (Stephen L Rose)

OVM1012: A Randomized Phase III Trial of Chemotherapy Doublet With or Without ABT888 in Platinum Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (213R) (Bradley J Monk)

OVM1013: Phase III multicenter; randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (Bradley J Monk)

OVM1014: A Randomized Phase III Trial Evaluating the Use of Tamoxifen Versus Pazopanib in Patients with Biochemical Recurrent Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy (Jay W Carlson)

OVM1016: A Phase III Study of Neoadjuvant Chemotherapy and Tumor Debulking Followed by I.V. vs. I.P. Chemotherapy (Michael M Frumovitz)

OVM1017: A Phase III Trial comparing Paclitaxel, Carboplatin, Bevacizumab with or without Sorafenib in patients with Recurrent, Platinum Sensitive Ovarian Carcinoma (GOG 213R) (Charles A Leath)

OVM1018: Phase III, Randomized Open-Label Study of NKTR-102 Versus Pegylated Liposomal Doxorubicin as Second-Line Therapy in Recurrent Platinum-Resistant Ovarian Cancer (Robert L Coleman)

OVM1020: (GOG212R) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with primary ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to primary platinum-taxane chemotherapy (David M O’Malley)

OVM1021: (213R) A phase III trial comparing carboplatin/paclitaxel (dose dense), carboplatin/PLD and carboplatin/gemcitabine regimens all of which contain Bevacizumab stratified by prior Bevacizumab exposure. (David M O’Malley)

OVM1022: (GOG213R/212R-Recurrence) A randomized phase III trial of maintenance chemotherapy comparing treatment with weekly paclitaxel versus biweekly bevacizumab versus combination weekly taxane and biweekly bevacizumab versus observation until documented relapse in women with recurrent ovarian, primary peritoneal or fallopian tube cancer who achieve a complete clinical response to secondary platinum-based chemotherapy. (David M O’Malley)

OVM1023: A randomized placebo controlled trial of pegylated liposomal doxorubicin (PLD) and carboplatin with or without the CTEP-Supplied PARP inhibitor ABT-888 (NSC #737664 IND# 77840) in platinum sensitive recurrent ovarian cancer (Deborah Armstrong)
OVM1024: A Phase III Trial Of Carboplatin And Dose Dense Paclitaxel Plus Placebo Versus Carboplatin And Paclitaxel Plus Concurrent And Extended AMG-386, In Women with Newly Diagnosed, Previously Untreated, Stage III or IV, Epithelial Ovarian, Primary Peritoneal Or Fallopian Tube Cancer (Robert M Wenham)

UC1007: A Phase II trial of BN83495 in the treatment of patients with recurrent, persistent or metastatic ER positive and ER negative endometrial cancer. (David S. Miller)

UC1009: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley)

UC1010: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bander)

UC1012: Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim)

UC1015: Randomized phase III trial of lymphadenectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy)

ADS1018: Detailed profile of chemotherapy associated neurotoxicity in ovarian cancer survivors (Steven C Plaxe)

ADS1020: Factors associated with toxicity in women with gynecologic cancers (Bradley J Monk)

QUESTIONS/DISCUSSION

EVALUATION
Radiation Oncology Workshop
Boston, MA

Chair: Ivy A. Peterson, MD

Friday, July 16, 2010 - 1:00 – 5:00 pm

Learning Objectives

Following this activity, participants will be better able to:

- Discuss the use of IMRT in endometrial and cervical cancer and the radiation quality assurance issues important in these patients
- Explain the impact of review of treatment films in ongoing randomized GOG trials
- Discuss radiation aspects of current concepts under review / in process within GOG
- Evaluate the impact of new concepts on the mission of GOG with respect to the role of radiation therapy

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

A. Review of January 2010 meeting

B. Updates/presentations
   1. RPC report
   2. Chart review results
   3. IMRT use report

C. Cervix / Vulvar Studies
   1. Review of Phase I Studies
   2. Review of Phase III Studies
   3. Concepts/Protocols in Process

D. Endometrial Studies
   1. Review of Phase I Studies
   2. Review of Phase III Studies
   3. Review of Concepts / Protocols in Process

E. Ovarian Studies

F. Old Business

G. New Business
   1. Evaluation of QA process of IMRT cases
   2. QA for CVM 1004

H. Educational Session –IMRT volume committee presentation/discussion
Rare Tumor Workshop
Boston, MA

Chair: David M. Gershenson, MD
Co-Chair: Allan L. Covens, MD

Session I  July 15, 2010  4:00 – 5:30 pm

Learning Objectives

Following this activity, participants will be better able to:

- Outline challenges and potential solutions involved in conducting clinical trials of rare gynecologic malignancies
- Discuss emerging and ongoing GOG clinical trials on rare gynecologic cancers
- Discuss promising translational research objectives and priorities for future clinical trials
- Discuss rationale for triaging women with specific rare tumors to separate clinical trials

Workshop materials are available for download prior to the meeting on the GOG website
Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Workshop Agenda

SESSION I

A. Closed Studies

None

B. Active Studies

GOG 0187: A phase II study of paclitaxel for ovarian stromal tumors as second-line therapy (Homesley)
GOG 0239: A phase II trial of AZD6244 (NSC 741078) in women with recurrent low-grade serous carcinoma of the ovary and peritoneum (Farley)
GOG 0251: A phase II trial of bevacizumab (rhuMAB VEGF) for recurrent sex cord-stromal tumors of the ovary (Brown)
GOG 0254: A phase II evaluation of SU 11248 (sunitinib malate) in the treatment of persistent or recurrent clear cell ovarian carcinoma (Chan)
RTM 0264: A 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 (Brown)

C. Proposed Studies

GOG-0241 (RTM0412): A CGIG Intergroup Multicentre Phase III Trial of Open Label Carboplatin and Paclitaxel +/- Bevacizumab Compared with Oxaliplatin and Capecitabine +/- Bevacizumab as First Line Chemotherapy in Patients with Mucinous Epithelial Ovarian Cancer (MEOC) (David Gershenson)
RTM0905: A Phase II Study of dasatinib in the Treatment of Vulvovaginal Melanoma Harboring Somatic Alterations of c-KIT (Mario M. Leitao, Jr.)
GOG-0268 (RTM0907): A Phase II Evaluation of Sunitinib Malate (Stutent ® SU11248, NCI-Supplied agent, NSC#736511, IND #74019) in Combination with Carboplatin and Paclitaxel as First-line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary. (John H. Farley)
Chair: David Scott Miller, MD  
Co-Chair: Marcus Randall, MD  

Session I:  July 16, 2010  8:00 am – 10:00 am  
Session II: July 17, 2010  10:00 am – 12:00 pm  

Learning Objectives  
Following this activity, participants will be better able to:  
• Discuss current and emerging research priorities of the Uterine Corpus Committee  
• Discuss proposed and ongoing GOG clinical trials on the prevention, diagnosis, and treatment of uterine corpus malignancies  
• Apply standards and procedures required to design, submit, and conduct a research protocol for support by the GOG  

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room  

Workshop Agenda  
A. GOG Site Visit Review (Miller)  
B. Closed Studies  
C. Active Studies  
1. Endometrial Protocols  
2. Uterine Sarcoma Protocols  
3. Gestational Trophoblastic Disease Protocols  
D. Approved Concepts/Protocols  
E. Proposed Concepts  
1. Primary review  
2. Secondary review  
F. New Business  
1. Report from Subcommittee on Gestational Trophoblastic Disease (Schink)  
2. Report from GOG-0210 Scientific Advisory Board (McMeekin)  

QUESTIONS / DISCUSSION  
EVALUATION
B. Review of Closed Studies

1. **GOG-0087M**: A Phase II Evaluation of Trabectedin (Yondelis, R279741, IND #75,111) in the Treatment of Advanced, Persistent, or Recurrent Uterine Leiomyosarcomas (Bradley J Monk): To be reviewed by Sutton

2. **GOG-0129Q**: A Phase II Evaluation of Gemcitabine (Gemzar, LY188011) in the Treatment of Recurrent or Persistent Endometrial Carcinoma (Eli Lilly Study B9E-US-X472) (0129 series) (David L Tait): To be reviewed by McMeekin

3. **GOG-0130E**: Evaluation of Docetaxel and Gemcitabine in Recurrent or Persistent Carcinosarcoma of the Uterus (130 Series) (Brigitte E Miller): To be reviewed by Sutton

4. **GOG-0167**: A Two-Part Study of the Treatment of Atypical Endometrial Hyperplasia: Part A: A Prospective Study of Immediate Hysterectomy; Part B: A Randomized Phase II Study of Medroxyprogesterone Acetate Versus Depo-Provera (John P Curtin): To be reviewed by Mutter

5. **GOG-0168**: A Phase II Study of Anastrozole (Arimidex) in Advanced Recurrent or Persistent Endometrial Cancer (Peter Rose): Gyn Onc 78:212 ’00

6. **GOG-0174**: A Randomized Phase III Trial of Weekly Parenteral Methotrexate versus "Pulsed" Dactinomycin as Primary Management for Low Risk Gestational Trophoblastic Neoplasia (Raymond Osborne): To be reviewed by Schink

7. **GOG-0184**: Tumor Volume-Directed Pelvic Plus or Minus Para-Aortic Irradiation followed by Cisplatin and Doxorubicin or Cisplatin, Doxorubicin and Paclitaxel for advanced Endometrial Carcinoma (Howard D Homesley): To be reviewed by Mutch

8. **GOG-0188**: Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma (Allan L Covens): To be reviewed by Leslie.

9. **GOG-0209**: A Randomized Phase III Trial of Doxorubicin/Cisplatin/ Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III & IV or Recurrent Endometrial Cancer (David Scott Miller)

10. **GOG-0211**: An Investigation of the Relationship of Short Term Depo-Provera (Medroxyprogesterone Acetate) Exposure to the Morphologic, Biochemical, and Molecular Changes in Endometrial Adenocarcinoma (Richard Zaino): To be reviewed by Leslie

11. **GOG-0229E**: A phase II evaluation of bevacizumab in the treatment of persistent or recurrent endometrial carcinoma (Carol Aghajanian)

12. **GOG-0229G**: A Phase II Evaluation of Combination Bevacizumab (NCI-Supplied Agent: NSC #704865, IND #7921) and Temsirolimus (CCI-779, NCI-Supplied Agent: NSC #683864, IND #61010) in the Treatment of
Recurrent or Persistent Endometrial Carcinoma (Edwin Alvarez): **To be reviewed by McMeekin**

13. **GOG-0230B**: A Phase II Evaluation of Thalidomide (NSC #66847, IND #48832) in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus (*D. Scott McMeekin*)

14. **GOG-0232B**: Phase II Evaluation of Paclitaxel (Taxol, NSC #673089) and Carboplatin (Paraplatin, NSC #241240) in the Treatment of Carcinosarcoma of the Uterus (*Matthew Powell*)

15. **GOG-9402**: Laparoscopic Staging in Patients with Incompletely Staged Endometrial Carcinoma or Uterine Sarcoma (*Nicola Spirtos*): *Am J Obstet Gynecol 193(5) 1645-9, 2005*

16. **GOGLAP2**: A Phase III Randomized Clinical Trial of Laparoscopic Pelvic and Para Aortic Node Sampling With Vaginal Hysterectomy and BSO Versus Open Laparotomy with Pelvic and Para Aortic Node Sampling and Abdominal Hysterectomy and BSO in Endometrial Adenocarcinoma and Uterine Sarcoma, Clinical Stage I, IIA, Grade I, II, III (Joan Walker): **To be reviewed by Spirtos**

**C. Review of Active Studies**

1. Endometrial Protocols:

   a. **GOG-0086P**: A three arm randomized phase II study of paclitaxel/carboplatin/bevacizumab (NSC #704865, IND #7921), paclitaxel/carboplatin/temsirolimus (NSC #683864, IND #61010), and Ixabepilone (NSC#710428 IND # 59699)/carboplatin/bevacizumab as initial therapy for measurable stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (*Carol Aghajanian*)

   b. **GOG-0210**: A Molecular Staging study of Endometrial Carcinoma (William T Creasman): **To be reviewed by McMeekin**

   c. **GOG-0224**: A Randomized, Controlled Phase II Evaluation of Megestrol (Megace) In Different Dose And Sequence In The Treatment Of Endometrial Intraepithelial Neoplasia (EIN) From A Referred Cohort Of Atypical Endometrial Hyperplasia (AEH) Or EIN: **To be reviewed by Mutter**

   d. **GOG-0229I**: 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*)

   e. **GOG-0229I**: A Phase II Evaluation of Cediranib (RECENTIN; AZD2171) in the Treatment of Recurrent or persistent Endometrial Cancer (David P Bender): **To be reviewed by McMeekin**

   f. **GOG-0238**: A Randomized Trial of Pelvic Irradiation with or Without Concurrent Weekly Cisplatin in patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus (Higinia R Cardenes): **To be reviewed by Schink**

   g. **GOG-0248**: Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy plus Temsirolimus in Women with Advanced or Recurrent Endometrial Cancer (Gini Fleming): **To be**
h. **GOG-0249**: Randomized Phase III Trial of Pelvic Radiation Therapy vs. Vaginal Cuff Brachytherapy + 3 cycles Paclitaxel/Carboplatin Chemotherapy (McMeekin)

i. **GOG-0258**: A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma. (Daniela Matei): **To be reviewed by Mutch**

j. **GOG-9920**: A Phase I Study of IV Plus Peritoneal (IP) Chemotherapy in Endometrial Cancer Patients at high Risk for Peritoneal Failure (D. Scott McMeekin)

2. **Uterine Sarcoma Protocols**:

a. **GOG-0232C** A Phase II Evaluation of Paclitaxel (Taxol, NSC #673089), Carboplatin (Paraplatin, NSC #241240), and BSI-201 in the Treatment of Advanced, Persistent, or Recurrent Uterine Carinosarcoma (Carol Aghajanian)

b. **GOG-0250**: 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)

c. **GOG-0261** A Randomized Phase III trial of Paclitaxel plus Carboplatin versus Ifosfamide Plus Paclitaxel in Chemotherapy Naive Patients with Newly Diagnosed Stage I-IV, Persistent or Recurrent Carinosarcoma (Mixed Mesodermal Tumors) of the Uterus (Matthew A Powell)

3. **Gestational Trophoblastic Disease Protocols**

a. **GOG-0242** Second Curettage: First-Line Management for Patients with Persistent Low-Risk Gestational Trophoblastic Disease [GTN] (Raymond Osborne): **To be reviewed by Schink**

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

a. **UC0904**: A Prospective Randomized Trial of Hysterectomy Bilateral Salpingo-Oophorectomy with and without aortic and pelvic lymphadenectomy in Patients with Stage IA (Grade 1, 2, 3) and IB (Grade 1and 2) endometrial cancer (Spirtos)

b. **UC1005**: A sequential phase II/III randomized trial comparing three widely used regimens for the management of low risk gestational trophoblastic neoplasia (John Tidy): **To be reviewed by Schink**

c. **UC1007**: A Phase II trial of BN83495 in the treatment of patients with recurrent, persistent or metastatic ER positive an ER negative endometrial cancer (David S. Miller)

E. Primary Review
a. **UC1008**: Aromatase Inhibition as Adjuvant Therapy for High-Risk and Advanced Estrogen Receptor-positive Endometrial Carcinoma (Jennifer F De Los Santos): To be reviewed by Filiaci, Leslie

b. **UC1009**: A Phase III randomized trial of gemcitabine plus docetaxel followed by doxorubicin v. letrozole for early stage high grade uterine leiomyosarcoma (Martee L Hensley): To be reviewed by

c. **UC1010**: A Phase III randomized clinical trial of laparoscopic pelvic/para-aortic node resection and hysterectomy/BSO versus robotic hysterectomy/BSO and pelvic and para-aortic node resection in endometrial adenocarcinoma and carcinosarcoma, clinical stage I Grades I-III (Christina Bandera): To be reviewed by

d. **UC1011**: Predictive value of modeled hCG clearance in patients with low-risk gestational trophoblastic neoplasias enrolled in UC1005 trial (Raymond Osbourne): To be reviewed by Schink

e. **UC1012**: Defining the Prognostic Role of Low Uterine Segment Involvement in Endometrial Cancer (Israel Zighelboim): To be reviewed by Mutter

f. **UC1013**: Defining the Role of Microsatellite Instability in Endometrial Cancer (Israel Zighelboim): To be reviewed by

g. **UC1014**: A Phase II Trial of Gemcitabine and Cisplatin in Patients with Advanced or Recurrent Endometrial Cancer (Jubilee Brown): To be reviewed by McMeekin

h. **UC1015**: Randomized phase III trial of lymphadenectomy in high risk patients with endometrial cancer (LYTEC) (Sean C Dowdy): To be reviewed by Spirtos

**Secondary Review:**

a. **ADS1019**: A retrospective comparison of toxicity events according to baseline creatinine clearance in patients with cervical, ovarian or endometrial cancer treated with platinum-based chemotherapy on GOG-trials (Paul Sabbatini): To be reviewed by Blank, Yashar

b. **CEM1005**: Evaluation of BRCA1 and 2 expression in papillary serous endometrial carcinoma (Thomas C Krivak): To be reviewed by Leslie

c. **CEM1006**: Micro RNA Expression Patterns in Endometrial Cancer Tumors and Biological Specimens (Kimberly K Leslie): To be reviewed by Leslie

d. **DTM1012**: A Phase II Evaluation of Vorinostat in the Treatment of Recurrent or Persistent Leiomyosarcoma of the Uterus (Martee L Hensley): To be reviewed by Powell, Sutton

e. **DTM1013**: Paclitaxel, Carboplatin and ABT-888 in recurrent or persistent endometrial carcinoma (86 series) (Linda R Duska): To be reviewed by Campos, McMeekin

f. **PIS1006**: Phase I Study of Intravenous Ifosfamide and Paclitaxel Chemotherapy followed by Radiation with Intravenous Cisplatin and Consolidation Therapy with Intravenous Paclitaxel and Carboplatin for uterine Carcinosarcoma (Anthony C Evans): To be reviewed by Lele, McMeekin

g. **RTM1006**: Molecular changes in large cell neuro endocrine carcinoma of the uterus (Shashikant B Lele): To be reviewed by Powell, Sutton

**F. New Business**
Learning Objectives

- Participants will become familiar with the current status of vaccine studies that are under development or activated for accrual.
- New concepts will be reviewed for approval or disapproval, including a discussion of preclinical and early clinical data related to investigational agents (as appropriate).
- Integration and prioritization of studies will be reviewed with reference to disease-site committees and the Committee on Experimental Medicine.
- Recommendations for action by the Protocol Development Committee will be summarized.

Workshop materials are available for download prior to the meeting on the GOG website Member Section (www.gog.org - Access ID required); or onsite in the IT Resource Room

Vaccine Studies (Active and Under Development):

CERVICAL CANCER

- DTM0941 (DTM0817) A randomized phase II study of E2 peptide vaccine + GM-CSF + montanide versus GM-CSF + montanide in HLA A2 positive patients with HPV16 associated early cervical lesions (LSIL or ASCUS) (S. Khleif). Concept JAN08. NCI Division of Cancer Prevention (DCP) approved pending response 3.5.10 (protocol due by the end of March 2011). 2:1 randomization. 200 patients.

OVARIAN CANCER

- GOG-0255 A phase II randomized, double-blind trial of a polyvalent vaccine-KLH conjugate (NSC 748933) + 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). Protocol UD.

New Vaccine Concepts

QUESTIONS / DISCUSSION
EVALUATION
Boehringer Ingelheim is committed to oncology research in the areas of:

- Angiogenesis Inhibition
- Signal Transduction Inhibition
- Cell Cycle Kinase Inhibition

Boehringer Ingelheim is a proud sponsor of the Gynecologic Oncology Group

Exhibit Booth #8
Gynecologic Oncologist

CHICAGO AREA

Advocate Medical Group (AMG), a multi-specialty organization comprised of over 900 physician members, seeks a qualified Gynecologic Oncologist to join our team. The ideal candidate for this exciting position will be a board certified / board eligible gynecologic oncologist with vision and a commitment to cancer services. The incumbent will participate in the provision of quality medical care while assuring optimal patient outcomes.

AMG physicians practice at Advocate Christ Medical Center (ACMC), a leading academic medical center located in the suburbs of Chicago. ACMC is part of Advocate Health Care, Chicago’s largest provider of care and one of the nation’s leading integrated health systems. ACMC’s cancer program offers multi disciplinary, collaborative capabilities to nearly 1,600 newly diagnosed cancer patients each year. Approved by the Commission on Cancer for the American College of Surgeons as a Teaching Hospital Cancer Program, services are provided to patients with nearly every type of cancer. ACMC is nationally renowned for the use of innovative technologies including the daVinci Robotics® and CyberKnife® radiosurgery. Coupled with a new 22 bed dedicated, state of the art, inpatient unit, ACMC provides cancer care that is second to none.

This position is full time, salary is competitive and the benefit package includes family medical coverage, malpractice insurance, pension plan, and vacation.

To be considered for this outstanding opportunity,
Please forward a CV and cover letter to:
Yvonne Collins, MD, FACOG
c/o Donna Kutka, RN, MS, Director, Physician Recruitment
donna.kutka@advocatehealth.com, or by fax: 708.684.4524
Or for more information, call 708.684.5009
EXHIBIT INFORMATION

The purpose of the exhibits is to allow companies an opportunity to inform the membership about drugs, supplies and services that are available in the field of gynecologic oncology. Please take the time to visit the exhibit booths located in the Grand Ballroom and Liberty Foyer.

Advocate Christ Medical Center
American Express
Belmont Instrument Corp
Boehringer Ingelheim Pharmaceuticals, Inc.
Caris Life Sciences
Centocor Ortho Biotech Products, L.P.
CTSU
Fujirebio Diagnostics, Inc
Genzyme Biosurgery
GlaxoSmithKline
GOG Cancer Prevention and Control Committee
Gynecologic Cancer Foundation
ImpediMed, Inc.
International Gynecologic Cancer Society
Laclede Inc.
Olympus
PharmaNet Development Group
Precision Therapeutics
Society of Gynecologic Oncologists
Vermillion, Inc.

Exhibit hours are:

Friday, July 16, 2010 - 7:00 am - 5:00 pm
Saturday, July 17, 2010 - 7:00 am - 1:00 pm

Complimentary coffee, tea and soft drinks will be served in the exhibit area at specified times on each day that exhibits are open.
EXHIBIT INFORMATION
The Gynecologic Oncology Group wishes to acknowledge the following exhibitors.

ADVOCATE CHRIST MEDICAL CENTER
The mission of Advocate Health Care is to serve the health needs of individuals and communities through a holistic philosophy rooted in our fundamental understanding of human beings as created in the image of God.

BELMONT INSTRUMENT CORPORATION
The Belmont Hyperthermia Pump is designed to be a safe and simple system for rapid circulation of warmed fluids and lavage therapy. It features a patented super efficient electromagnet induction heating technology which delivers fluid at a user-specified target temperature in a single pass. The Hyperthermia Pump continuously monitors both the infusion process and the control system for unsafe conditions with a built-in monitoring/alarms system.

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.
Boehringer Ingelheim Pharmaceuticals, Inc., (Ridgefield, CT) is a research-driven company dedicated to researching, developing, manufacturing and marketing pharmaceuticals that improve health and quality of life.

CANCER TRIALS SUPPORT UNIT (CTSU)
To provide demonstrations of and information about the CTSU’s Oncology Patient Enrollment Network (OPEN), the patient registration system that has been developed for NCI Cooperative Group trials.

CARIS LIFE SCIENCES
Caris Life Sciences is a provider of world-class anatomic pathology and hematopathology services coupled with advanced molecular analyses and proteomic/genomic tumor profiling for physicians who identify, treat and manage cancer.

CENTOCOR ORTHO BIOTECH PRODUCTS, L.P.
Centocor Ortho Biotech Products, L.P. harnesses innovations in large- and small-molecule research to create important new therapeutic options. The company also is at the forefront of developing education and public policy initiatives to ensure patients, caregivers, advocates, and healthcare professionals have access to the latest treatment information, support services, and quality care.

FUJIREBIO DIAGNOSTICS, INC.
Fujirebio Diagnostics, Inc. (FDI) is a premier diagnostics company and the industry leader in the development of oncology biomarkers. Fujirebio Diagnostic's primary focus is the development, manufacture, and commercialization of in vitro diagnostic oncology products. Our core products include CA 125II a biomarker considered the gold standard for ovarian cancer. The Fujirebio Diagnostics HE4 is a new biomarker now cleared in the U.S. as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer.

GENZYME BIOSURGERY
Seprafilm Adhesion Barrier (Genzyme Corporation) is indicated to reduce the incidence, extent, and severity of postoperative adhesions. FDA approved in 1996 for abdominopelvic laparotomies, Seprafilm has been studies in more than 20 published clinical reports and over 4,000 patients. More than 1,000,000 patients have been treated with Seprafilm since 1996.

GOG CANCER PREVENTION AND CONTROL COMMITTEE
Our objective is to provide information to the broader GOG membership about ongoing and upcoming CPC studies.

GYNECOLOGIC CANCER FOUNDATION
The Gynecologic Cancer Foundation (GCF) is the foundation of the Society of Gynecologic Oncologists (SGO). GCF’s mission, in concert with SGO, is to support research, education and public awareness of gynecologic cancer prevention, early diagnosis and optimal treatment.

GLAXOSMITHKLINE
GlaxoSmithKline offers a number of programs to support effective health management strategies and improve patient care. Visit our exhibit for information about our products and programs.
IMPEDIMED, INC.

Introduce GOG members to a new FDA cleared technology for assisting the clinician in the assessment of subclinical Lymphedema; demonstration of device for GOG0812 in conjunction with Dr. Joy Carlson.

INTERNATIONAL GYNECOLOGIC CANCER SOCIETY

The IGCS is a non-profit, international organization working toward the prevention and treatment of gynecologic cancer and toward improving the quality of life of women suffering from gynecologic cancer throughout the world. It has over 1,700 members in more than 75 countries and is involved in educational efforts around the globe.

LACLEDE, INC.

Laclede incorporated is the manufacturer of Luvena vaginal moisturizer. Luvena is a safe and natural lubricant and moisturizer that contains pre-biotic ingredients and enzymes proven to help restore a healthy pH to the vagina. Helps eliminate dryness, unpleasant odor, and itchiness.

OLYMPUS

Olympus and Gyrus, two of the world’s leading suppliers of minimally invasive surgical technologies have joined forces to create a more versatile organization. The best in class tissue management systems of Gyrus ACMI perfectly compliment the innovative array of world class medical systems and leading-edge Opto Digital technology offered by Olympus.

PHARMANET DEVELOPMENT GROUP

PharmaNet Development Group, a global, drug development services company, provides expertise to the pharmaceutical, biotechnology, generic drug, and medical device industries. PharmaNet companies offer clinical development solutions including consulting services, Phase I clinical studies, bioequivalence and pharmacodynamic studies, bioanalytical analyses, and Phase II, III, and IV clinical development programs. With more than 2,300 professionals in 43 offices around the world, PharmaNet is a recognized leader in outsourced clinical development.

PRECISION THERAPEUTICS

Precision Therapeutics is a life sciences company dedicated to providing physicians and patients with actionable clinical information to personalize cancer treatments. Precision’s ChemoFx®, a proprietary live tumor cell-based platform, measures an individual patient’s tumor sensitivity and resistance to a range of therapeutic alternatives under consideration by a physician.

SOCIETY OF GYNECOLOGIC ONCOLOGISTS

The SGO is an organization of multidisciplinary women’s cancer specialists trained in the comprehensive management of women with gynecologic cancers. Its purpose is to promote and ensure the highest quality prevention, research and treatment for women including screening, chemotherapy, radiation therapy, surgery and supportive care. Our current initiatives include promoting the cancer control team’s role in advocating for women’s cancer research, prevention, treatment and palliation. In addition, SGO offers a wide range of educational products, conferences and leadership opportunities to further develop collaborative exchange between cancer control team members. More information on the SGO can be found at www.sgo.org.

VERMILLION, INC.

Vermillion, Inc. is dedicated to the discovery, development and commercialization of novel high value diagnostic tests that help physicians diagnose, treat and improve outcomes for patients. Vermillion, along with its prestigious scientific collaborators has ongoing diagnostic programs in oncology/hematology, cardiology and women’s health with an initial focus in ovarian cancer.

The Exhibitors make a significant contribution to the educational value of the GOG Meeting. If your organization would like to apply for exhibit space at our upcoming meetings, please contact:

Director of Exhibits
Gynecologic Oncology Group, Administrative Office
Phone - 215-854-0770, Email - dmackey@gog.org

GOG 81st Semi-Annual Summer Meeting 2010
The Gynecologic Oncology Group wishes to thank Eli Lilly & Company for their educational grant support associated with this Semi Annual Meeting.
Save the

For the Gynecologic Oncology Group
82nd Semi-Annual Meeting

January 27 - 30, 2011
Manchester Grand Hyatt, San Diego, CA

Registration Opens October 2010
Save the Date for these upcoming meetings!

January 28-30, 2011
Manchester Grand Hyatt
San Diego, CA
(Symposium - January 27)

July 15-17, 2011
Philadelphia Marriott Downtown Hotel
Philadelphia, PA
(Symposium - July 14)

January 27-29, 2012
Manchester Grand Hyatt
San Diego, CA
(Symposium - January 26)

July 27-29, 2012
Sheraton Hotel
Boston, MA
(Symposium - July 26)

January 25-27, 2013
Manchester Grand Hyatt
San Diego, CA
(Symposium - January 24)

July 19-21, 2013
Marriott River Center
San Antonio, TX
(Symposium - July 18)

January 24-26, 2014
Manchester Grand Hyatt
San Diego, CA
(Symposium - January 23)

July 18 - 20, 2014
Hyatt Regency Chicago
Chicago, IL
(Symposium - July 17)

January 23-25, 2015
Manchester Grand Hyatt
San Diego, CA
(Symposium - January 22)

Visit the GOG Website at www.gog.org for daily updates.