Chair’s Corner

Update: Cooperative group system developments

During these times of great change I will use this platform to try to keep you abreast of future developments within the cooperative group system.

It would appear that the new funding opportunity application (FOA), previously known as the RFA, will be forthcoming. Sometime in 2012 our application will be submitted as multiple principal investigators in an alliance of GOG, NSABP and RTOG. At this point it would appear that there would be a separate grant for statistical office support however, the grant application must describe how all the components work together. Review of the grant application will take place in early 2013 following submission in the fall of 2012. Funding will probably be in early 2014. Our group and all groups will be funded through noncompetitive grants or supplements until the final awards are made.

A similar mechanism will be in place for funding the biorepositories through the U24 grant mechanism. The applications will follow the FOA for the cooperative groups themselves. There are many rumors about how many banks will be allowed but no final decision has been made to date. In addition, imaging and radiation therapy core services will be established as a new program. These core services will provide quality control for radiology and radiation oncology within the groups. More details on this new endeavor will be forthcoming.

At this point in time U10 grants for translational science are anticipated. The fact that these grants will be part of the future of the cooperative group system is a welcome addition. What structure the application will take awaits further review of a draft FOA which hopefully will be seen sometime in 2012. There are a lot of changes going on at one time and I am sure this creates a budgetary nightmare for the NCI which must absorb a three percent cut this year. How all of these changes will be financed given the budgetary restraints is a question that no one has satisfactorily answered as of yet. Most of the inquiries have been referred to the Director of the NCI. Whatever the changes, the GOG will accommodate and thrive as we have in the past.
GOG and GOG Partners Trial Development

GOG investigators and GOG Industry partners submit concepts in the same way for CTEP sponsored trials and GOG Partners trials. The GOG and Partners Concept form is available on the GOG Website. Instructions are provided to submit to Protocol-concepts mailbox. One difference between the two processes is that a Partners submission may be reviewed outside of the normal meeting deadlines. There is also the opportunity for rapid development of key studies through the Partners mechanism. The decision for rapid development is the Group Chair’s in consultation with the Chairs of the Protocol Development Committee (PDC), the Operations Committee (OC) and the GOG Partners Task Force.

Committee review is conducted in the same way for both CTEP and Partners proposals. The primary managing committee, e.g., DTM or OVM, reviews the concept for scientific merit and how it may advance patient care. If the concept is approved at the committee level, the concept is referred to PDC. If a Partners proposal is reviewed outside of the semi-annual meeting, appropriate input will be obtained from members of the primary managing committee prior to review by the PDC.

For protocols developed with NCI, once the concept is approved, for proposed trials of less than 100 patients and/or using investigational agent, an LOI is submitted to CTEP. For Phase III and Randomized Phase II trials of greater than 100 patients, the concept is submitted to an NCI disease specific task Force.

If the LOI is approved, protocol development proceeds and the protocol ultimately is submitted to NCI for consensus review. Under the Operational Efficiency Working Group (OEWG) guidelines, this process takes approximately nine to twelve months from LOI approval to protocol approval and activation.

If the disease specific task force approves the concept, then the protocol is developed for submission to the Gynecologic Cancer Steering Committee (GCSC). If GCSC approves the concept, a full protocol is developed to submit to CTEP for consensus review. Under the OEWG guidelines this process takes approximately twelve to eighteen months from GCSC submission to protocol approval.

For protocols developed through Partners Mechanism, the protocol template is provided to the study team for protocol development. Partners’ trials require the same levels of internal review as NCI trials to assure the scientific integrity of trial design and to obtain input from appropriate modalities. Projected time from PDC concept approval to trial activation is six months or less.

Internal layers of review will be the same for both mechanisms. The study team is comprised of the Study Chair, Co-chair, Medical oncologist and/or Gynecologic oncologist and Radiation oncologist depending on the trial design, Statistician, Nurse, Data Manager, Regulatory and Protocol Administrator. Once protocol documents are drafted they undergo team review. The GOG Human Research Committee reviews the protocol for patient safety and a final technical review is conducted prior to NCI Submission, or in the case of Partners trial, prior to activation.

In Memorium: George Omura, M.D.

Dr. George Omura passed away on April 19, 2011. Born on April 30, 1938 in New York City, NY, he went on to attend Cornell University Medical College and completed his residency in Internal Medicine at Bellevue and New York Hospital/Cornell, as well as a fellowship in Hematology/Oncology at Memorial Sloan-Kettering Cancer Center. Dr. Omura served as a lieutenant in the US Navy from 1964 -1966. He joined the faculty at University of Alabama in 1970 as Professor of Medicine in Hematology/Oncology. Dr. Omura was named Professor Emeritus of Gynecologic Oncology upon retiring in 1995.

He was a member of the Gynecologic Oncology Group for 25 years. He led several of the earlier studies by the GOG, as can be documented in the list of GOG publications. He was past chair of the GOG Publications Sub-committee and in that capacity was an active participant of the GOG Protocol Committee.

Dr. Omura could always be counted on for voting “against the crowd” if he believed that an important point was overlooked. In fact, his low-key arguments often prevailed, reflecting his logical thinking and uncompromising toughness against inadequate solutions to problems.

OvaGene Oncology, A focused approach towards personalizing gynecologic cancer care

Latest News from OvaGene!
The announcement we have all been waiting for... OvaGene Oncology has received CLIA-certification for our newly constructed advanced molecular diagnostics laboratory. We will begin accepting clinical specimens for diagnostic testing in October 2011.

First Product Offerings
Our proprietary Endometrial Recurrence Risk Assay using the Stathmin (STMN-1) biomarker will be one of the first tests launched along with other complementary assays. Recently published clinical studies on over 1,000 endometrial cancer patients correlates strong expression of STMN-1 to lymph node metastasis and poor survival. We welcome the opportunity to share this compelling data with the gynecologic oncology community.

Interested in Future Products?
Over the next few months, we will continue to expand our product offerings with additional assays specifically designed to assess ovarian and cervical cancers. We look forward to becoming your trusted provider of innovative gynecologic oncology diagnostics. If you would like to join our mailing list to receive updates, please e-mail your request and contact information to info@ovagene.com or visit our website at www.ovagene.com to fill out the Contact Us form.
The Office for Human Research Protections (OHRP) has announced the availability of the revised Federal-wide Assurance (FWA) form, Terms of Assurance and related documents, which have been approved by the Office of Management and Budget (OMB).

On September 23, 2010, OHRP published a Federal Register notice to solicit public comment on several proposed changes to the FWA and Terms that would simplify and shorten the FWA form and Terms of Assurance approved for use by OMB through May 31, 2011, under Control Number 0990-0278. Six individuals and two organizations submitted comments on the proposed changes; the majority supported the changes.

The revised OMB-approved FWA form and terms of Assurance have been approved for use through June 30, 2014 and adopted the changes in the FWA form and terms of assurance largely as proposed in the September 2010 notice. The key changes in the revised form and terms are the following:

(i) The revised FWA form replaces a requirement that all IRBs (both internal and external IRBs) relied upon by the institution be specifically designated with a requirement that only internal IRBs be specifically designated or that, if an institution does not have an internal IRB, only one external IRB be specifically designated. All IRBs must be registered with OHRP before they can be designated on an OHRP-approved FWA.

(ii) The revised FWA form allows the FWA to be signed electronically by the institution's signatory official, eliminating the prior need for submission of a hard-copy signature page by mail or facsimile. OHRP now require that institutions submit all FWAs (including new submissions, updates, and renewals) using the electronic submission system available through the OHRP website at http://ohrp.cit.nih.gov/efile/, unless an institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email and explain why it is unable to submit its FWA electronically.

(iii) The standard period of approval for an FWA is increased from a 3-year period to a 5-year period.

(iv) The prior separate FWA forms for U.S. and non-U.S. institutions are combined into a single form that will still collect the same basic information previously requested in the separate forms, except as noted in items (i) and (vii).

(v) The Terms of Assurance document is shortened and simplified. In the prior version, some portions of the text appeared twice; those duplications were eliminated by re-organizing portions of the document. In addition, there were several items covered in the prior version that OHRP no longer sees as necessary to include, or which are addressed in the FWA form itself. These items have been eliminated from the Terms of Assurance document.

(vi) International institutions no longer have a separate FWA form or separate Terms of Assurance.

(vii) The revised FWA form no longer requests submission of the HHS Institution Profile code or the Federal Entity Identification number.

The OMB-approved revised FWA documents are posted on OHRP's website at:

http://www.hhs.gov/ohrp/assurances/forms/index.html

OHRP has posted on its website a revised set of Frequently Asked Questions and Answers (FAQs) on the Assurance Process that can be accessed at:

http://answers.hhs.gov/ohrp/categories/1563

These FAQs include information on recent changes in the Federalwide Assurance (FWA) form and Terms of Assurance, which have been approved by the Office of Management and Budget (OMB).
Let's Think

Boehringer Ingelheim is committed to oncology research in the areas of:

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

Boehringer Ingelheim recognizes the efforts of GOG investigators and their endeavor to advance patient care.

If you are a healthcare professional who may be interested in becoming a clinical investigator, please visit us at www.inoncology.com.
Satellite Symposium speakers address management of ovarian cancer


The speakers for the event titled Integrating Emerging Therapies Into Optimal Treatment Decision-Making for Patients With Ovarian Cancer, included: Bradley J. Monk, MD (chairperson) from Creighton University School of Medicine at St. Joseph’s Hospital and Medical Center; Robert L. Coleman, MD from The University of Texas M. D. Anderson Cancer Center; Paul A. DiSilvestro, MD from Alpert School of Medicine at Brown University; and Robert S. Mannel, MD from The University of Oklahoma Health Sciences Center.

The current and emerging evidence on the optimal management of ovarian cancer were presented including ongoing GOG and other clinical trials concerning antiangiogenic agents as well as other novel targeted agents. The opinions of GOG members were also surveyed and are summarized below:

The GOG membership who attended the symposium felt scientific merit is the most important factor in choosing which clinical trial to participate in.

Over half of those that attended also participate in industry funded clinical trials making this an important consideration in the future of GOG studies.

The most significant barrier to clinical trial enrollment was thought to be related to the lack of clinical material eligible for GOG studies and the low physician enthusiasm for clinical trial participation.

With regard to the future: 43% felt clinical trial reimbursement will continue to fall and trial complexity will continue to increase making it difficult to participate in cooperative group studies. 28% were concerned the FDA is going to require an improvement in overall survival for new drug approval limiting the study of novel agents in ovarian cancer and; 20% feared President Obama’s healthcare reform will make clinical research no longer feasible.
Lilian Glen, MD
Sunnybrook Health Sciences Center
Toronto, Ontario

“Examining the paradigm for treating systematic therapies in recurrent and advanced cervical cancers.”

Nefertiti C. duPont, MD, MPH, FACOG
Roswell Park Cancer Center
Buffalo, NY

“Do disparities in cancer survival exist in African American, Hispanic, Asian and elderly women?”

Young Investigator Awards sponsored by:
“Chasing The Cure” makes great strides for ovarian cancer research

For the second consecutive year, the town of Sturgis, Mich. played host to the second annual “Chasing The Cure” 5K race and 1 mile walk - a grass roots effort to help raise awareness and funds for GOG research into ovarian cancer.

This year, close to 190 participants gathered on the morning of September 19 to take part in the event. Due to the tireless efforts of race founder and coordinator, Terra Draper, the event drew even more participants than the previous year. Thanks to the generosity of race participants and donors, the event raised over $7,000, which was donated to GOG’s New Horizons Research Fund.

Terra organized the first race over two years ago. She conceived the event as a way to help raise awareness about ovarian cancer – the disease that her aunt, Joan Dykstra, is battling. Draper dedicated the race to her aunt.

“I’m extremely humbled by the turnout this year,” Terra said. “It’s great to see so many returning participants and a number of new ones.”

The GOG would like to express it’s thanks to Terra, the race participants and sponsors for their generosity to help support research for eradicating this devastating disease.
Thank You, Sturgis!

Race Participants
Kim Adams
Patti Anderson
Sean Andrews
Wendy Andrews
Bryce Arver
Sarah Arver
Trent Arver
Jackalyn Barnard
Andrea Barnard
Leanne Barnell
Keith Barns
Zachary Blair
Kathy Block
Chris Block
Trisha Brokus
Deborah Brown
Brendan Bundy
Lori Bundy
Chris Bundy
Rylie Bundy
Debbie Burzynski
Tammy Cain
McKenzie Cain
Rylee Cain
Carrigan Capenter
Veana Capenter
Karen Cardwell
James Cardwell
Michael Carr
Marita Chupp
Lisa Chupp
Richard Craig
Roberta Craig
Patty Davidson
Brett Degroff
Quinn Degroff
Max Degroff
Zoe Degroff
Marisa Degroff
Shandra Dele
Jerry Downing
Keliee Duggan
Shawn Duggan
Terry Dykstra
Elizabeth Dykstra
Joan Dykstra
Dan Dykstra
David Dykstra
Brian Dykstra
Dorothy Erlanger
Jenny Fair
Rachel Fehring
Rhonda Fehring
Teresa Fish
Diane Foote
Bill Furr
Ana Garcia
Celia Geark
Doris Gearring
Kelly Gilbert
Ray Gilbert
Joyce Gilbert
Steve Gilbert
Pam Gilbert
Ellie Gilbert
Samantha Gossard
Joseph Graber
Jennifer Graber
Helen Guisinger
Renee Guzy
Kevin Hahn
Fronie Halfface
Sharon Harker
Mary Harris
Scott Heard
John Hollar
Jodi Houtz
Kody Hurley
Patty Ibbenston
Francisco Iniguez
Cesar Iniguez
Pat Janes
Dustin Jasper
Brittany Johnson
Lue Kanouse
Madison Kanouse
Tara Kanouse
Beth Kelley
Phillips Kellogg
Debra Kimble
Heather Kimble
Darian Kirby
Kathy Kordewick
Katelyn Kozlowski
Sheri Lackey
Atlee Lambert
Barb Laws
Benita Lewis
Kathy Lindeman
Jan Loftis
Cindy Logan
Colton Longpre
Angela Marks
Lindsey Maxwell
Chelsey McCann
Jessica McCoy
Kathy McPherson
Courtney Melville
Grace Melville
Traci Melville
Michelle Merritt
Rodney Mesick
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Tim Miller
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Patty Rutenbar
Mike Rutenbar
Gloria Sames
Janice Saxman
Heather Saxman
Jennel Schulz
Dan Scott
James Sienkowska
Jamie Slone
Brian Stears
Lyn Strang
Annette Stratton
Emily Stump
Alyssa Supplee
Darlene Tate
Susan Taylor
Barb Taylor
Wayne Taylor
Samantha Taylor
Mandi Taylor
Cathie Thomasma
Mike Thomasma
Sarah Thomasma
Lynelle Thresher
Lavera Troyer
Melissa Turner-Chambers
Krina Vakharia
Carrie VanDeventer
Kara Viozick
Angie Viozick
Adria West
Julie White
Kathy Wicaua
Dawn Wilson
Alexis Wood
Mary Wood
Valerie Wuori
Jonathan York

Thank You, Sturgis!

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New Horizons GYN Cancer Research Fund

The GOG would like to thank the following individuals and families for their generous contributions to the New Horizons GYN Cancer Research Fund:

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Marianne L. Daley

In Memory of Marisa Lynn Lee
Jim & Judy Knight
Honey A. Lewis, Esq.

In Memory of Holly Hoezee
Elizabeth Hoezee

In Memory of George A. Omore, MD
Dr. & Mrs. Howard Homesley

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JT Mansuzak
Mr. & Mrs. Albert Koster
Patricia & Kenneth Westerfield

Anononyous (several)

New Horizons GYN Cancer Research Fund
SAVE THE DATE

Friday, January 27, 2012 • 12:00 - 1:30 PM
San Diego, California
New for the Gynecologic Oncology Group
84th Semi-Annual Meeting
A 90-minute Complimentary CME-certified Luncheon Satellite Symposium to be held in conjunction with the GOG’s Semi-Annual Meeting, immediately following the GOG General Session.

Target Audience
This activity is intended for medical/gynecologic/radiological/surgical oncologists, pharmacists, and other healthcare professionals who treat and manage the care of patients with ovarian cancer.

Chairperson
Robert L. Coleman, MD, FACOG, FACS
The University of Texas M. D. Anderson Cancer Center

Physician Continuing Education
This activity is approved for AMA PRA Category 1 Credits™
This activity is not part of the Official GOG Semi-Annual Meeting.

Please check back at www.imeronline.com/GOG_84 in the coming days for more information and registration for this symposium.