Welcome to SWOG’s Fall 2015 Meeting!

Patients are our highest priority at SWOG. I know I say that a lot. Here in Chicago, I’m proud to say SWOG is adding even more walk to the talk.

Our general plenary session is devoted to patient advocacy. We’ve got not one but two speakers on the subject of patient advocates and how we can best use them to improve our trials, from earliest concept to final dissemination. We’ll get research findings on their use in cooperative groups, as well as success stories of how advocates have had a direct and positive impact on cancer trial outcomes.

And we won’t stop there.

SWOG prides itself on collaboration and inclusion, and we have our first-ever research workshop on NCORP, a meeting on Lung-MAP, our multi-group precision medicine trial, and a roundtable for the young investigators working group, which is charged with bringing fresh ideas to early career researcher engagement. Finally, at SWOG the best science drives our research. Our translational plenary proves it, with talks on immune therapy, cell cycle inhibitors, and an overview of the new NCI Core Correlative Sciences Committee on deck.

I’m excited to be here with you in Chicago. Have a fun and fulfilling meeting!

Sincerely,

Charles D. Blanke, M.D.
SWOG Chair

Welcome to SWOG’s Fall 2015 Meeting!
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SWOG • Leading Cancer Research. Together.
Plenary Part I (TM)
The fall meeting’s Translational Medicine Plenary will take place Thursday, Oct 8, 3:00 - 4:30 pm, in Regency A-C. Speakers and topics will include the following:

Introduction
Lee M. Ellis, MD, SWOG Vice-Chair for Translational Medicine

Cell cycle inhibitors come of age
Gary K. Schwartz, MD, Chief, Hematology/Oncology, Columbia University

An overview of the NCTN Core Correlative Sciences Committee
Elise C. Kohn, MD, Head, Gynecologic Cancers Therapeutics, National Cancer Institute

A critical appraisal of biomarkers for immune therapy: The Pathologist’s Perspective
Robert A. Anders, MD, PhD, Associate Professor of Pathology & Oncology, Johns Hopkins University

Plenary Part II (General)
Making Patients Our Partners: From TALK to WALK

How to bring patient advocate knowledge into clinical trials, from design to dissemination.

Friday, Oct 9, 12:00 - 2:00 pm, Regency A-C

The General Plenary session will feature talks by two experts in patient advocacy in cancer research, followed by a panel discussion with the chairs of SWOG’s Genitourinary and Patient Advocate Committees.

Mira L. Katz, PhD, Professor of Public Health, The Ohio State University
Speaker: Research on Patient Advocate Contributions to Cancer Research

Nancy A. Roach, Founder & Chair, Fight Colorectal Cancer
Speaker: Case Studies of Patient Advocate Contributions to Cancer Research

Rick Bangs, Chair, SWOG Patient Advocate Committee
Discussant

Ian M. Thompson, MD, Chair, SWOG Genitourinary Committee
Discussant

Charles D. Blanke, MD, SWOG Group Chair
Moderator
THE HOPE FOUNDATION

Because answers to cancers come from clinical trials

We fund grants, fellowships, professional development opportunities, and more to support SWOG and the important work of researchers like you.

Visit us to learn more and give your gift today. OR GIVE ONLINE thehopefoundation.org/donate
Fall 2015 Group Meeting Commercial Supporters*

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*Supporters as of September 1, 2015

We appreciate their support!
Go Mobile at the Meeting!

To manage your Group Meeting experience from your smartphone, download our mobile guidebook.

You’ll be able to plan your day with a personalized schedule and browse exhibitors, maps and general show info, all in the palm of your hand.

The guidebook app is compatible with iPhones, iPads, Android, and Blackberry devices.

To get the app, use your phone’s QR-code reader to scan the code at right. Or choose one of these methods:

1. Download ‘Guidebook’ from the Apple App Store or the Android Marketplace OR
2. Go to m.guidebookapp.com from your Blackberry OR
3. Visit guidebookapp.com/getit from your phone’s browser.

Once you’ve installed the Guidebook app, search for the SWOG Fall 2015 Group Meeting Guide in the “download guides” section of the app.

Tweeting the Meeting?

Tag your Group Meeting tweets with

#swogonc

We’ll post the live stream of tagged Group Meeting updates to the SWOG website, for ease of following by those who couldn’t make it.

Follow SWOG at twitter.com/SWOG. Our username is @SWOG.
HYATT REGENCY CHICAGO

Stetson A-F Meeting Rooms located on the Purple Level of the West Tower (one level below the Gold Level). Business Center and Package Pick-Up located on the Purple Level of the East Tower.

Meeting Rooms / Hotel Services

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SWOG • Leading Cancer Research. Together.
Chicago Travel & Hotel Information

Hyatt Regency Chicago
151 East Wacker Drive
Chicago, Illinois 60601
Phone: 312-565-1234
Fax: 312-239-4414

Arrival/Departure:
Check-in time is 3:00 p.m. Check-out time is 12:00 noon. Room amenities include a full bath, hair dryer, ironing board and iron. The concierge staff serves as a liaison between guests and the hotel and outside services.

Hotel Safety Deposit Boxes:
For your convenience, safety deposit boxes are available at the front desk for your valuables. Please do not leave valuables in your room.

Recreational Facilities:
The fitness center offers a variety of exercise equipment, free weights, treadmills, and more, exclusively for hotel guests. It is open 24 hours a day.

Hotel Restaurants and Lounges:
• Stetsons Modern Steak & Sushi: Non-traditional steakhouse experience in a comfortable urban setting, specializing in steaks and seafood. Restaurant is open daily from 5:00 p.m. - 11:00 p.m.
• American Craft Kitchen & Bar: Regionally inspired by all corners of the country, they offer an approachable dining experience with handcrafted food and drink. This atrium restaurant is the perfect stop for breakfast or lunch. Open daily from 6:00 a.m. - 3:00 p.m.
• Market Chicago: Offers breakfast, lunch or dinner for a quick meal or coffee to go. Open 24 hours a day.
• DaddyO’s Pub & Game Room: Corner pub featuring juicy burgers, local beers and wall-to-wall entertainment. Open 5:00 p.m. - 1:00 a.m.
• The BIG Bar features the longest free-standing bar in North America and specializes in a wide variety of cocktails, wines, champagnes and cognacs and snacks. Open daily at 5:00 p.m.
• In-room dining is available from 6:00 a.m. - 12:00 a.m. daily.

Business Center:
The Business Center is located on the Purple level in the East Tower of the hotel. It is open 24 hours a day, 7 days a week. The Business Center offers fax machines, computer services, color copies, mail drop, Internet access and photocopying.

Ground Transportation:
• A taxi ride from O’Hare airport to the hotel is approximately $35.00 one-way.
• A taxi ride from Midway airport to the hotel is approximately $30.00 one-way.
• Valet parking at the hotel is $59.00 per day for hotel guests.

Temperature:
The average high for October is 64 degrees and the average low is 46 degrees.

Area Attractions:
• Adler Planetarium and Astronomy Museum
• Architectural Boat Tours
• Art Institute of Chicago
• Brookfield Zoo
• Chicago ArchiCenter
• Chicago Architecture Foundation
• Chicago Botanic Garden
• Field Museum of National History
• John G. Shedd Aquarium
• John Hancock Center Observatory
• Millennium Park
• Museum of Contemporary Art
• Museum of Science and Industry
• Rockefeller Memorial Chapel
• Sears Tower Skydeck

Local Restaurants:
(The hotel concierge can assist with reservations and suggestions)
• Alinea - Eclectic
• Atwood Cafe - American
• Bistro 110 - Continental
• Cape Cod Room - Seafood
• Charlie Trotters - Eclectic
• Mia Francesca - Italian
• Mon Ami Gabi - French
• Shaw’s Crab House and Blue Crab Lounge - Seafood
• Silver Cloud - American
• Spiaggia - Italian
**Group Meeting Target Audience and Educational Objectives**

SWOG meets semi-annually to keep its members abreast of Group science. The target audience for these meetings are Physicians, Nurse Oncologists and Clinical Research Associates.

The educational objectives of these meetings are: to educate attendees about active and proposed studies so that they may implement the studies at their local institutions; to educate attendees about new treatments and prevention strategies that are available; to identify areas that can be improved in cancer research and study implementation and educate attendees on the best ways to implement the solutions at the local level.

These objectives apply to the following areas: Cancer Control and Prevention, including Cancer Care Delivery Committee, Symptom Control and Quality of Life Committee, Prevention & Epidemiology Committee, Cancer Survivorship Committee and Harry Hynes Symposium; Genitourinary Committee; Early Therapeutics & Rare Cancers Committee; Myeloma Committee; Melanoma Committee; Surgery Committee; Radiation Oncology Committee; Plenary Sessions Part I and II; Leukemia Committee; Breast Committee; Gastrointestinal Committee; Lung Committee, and Lymphoma Committee.

**Continuing Medical Education Credit**

The Hope Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Hope Foundation designates this live activity for a maximum of 28.0 **AMA PRA Category 1 Credits™**. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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**CME Credit Information**

**Procedures for CME Credit**

CME credit forms for the Group Meeting are available in the back of the Group Meeting agenda booklet. Only one form per person is required to list the CME credits for the entire meeting. Credits for each committee session are listed on the form.

Forms should be turned in to the Registration Desk before the desk closes at 11:00 a.m. on October 10, 2015. If the forms are not turned in to the desk, they can be mailed to the Operations Office the week following the Group Meeting. The Operations Office will submit all CME forms to the accrediting institution at one time. **Forms will be submitted 30 days following the meeting. You will then receive a certificate of completion in the mail following submission and processing of the CME forms by the accrediting institution.**

**SWOG gratefully acknowledges the support of our CME Commercial Supporters***

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**Speaker and Planner CME Disclosure Information**

Each speaker and planner for The Hope Foundation - CME courses has been requested to complete a Faculty Disclosure Form prior to the activity in accordance with ACCME standards. THF strives to provide accurate and up-to-date information regarding affiliations or interests that might be perceived as a potential conflict of interest for those who control CME content. Please see the disclosure handout available at the SWOG self-service and onsite registration desks. Best attempts will also be made to provide up to date information on introductory slides at each CME session.
SCHEDULE OF EVENTS

WEDNESDAY, OCTOBER 7, 2015

8:00 a.m. - 10:00 a.m.
Gold Level, West Tower
GU Organ Site Chair Meeting
Room: Toronto
(Organ Site Chairs Only)

8:00 a.m. - 2:00 p.m.
Gold Level, West Tower
Executive Retreat (Invitation Only)
Room: Acapulco

10:30 a.m. – 12:30 p.m.
Gold Level, West Tower
ORP Executive Committee
Room: San Francisco
(Committee Members Only)

10:30 a.m. - 1:30 p.m.
Gold Level, West Tower
GU Organ Site Meeting
Room: Toronto
(Working Group Members Only)

12:00 p.m. – 1:45 p.m.
Gold Level, West Tower
Nursing Research Subcommittee
Room: New Orleans

2:00 p.m. - 5:00 p.m.
Gold Level, West Tower
SWOG NCORP Research Base Clinical Trials Workshop
Room: Regency B

2:00 p.m. - 5:00 p.m.
Gold Level, West Tower
GU COMMITTEE
Room: Regency A

3:30 p.m. - 5:30 p.m.
Silver Level, West Tower
Hope Foundation Board Meeting
Room: Dusable
(Board Members Only)

4:30 p.m. – 5:30 p.m.
Gold Level, West Tower
ORP Liaison Subcommittee
Room: Acapulco
(Formerly Disease & Discipline and Research)

5:30 p.m. – 7:30 p.m.
Bronze Level, East Tower
Site Operations - Open to Member, Affiliate and NCORP Head CRAs Only
Room: Michigan

5:30 p.m. – 8:00 p.m.
Gold Level, West Tower
Cancer Control and Prevention Executive Meeting (Committee Members Only)
Room: Regency C

THURSDAY, OCTOBER 8, 2015

7:00 a.m. – 8:00 a.m.
Advocates Committee Meeting
Bronze Level, West Tower
Room: Wrigley
(Committee Members Only)

7:00 a.m. – 8:00 a.m.
SWOG Tissue Banking Meeting
Bronze Level, West Tower
Room: New Orleans
(Invitation Only)

7:30 a.m. – 8:00 a.m.
Jeri and Noboru Oishi
Gold Level, West Tower
Symposium & Continuing Education Workshop Check-In
Room: Regency A Foyer

8:00 a.m. – 8:15 a.m.
New Nurse/CRA Orientation / Business Meeting (Open Session)
Room: Regency AB

Note: The Hope Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Hope Foundation designates this live activity for a maximum of 28.00 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.
### Schedule of Events

**Thursday, October 8, 2015**

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<th>Time</th>
<th>Event</th>
<th>Room</th>
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</thead>
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<tr>
<td>8:15 a.m. – 12:00 p.m.</td>
<td>Jeri and Noboru Oishi Symposium &amp; Continuing Education Workshop (Open Session)</td>
<td>Regency AB</td>
</tr>
<tr>
<td>8:00 a.m. – 10:00 a.m.</td>
<td>Symptom Control &amp; Quality of Life Committee</td>
<td>Michigan</td>
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<td>8:00 a.m. – 10:00 a.m.</td>
<td>Quality Initiative Meeting (Committee Members Only)</td>
<td>Columbian</td>
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<tr>
<td>10:00 a.m. – 12:00 p.m.</td>
<td>Social Media Working Group (Working Group Members Only)</td>
<td>Gold Coast</td>
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<tr>
<td>10:00 a.m. – 12:15 p.m.</td>
<td>Early Therapeutics &amp; Rare Cancers Committee</td>
<td>Regency C</td>
</tr>
<tr>
<td>10:15 a.m. – 11:15 a.m.</td>
<td>Prevention &amp; Epidemiology Committee</td>
<td>Michigan</td>
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<tr>
<td>10:15 a.m. – 12:15 p.m.</td>
<td>Advocates Committee Meeting (Committee Members Only)</td>
<td>Wrigley</td>
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<tr>
<td>11:15 a.m. – 1:30 p.m.</td>
<td>Physical Activity and Weight Reduction Symposium (Joint symposium between Prevention and Survivorship Committees)</td>
<td>East Tower</td>
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<tr>
<td>12:00 p.m. – 2:00 p.m.</td>
<td>Adolescent and Young Adult (AYA) Committee</td>
<td>West Tower</td>
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<tr>
<td>12:30 p.m. – 2:00 p.m.</td>
<td>ORP Open Forum (ORP Session)</td>
<td>West Tower</td>
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<tr>
<td>1:00 p.m. – 2:00 p.m.</td>
<td>Navigating SWOG for Young Investigators (Open for drop-ins)</td>
<td>Wrigley</td>
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<tr>
<td>1:00 p.m. – 5:00 p.m.</td>
<td>SoCRA Examination</td>
<td>Soldier Field</td>
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<td>1:30 p.m. – 2:30 p.m.</td>
<td>Cancer Survivorship Committee</td>
<td>East Tower</td>
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<td>2:00 p.m. – 3:00 p.m.</td>
<td>ORP Education Subcommittee (Formerly Education &amp; Program)</td>
<td>Comiskey</td>
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<td>2:15 p.m. – 3:00 p.m.</td>
<td>Plenary Reception (Desserts &amp; Coffee)</td>
<td>Hong Kong</td>
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<td>3:00 p.m. – 4:30 p.m.</td>
<td>PLENARY I (Translational Medicine)</td>
<td>Regency A-C</td>
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<td>4:30 p.m. – 5:30 p.m.</td>
<td>Eagle II Reception (Invitation Only)</td>
<td>Hong Kong</td>
</tr>
</tbody>
</table>

**Group Meeting Registration & Information Desk**
- 7:00 a.m. - 5:00 p.m. - Regency Foyer (Gold Level, West Tower)

**Hope Foundation Information Desk & Donor Lounge**
- 7:00 a.m. - 5:00 p.m. - Regency Foyer

**Exhibits & Complimentary Coffee Service**
- 7:00 a.m. - 4:00 p.m. - Toronto
SCHEDULE OF EVENTS

THURSDAY, OCTOBER 8, 2015

4:30 p.m. – 6:30 p.m.
*Bronze Level, West Tower*
Lymphoma Working Group
(Working Group Members Only; Industry attendance by invitation only)

5:00 p.m. – 7:00 p.m.
*Gold Level, West Tower*
GI Working Group Meeting
(Working Group Members Only; Industry attendance by invitation only)

5:00 p.m. – 7:00 p.m.
*Bronze Level, East Tower*
CANCER CARE DELIVERY COMMITTEE
Room: Michigan

5:00 p.m. – 7:00 p.m.
*Gold Level, West Tower*
Conflict Management Committee
(Committee Members Only)

5:30 p.m. – 7:30 p.m.
*Bronze Level, West Tower*
SLAI Leadership Meeting
(Invitation Only)

6:00 p.m. – 9:00 p.m.
*Gold Level, West Tower*
TM Subcommittee Chairs/ITSC Leadership Meeting
(Invitation Only)

FRIDAY, OCTOBER 9, 2015

7:30 a.m. – 9:30 a.m.
*Bronze Level, West Tower*
Myeloma Working Group
(Working Group Members Only; Industry attendance by invitation only)

7:30 a.m. – 9:30 a.m.
*Bronze Level, West Tower*
Imaging Committee (Committee Members Only)

7:30 a.m. – 9:30 a.m.
*Gold Level, West Tower*
SWOG Data & Safety Monitoring Committee (Committee Members Only)

8:00 a.m. – 10:00 a.m.
*Bronze Level, West Tower*
Drug Information Subcommittee and Working Group (Working Group Members Only)

8:00 a.m. – 11:00 a.m.
*Gold Level, West Tower*
LUNG WORKING GROUP
Room: Regency D

9:30 a.m. – 11:30 a.m.
*Gold Level, West Tower*
Lung Working Group (Working Group Members Only; Industry attendance by invitation only)
SCHEDULE OF EVENTS

FRIDAY, OCTOBER 9, 2015

Group Meeting Registration & Information Desk
7:00 a.m. - 5:00 p.m. - Regency Foyer (Gold Level, West Tower)

Hope Foundation Information Desk
7:00 a.m. - 5:00 p.m. - Regency Foyer

Exhibits & Complimentary Coffee Service
7:00 a.m. - 4:00 p.m. - Toronto

CANCER CONTROL AND PREVENTION OUTREACH (HARRY HYNES SYMPOSIUM)

9:30 a.m. – 11:30 a.m.
Green Level, West Tower
Room: Crystal B

10:00 a.m. – 10:30 a.m.
Quality Assurance Committee Meeting (Committee Members Only)
Bronze Level, West Tower
Room: Columbian

10:00 a.m. – 12:00 p.m.
Gold Level, West Tower
Room: Crystal A

10:00 a.m. – 12:00 p.m.
S1415 Protocol Training
Bronze Level, West Tower
Room: Gold Coast

10:30 a.m. – 12:00 p.m.
Bone Marrow & Stem Cell Transplantation Committee
Green Level, East Tower
Room: Plaza Ballroom

11:00 a.m. – 12:00 p.m.
Plenary Reception (Light Hors D’oeuvres)
Gold Level, West Tower
Room: Regency Foyer

12:00 p.m. – 2:00 p.m.
PLENARY II (General)
Gold Level, West Tower
Room: Regency A-C

2:15 p.m. – 3:15 p.m.
S1400 LUNG-MAP Update Meeting
Green Level, West Tower
Room: Crystal A

2:30 p.m. – 4:30 p.m.
SURGERY COMMITTEE
Gold Level, West Tower
Room: Acapulco

2:30 p.m. – 4:30 p.m.
BARLOGIE-SALMON MYELOMA COMMITTEE
Bronze Level, East Tower
Room: Michigan

2:30 p.m. – 4:30 p.m.
Melanoma Working Group (Working Group Members Only; industry attendance by invitation only)
Green Level, East Tower
Room: Plaza B

3:00 p.m. – 5:00 p.m.
Recruitment and Retention Core Meeting (Committee Members Only)
Gold Level, West Tower
Room: New Orleans

3:00 p.m. – 5:00 p.m.
ORP Planning Meeting (Committee Members Only)
Bronze Level, West Tower
Room: Water Tower

3:30 p.m. – 6:30 p.m.
LUNG COMMITTEE
Gold Level, West Tower
Room: Regency D

4:30 p.m. – 5:30 p.m.
S1316 Protocol Meeting
Gold Level, West Tower
Room: San Francisco

4:30 p.m. – 6:30 p.m.
Pharmaceutical Sciences Committee
Bronze Level, West Tower
Room: Columbian

4:30 p.m. – 7:30 p.m.
Breast Working Group (Working Group Members Only; Industry attendance by invitation only)
Green Level, West Tower
Room: Crystal A

5:00 p.m. – 7:00 p.m.
Leukemia Working Group (Working Group Members Only; Industry attendance by invitation only)
Green Level, West Tower
Room: Crystal C

6:45 p.m. – 8:00 p.m.
Reception
Gold Level, West Tower
Room: Regency AB
SCHEDULE OF EVENTS

SATURDAY, OCTOBER 10, 2015

Group Meeting Registration & Information Desk
7:00 - 11:00 a.m. - Regency Foyer (Gold Level, West Tower)

Hope Foundation Information Desk & Donor Lounge
7:00 - 11:00 a.m. - Regency Foyer

7:00 a.m. – 8:00 a.m.
Gold Level, West Tower
Room: Regency B
Board of Governors (Board Members Only)

8:15 a.m. – 9:15 a.m.
Gold Level, West Tower
Room: Regency B
Committee Chairs (Committee Members Only)

9:30 a.m. – 11:00 a.m.
Bronze Level, West Tower
Room: Wrigley
RADIATION ONCOLOGY COMMITTEE

9:30 a.m. – 11:30 a.m.
Gold Level, West Tower
Room: Regency A
MELANOMA COMMITTEE

9:30 a.m. – 11:30 a.m.
Gold Level, West Tower
Room: Regency C
LEUKEMIA COMMITTEE

9:30 a.m. – 12:30 p.m.
Gold Level, West Tower
Room: Regency D
BREAST COMMITTEE

10:00 a.m. – 11:00 a.m.
Gold Level, West Tower
Room: New Orleans
VA Working Group Meeting
(Working Group Members Only)
Roster of Committee Speakers

Wednesday, October 7, 2015

Genitourinary Committee, 2:00 p.m. - 5:00 p.m. - Regency A
Update: PCORI, A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information – Rick Bangs, Chair, SWOG Patient Advocates Committee

Thursday, October 8, 2015

Symptom Control & Quality of Life Committee, 8:00 a.m. - 10:00 a.m. - Michigan
SWOG SxQOL, Where we have been, where we are now, and what great road(s) are yet ahead!
James L. Wade III, M.D., Cancer Care Specialists of Central Illinois

Priority setting and new directions for SWOG SxQOL – Norah Lynn Henry, M.D., Ph.D., University of Michigan Comprehensive Cancer Center

Prevention and Epidemiology Committee, 10:15 a.m. - 11:15 a.m. - Michigan
Increased use of multigene panels for hereditary cancer testing and impact on cancer risk assessment, screening and prevention – Banu Arun, M.D., MD Anderson Cancer Center

Epidemiologic and Translational Research Opportunities Using PCPT and SELECT Data and Biorepositories – Cathy Tangen, Ph.D., SWOG Statistical Center

Cancer Survivorship & Prevention Committee Joint Symposium: Physical Activity and Weight Reduction, 11:15 a.m. - 1:30 p.m. - Michigan
What do we know about weight loss and energy balance for cancer prevention: current knowledge & research gaps – Marian Neuhouser, Ph.D., R.D., Fred Hutchinson Cancer Research Center

Testing weight loss and exercise strategies in SWOG: lessons learned and next steps – Heather Greenlee, N.D., Ph.D., Columbia University Medical Center

Current knowledge about weight loss and physical activity for cancer survivorship: ongoing trials & research gaps – Carol Fabian, M.D., University of Kansas Medical Center

Should SWOG attempt an exercise study? What kind? What are the important outcomes?
Jennifer Klemp, Ph.D., University of Kansas Cancer Center & Medical Pavilion

Cancer Care Delivery Committee, 5:00 p.m. - 7:00 p.m. - Michigan
Stakeholder Engagement in Cancer Care Delivery Studies - Discussion/Panel – Kate Castro, R.N., M.S., National Cancer Institute; Anne Marie Cicarella, Patient Advocate; and Trent T. Haywood, M.D., BlueCross BlueShield Association
Roster of Committee Speakers

Friday, October 9, 2015

Harry E. Hynes Symposium, 9:30 a.m. - 11:30 a.m. - Crystal B
NCI Overview – Worta McCaskill-Stevens, M.D. and Kate Castro, R.N., National Cancer Institute

Coordinating Committee and CCDR – Scott Ramsey, M.D., Fred Hutchinson Cancer Research Center

Symptom Control and Quality of Life – Lynne I. Wagner, Ph.D., Wake Forest School of Medicine

Surgery Committee, 2:30 p.m. - 4:30 p.m. - Acapulco
Colorectal Cancer Survivorship and Surgery – Y. Nancy You, M.D., M.HSc., MD Anderson Cancer Center

Cancer Survivorship and Quality of Life afterRectal Surgery – Joe Carmichael, M.D., UC Irvine

Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes – Hill Hamilton-Reeves, Ph.D., R.D., C.S.O., University of Kansas Medical Center

Saturday, October 10, 2015

Melanoma Committee, 9:30 a.m. - 11:30 a.m. - Regency A
Translating the Molecular Biology of Melanoma into the Clinic – Michael Davies, M.D., MD Anderson Cancer Center

Breast Committee, 9:30 a.m. - 12:30 p.m. - Regency D
Humanized Mouse PDX Models: Applications in Triple Negative Breast Cancer (TNBC) – Edison Liu, M.D., Ph.D., Jackson Labs

Targeting Metaplastic and Mesenchymal TNBC – Stacy Moulder, M.D., MD Anderson Cancer Center

Discerning Cytotoxic and Biological Impacts in Metastatic HER2 + Breast Cancer – Anthony Elias, M.D., University of Colorado
SWOG ADMINISTRATIVE COMMITTEES

Adolescent & Young Adults
Chair: Mark A. Lewis, M.D.

Board of Governors
Chair: Charles D. Blanke, M.D.

Bone Marrow and Stem Cell Transplantation Committee
Chair: Patrick J. Stiff, M.D.

Conflict Management Committee
Chair: Paul Okunieff, M.D.

Data & Safety Monitoring Committee
Chair: Lawrence E. Flaherty, M.D.

Imaging Committee
Chair: Lawrence H. Schwartz, M.D.

Membership Committee
Chair: James K. Weick, M.D.

Oncology Research Professionals Committee
Chair: Keisha C. Humphries, R.N., B.S.N.

Patient Advocates Committee
Chair: Rick Bangs

Pharmaceutical Sciences Committee
Co-Chair: Siu-Fun Wong, Pharm.D.
Co-Chair: Susan Kadlubar, Ph.D.

Professional Review Committee
Chair: Primo N. Lara, Jr., M.D.

Quality Assurance Committee
Chair: Manuel Valdivieso, M.D.

Radiation Oncology Committee
Chair: Paul Okunieff, M.D.

Surgery Committee
Chair: George H. Yoo, M.D.
Special Symposia

Jeri and Noboru Oishi Symposium
Thursday, October 8, 2015 - 8:00 a.m. - 12:00 p.m.
Location: Regency AB (Gold Level, West Tower)

Featured Speakers:
• CTSU Updates - Lena Muwakki and Lucille Patrichuk, R.N.
• Site Experience with CIRB Implementation - Annette Betley, B.S.
• Fertility & Banking in the Cancer Survivor - Rebecca Flyckt, M.D.

This activity has been submitted to the Oncology Nursing Society for approval to award contact hours. ONS is accredited as an approver of continuing nursing education by the American Nurses Credentialing Center’s COA.

Certificates for continuing education credits (CEUs) will be distributed to attendees upon completion and return of their evaluation sheets. Certificates of attendance will be given for Society of Clinical Research Associates.

Oncology Research Professionals Open Forum
Thursday, October 8, 2015 - 12:30 p.m. - 2:00 p.m.
Location: Regency D (Gold Level, West Tower)

Topic: This forum offers an opportunity to get answers to your clinical trial questions and address the science and technical research issues that challenge us today.

Featured Topics:
• Quality Assurance Audits
• Regulatory Affairs
• Data Management Tips & Tools for CRAs
• CTCAEs v4.0 and SAE Q&A
• Cancer Treatment Modalities Q&A
• Specimen Preparation and Shipment
• SWOG Federal Reimbursements
• SWOG CTI Non-Federal Reimbursements
• Hot Topics in Site Administration
• Recruitment Efforts Maximized
Special Symposia

Cancer Survivorship & Prevention Committee Joint Symposium: Physical Activity and Weight Reduction
Thursday, October 8, 2015 - 11:15 a.m. - 1:30 p.m.
Location: Michigan (Bronze Level, East Tower)

This symposium will discuss the capacity of SWOG to engage in weight reduction and physical activity interventions for both cancer prevention and cancer survivorship in the cooperative group setting.

Featured Speakers:
- What do we know about weight loss and energy balance for cancer prevention: current knowledge & research gaps - Marian Neuhouser, Ph.D., R.D.
- Testing weight loss and exercise strategies in SWOG: lessons learned and next steps - Heather Greenlee, N.D., Ph.D.
- Current knowledge about weight loss and physical activity for cancer survivorship: ongoing trials & research gaps - Carol Fabian, M.D.
- Should SWOG attempt an exercise study? What kind? What are the important outcomes? - Jennifer Klemp, Ph.D.
- Commentary - Dawn Hershman, M.D. and Audience participation

Surgery Committee
Friday, October 9, 2015 - 2:30 p.m. - 4:30 p.m.
Location: Acapulco (Gold Level, West Tower)

Topic: Cancer Survivorship for Surgery

Featured Speakers and Topics:
- Colorectal Cancer Survivorship and Surgery - Y. Nancy You, M.D., M.HSc, Associate Professor, Section Colorectal Surgery, Department of Surgical Oncology, MD Anderson Cancer Center
- Cancer Survivorship and Quality of Life after Rectal Surgery - Joe Carmichael, M.D., Assistant Clinical Professor, Surgery, UC Irvine
- Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes - Jill Hamilton-Reeves, Ph.D., R.D., C.S.O., Associate Professor, Department of Dietetics and Nutrition, University of Kansas Medical Center
BARLOGIE-SALMON MYELOMA COMMITTEE

Committee Leadership
Chair: Robert Z. Orlowski, M.D., Ph.D.
Vice-Chair: Brian G.M. Durie, M.D.
Executive Officer: Susan M. O’Brien, M.D.
Statisticians: Antje Hoering, Ph.D.
Rachael Sexton, M.S.

Scientific Leadership
Translational Medicine: Joshua Epstein, D.Sc.
Radiation: Michael Tomblyn, M.D.
Surgery: J. Sybil Biermann, M.D.
Imaging: Saad Z. Usmani, M.D.
Pathology: Eric M. Rohren, M.D., Ph.D.
Early Therapeutics: Frits van Rhee, M.D., Ph.D.

Designates
NCORP Representative: James D. Bearden, III, M.D.
Data Coordinators: Jeri Jardine, Laura Kingsbury, M.R.T.

Oncology Research Professionals:
CRAs: TBD
Nurses: Deborah A. Halk, R.N.
Steven M. Burt, NP-C
Patient Advocate: Jack Aiello
Pharmaceutical Science: Lara M. Au, Pharm.D.
Craig Elg, Pharm.D.
Protocol Coordinator: Cara Laubach, M.I.I.M.

Time/Location
Friday, October 9, 2015
Room: Michigan (Bronze Level, East Tower)
2:30 p.m. - 4:30 p.m.

Agenda
Introduction - Robert Z. Orlowski, M.D., Ph.D.

Active Studies


- CTSU/E1A11, “Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE).” Dr. Zonder. Activated by ECOG: 11/13/13; Activated by SWOG: 2/1/14.

Proposed Studies
- S1606, “Randomized Phase III Study of Lenalidomide (L) vs. Lenalidomide + Ixazomib (LI) (NSC-XXXX) as Maintenance Therapy Post-Autologous Stem Cell Transplant in Patients with Multiple Myeloma (MM).” Dr. Shah.

- SXXXX, “A Phase III Randomized Study Comparing Bortezomib, Rituximab and Dexamethasone with or without Ibrutinib in Previously Untreated Waldenström’s Macroglobulinemia (WM).” Dr. Ailawadhi.

- SXXXX, “Elotuzumab (E) + Lenalidomide (L) + low dose Dexamethasone (d) Consolidation and Maintenance Therapy for Patients not in Complete Hematologic Remission after Initial Therapy for Newly Diagnosed AL Amyloidosis.” Drs. Scott and Zonder.


- S1503, “Randomized Phase II Multicenter Non-Inferiority Trial of Apixaban 2.5 mg BID versus Low Molecular Weight Heparin for Prevention of Thromboembolism in Patients Being Treated with an Immunomodulatory-Based Regimen for Multiple Myeloma.” Dr. Calverley.
BARLOGIE-SALMON MYELOMA COMMITTEE

- SXXXX, “Monoclonal Antibody Metronomic Therapy for Relapsed Multiple Myeloma.” Dr. Scott.

Working Groups
- Amyloidosis Working Group update
- Waldenström’s Working Group update
- Myeloma Translational Medicine Subcommittee update

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts


Submitted Manuscripts
# BREAST COMMITTEE

## Agenda

### 9:30 – 9:35 a.m.
Welcome and Introductions – Gabriel Hortobagyi, M.D. and Debu Tripathy, M.D.

### 9:35 – 10:50 a.m.
Breast Committee Mini-Symposium "Optimizing Human Tumor Models to Design Clinical Trials" (9:35 - 10:50 a.m.)

### 10:30 – 10:50 a.m.
Panel discussion and audience Q & A

### 10:50 – 11:00 a.m.
Publications update - Bill Barlow, Ph.D.

### 11:00 – 11:30 a.m.
Update of open SWOG and CTSU trials - All

### 11:30 – 11:50 a.m.
Studies in Development - All

### 11:50 – 12:05 p.m.
Reports from Committee Liaisons
- Radiotherapy - Reshma Jagsi, M.D.
- Surgery - Christine Lee, M.D.
- Cancer Survivorship - Carol Fabian, M.D.
- Health Disparities - Dawn Hershman, M.D.
- Prevention - Melanie Palomares, M.D.
- NCORP (NCI Community Oncology Research Program) – Melanie Royce, M.D.
- Patient Advocate – Nancy Singleton

### 12:05 – 12:15 p.m.
Translational Medicine Sub-Committee – Daniel Hayes, M.D.

### 12:15 – 12:30 p.m.
New Business – All

### 12:30 p.m.
Adjourn

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## Committee Leadership

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
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<tbody>
<tr>
<td>Chair</td>
<td>Gabriel N. Hortobagyi, M.D.</td>
</tr>
<tr>
<td>Vice-Chair</td>
<td>Debasish Tripathy, M.D.</td>
</tr>
<tr>
<td>Executive Officer</td>
<td>Julie R. Gralow, M.D.</td>
</tr>
<tr>
<td>Statisticians</td>
<td>William E. Barlow, Ph.D.</td>
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<td>Danika Lew, M.A.</td>
</tr>
<tr>
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<td>Jieling Miao, M.S.</td>
</tr>
</tbody>
</table>

## Scientific Leadership

- **Translational Medicine:** Daniel F. Hayes, M.D.
- **Radiation Oncology:** Reshma Jagsi, M.D.
- **Surgery:** Christine Lee, M.D.
- **Imaging:** Anne F. Schott, M.D.
- **Pathology:** Allen M. Gown, M.D.
- **Early Therapeutics:** George Somlo, M.D.

### Designates

- **Cancer Control Liaisons:**
  - Carol J. Fabian, M.D. (Cancer Survivorship)
  - Dawn L. Hershman, M.D. (Cancer Care Delivery)
  - Melanie R. Palomares, M.D. (Prevention)
  - Helen K. Chew, M.D. (Symptom Control & QOL)
- **NCORP Representative:** Melanie E. Royce, M.D., Ph.D.
- **Data Coordinators:**
  - Jean Barce
  - Jennie Barrett
  - Larry Kaye
  - Iris Syquia
- **Oncology Research Professionals:**
  - CRAs: Karyn N. Hart, C.C.R.P.
  - Caralee Applequist, R.N., M.S.N.
  - Nurses: Dorothy Coleman, R.N., M.S.
  - Kathy L. Ziaplicki, R.N., M.S.N.
- **Patient Advocate:** Nancy Singleton
- **Pharmaceutical Science:** Jessie Modlin, Pharm.D.
- **Protocol Coordinator:** Megan Hardin

## Time/Location

- **Saturday, October 10, 2015**
- **Room:** Regency D (Gold Level, West Tower)
- **9:30 a.m. - 12:30 p.m.**

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**Active Adjuvant Studies**


BREAST COMMITTEE

Active Advanced Disease Studies

- CTSU/NSABP B-55, “A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy.” Dr. Sharma. Activated: 7/3/14.

Active Cancer Control Studies


Closed Studies

- S1007, “A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone-Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less.” Drs. Kalinsky, Gralow, Meric-Bernstam, Hortobagyi, Albain and Barlow. Activated: 1/15/11; Closed: 10/15/15.

- S1008, “Feasibility Study of a Physical Activity and Dietary Change Weight Loss Intervention in Breast and Colorectal Cancer Survivors Phase II.” Drs. Greenlee and Hershman. Activated: 3/1/12; Closed: 7/1/14.

- S1222, “Fulvestrant Alone Versus Fulvestrant and Everolimus Versus Fulvestrant, Everolimus and Anastrozole: A Phase III Randomized Placebo-Controlled Trial in Postmenopausal Patients with Hormone-Receptor Positive Stage IV Breast Cancer.” Drs. Somlo, Moore, Hayes, Kuhn and Hicks. Activated: 5/9/14; Closed: TBD.


Studies in Development

- S1510, “A Randomized Phase II Study of Liposomal Doxorubicin vs Combination Therapy with Liposomal Doxorubicin and Temsirolimus (+/- Bevacizumab) for the Treatment of Patients with Locally Advanced or Metastatic Metaplastic/Mesenchymal Breast Cancer for which Curative Therapy is not Available.” Dr. Moulder.

- S1412, “Phase II Randomized Trial of Adjuvant Vaccine Therapy in Patients with High-Risk HER2-Positive Breast Cancer.” Dr. Mittendorf.

- S1418, “A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with > 1 cm Residual Invasive Cancer or Positive Lymph Nodes (pNmic) After Neoadjuvant Chemotherapy.” Drs. Pusztai, Sharma and Mammen.
BREAST COMMITTEE

- **S1501** “Prospective Evaluation of Carvedilol vs No Treatment in Prevention of Cardiac Dysfunction in Women with Metastatic HER2+ Breast Cancer.” Drs. Floyd and Leja.

- **S1506** “Phase II Randomized Study of Ado-Trastuzumab Emtansine (T-DM1) With or Without Paclitaxel in Her2+ Metastatic Breast Cancer (MBC).” Dr. Elias.

- **S1509** “A Phase II Study of Veliparib Administered Concurrently with Radiotherapy for Inflammatory or High-Risk Triple-Negative Breast Cancer to A Phase II Randomized, Double-Blinded, Placebo-Controlled Trial of Veliparib Administered Concurrently with Radiotherapy for Inflammatory or High-Risk Triple-Negative Breast Cancer.” Dr. Jagsi.

New Proposals

- “Randomized Phase II Study of TDM-1 vs. TDM-1 and Continuous Low-Dose Temozolomide in 1-4 HER-2+ Breast Cancer Brain Metastases Following Stereotactic Radiosurgery with Phase 1 Lead-in Study.” Drs. Tsien and Conlin.

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

**Published/Accepted Manuscripts**


**Submitted Manuscripts**

Cancer Epidemiology, Biomarkers & Prevention, under review.
[also under SCQOLCommittee]

CANCER CONTROL & PREVENTION COMMITTEES

Committee Leadership
Co-Vice-Chair, NCORP:
  Frank L. Meyskens, Jr., M.D.*
  Dawn L. Hershman, M.D., M.S.*
Co-Vice-Chair, NCORP:
  Dawn L. Hershman, M.D., M.S.
  Scott D. Ramsey, M.D., Ph.D.*
Cancer Care Delivery Co-Chairs:
  Carol J. Fabian, M.D.*
  Robert S. Krouse, M.D.*
Cancer Survivorship Co-Chairs:
  Carol J. Fabian, M.D.*
  Robert S. Krouse, M.D.*
Prevention & Epidemiology
Co-Chairs:
  Banu Arun, M.D.*
  Marian Neuhouser, Ph.D., R.D.*
Symptom Control & QOL
Co-Chairs:
  Michael Fisch, M.D., Ph.D.*
  James L. Wade III, M.D.*
Executive Officer:
  Craig R. Nichols, M.D.*
Statisticians:
  Garnet Anderson, Ph.D.*
  William E. Barlow, Ph.D.*
  Katherine Guthrie, Ph.D.*
  Cathy Tangen, Dr.P.H.*
  Joseph M. Unger, Ph.D.*
  Kathryn B. Arnold, M.S.*
  Amy K. Darke, M.S.*
  Phyllis Goodman, M.S.*
  Danika Lew, M.A.*
  Hongli Li, M.S.*
  Cathy Till, M.S.*
Administrative Lead (Stat. Ctr.):
  Monica Yee, C.C.R.P.*
  TBD*
Administrative Lead (UCI):
  TBD*

Scientific Leadership
NCORP Representative:
  Mark A. O’Rourke, M.D.*
Radiation Therapy Committee:
  Louis “Sandy” Constine, M.D.
Surgery Committee:
  Robert S. Krouse, M.D.FACS*
Translational Medicine:
  James (Jimmy) Rae, Ph.D.*
Liaisons:
  Breast Committee:
    Carol J. Fabian, M.D.
    (Survivorship)*
    Helen Chew, M.D.
    (Symptom Control & QOL)
    Dawn Hershman, M.D, M.S.
    (CCDC)*
    Melanie Palomares, M.D.
    (Prevention)
  Gastrointestinal Committee:
    Afsaneh Barzi, M.D.
  Gastrointestinal Committee Colon:
    Jason, Zell, D.O.
  Genitourinary Committee:
    Peter J. Van Veldhuizen, Jr., M.D.
  International Liaison:
    Kathy S. Albain, M.D.*
  Lung Committee:
    Gary E. Goodman, M.D.*
  Lymphoma Committee:
    TBD
  Melanoma Committee:
    Sancy Leachman, M.D., Ph.D.

Designates
Oncology Research Professionals
  CRAs:
    Connie Szczepanek, R.N., B.S.N.
    Joyce N. Tull, R.N., B.S.N.
    Amanda R. Dinsdale, M.H.A.,
      C.C.R.C.
    Mindy Whisnant, C.C.R.P.
  Nurses:
    Joan Long, R.N.
    Michaela S. Sherbec, R.N., B.S.N.
  Pharmaceutical Science:
    Manj Randhawa, Pharm.D.
    Siu-Fun Wong, Pharm.D.*
    Susan A. Kadlubar, Ph.D.
  Statistical Center Support:
    Karen Anderson*
    Monica Yee, B.A., C.C.R.P.*
    Dona Marrah, C.C.R.P.
    Diane Liggett, B.S. C.C.R.P.*
    Roxanne Topacio, C.C.R.P.*
  Patient Advocates:
    Anna Gottlieb
    Amy Geschwender, Ph.D.
  Protocol Coordinator (Cancer Care
  Delivery Cmte):
    Patricia O’Kane*
  Protocol Coordinator (Survivorship;
  Symptom Control and QOL Cmtes):
    Kimberly Kaberle*

*Executive Committee Members and Staff
CANCER CONTROL & PREVENTION COMMITTEES

Harry E. Hynes NCORP Symposium (Joint Session)

Friday, October 9, 2015
Room: Crystal B (Green Level, West Tower)
9:30 a.m. – 11:30 a.m.

Agenda

9:30 – 9:35 a.m.  WELCOME
                  Mark O’Rourke, M.D.

9:35 – 9:40 a.m.  Associate Chair Report
                  Frank L. Meyskens, M.D.

9:40 – 10:00 a.m. NCI Overview
                  Worta McCaskill-Stevens, M.D. &
                  Kate Castro, R.N.

10:00 – 10:15 a.m. Coordinating Committee and CCDR
                   Scott Ramsey, M.D.

10:15 – 11:00 a.m. “Symptom Control and Quality of Life”
                   Lynne I. Wagner, Ph.D.

11:00 – 11:30 a.m. Open Forum for NCORP Investigators
                   Gary Lyman, M.D. &
                   Dawn Hershman, M.D.
CANCER CARE DELIVERY COMMITTEE

Cancer Care Delivery Committee Co-Chairs:
Dawn L. Hershman, M.D., M.S.
Scott D. Ramsey, M.D., Ph.D.

Time/Location
Thursday, October 8, 2015
Room: Michigan (Bronze Level, East Tower)
5:00 p.m. - 7:00 p.m.

Agenda
Presentations/Concepts
Stakeholder Engagement in Cancer Care Delivery Studies – Discussion / Panel.
1. Kate Castro, RN, MS, Program Director, Division of Cancer Control and Population Sciences; National Cancer Institute
2. Anne Marie Cicarella, Patient Advocate
3. Trent T. Haywood, MD, JD; SVP, Office of Clinical Affairs and Chief Medical Officer BlueCross BlueShield Association

New Concepts (Reducing Overuse/Surveillance)
- Randomized multicenter trial comparing fixed interval tumor surveillance testing to usual care in patients with metastatic breast, colorectal, and ovarian cancers. Dr. Accordino.
- Cluster randomized trial to determine the impact of audit and feedback on use surveillance testing for patients with common solid tumors. Dr. Wright.

Concepts/Protocols approved by DCP
- S1417, “Implementation of a Prospective Financial Toxicity Assessment Tool in Patients with Metastatic Colorectal Cancer.” Update on Concept. - Dr. Shankaran.
- S1415, “A Pragmatic Trial To Improve Colony Stimulating Factor Use in Cancer.” Drs. Ramsey, Lyman, Barlow, and Hershman.

Ongoing Database/Grant Funded Projects
- Scientific Value of Positive and Negative Clinical Trials. Dr. Unger.
- Value of Information and SWOG Trials, PCORI Project. Drs. Ramsey and Carlson.

Ongoing Database Studies. Dr. Hershman.

Studies Closed To Accrual
- S1105, “Randomized Controlled Trial of a Behavioral Intervention to Improve Adherence to Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer.” Drs. Hershman and Neugut.

Active Studies
- S1007, “Update on Quality of Life and Economic Analysis Sub-study of Breast protocol S1007.” Dr. Barlow.
- S1207, Cost Effectiveness Analysis of “Phase III Randomized, placebo-controlled clinical trial evaluating the use of adjuvant endocrine therapy +/- one year of everolimus in patients with high-risk, hormone receptor-positive and HER2/neu negative breast cancer.” Dr. Chavez-MacGregor.

Ongoing Database/Grant Funded Projects
- Medicare claims data as a core resource for comparative effectiveness studies. Drs. Hershman and Unger.
- Value of Information and SWOG Trials, PCORI Project. Drs. Ramsey and Carlson.

Publications
The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts
- Multiple Studies The globalization of cooperative groups. M Valdivieso, BW Corn, JE Dancey, DL Wickerham, LE Horvath,
CANCER CARE DELIVERY COMMITTEE


- Enhancing adolescent and young adult oncology research within the National Clinical Trials Network: rationale, progress, and emerging strategies. AR Weiss, CR Nichols, DR Freyer. Seminars in Oncology, in press. (special invited issue: Progress and Infrastructure for Clinical Research: The NCI National Clinical Trials Network; guest editor: CD Blanke).

Submitted Manuscripts

- S1204 Stepwise development of a cancer care delivery research study to evaluate viral infections in cancer patients: SWOG S1204. JM Unger, DL Hershman, K Arnold, R Loomba, R Chugh, JP Hwang, MA O’Rourke, N Bhadkamkar, LX Wang, AB Siegel.

- S9346 Long-term consequences of intermittent and continuous androgen deprivation in patients with metastatic prostate cancer. DL Hershman, JM Unger, JD Wright, S Ramsey, C Till, CM Tangen, W Barlow, C Blanke, IM Thompson, M Hussain. Journal of the National Cancer Institute, under review.
CANCER SURVIVORSHIP COMMITTEE

Cancer Survivorship Committee Co-Chairs:
Carol J. Fabian, M.D.
Robert S. Krouse, M.D.

Time/Location
Thursday, October 8, 2015
Room: Michigan (Bronze Level, East Tower)
1:30 p.m. - 2:30 p.m.

Agenda

Update of Concepts Previously Proposed
1:30 - 1:45  S1501, “Carvedilol vs Placebo to Decrease the Incidence of Left Ventricular Myocardial Dysfunction in High Risk Patients with Metastatic Breast Cancer on Trastuzumab Therapy.” (Secondary Committee Breast). Justin Floyd, D.O. and Monika Leja, M.D. (TM components Andrew Goodwin, Ph.D. and Carol Fabian, M.D.) Present revised concept for Resubmission to Steering Committee.

1:45 - 1:50  Cancer Survivorship Website Project. Mark O’Rourke, M.D., Jennifer Klemp, Ph.D., and Marian Neuhausser, Ph.D., R.D. Update progress.

Others (Will not be presented this meeting due to time constraints)
■ “Docosahexaenoic Acid (DHA) vs Placebo during Adjuvant Therapy for Prevention of Cognitive Dysfunction Pilot feasibility study (Secondary Committee Breast).” Drs. Fabian and Wefel. Study should start accrual September 2015.

■ “Quality of Life after Surgical Treatment of Rectal Cancer: A Pilot Study.” Dr. Carmichael.

New Concepts:
■ 1:50 - 2:05  “A trial to identify the most effective method to increase physical activity among colorectal cancer survivors.” Heather Greenlee, N.D., Ph.D.

Activated Studies

Closed Studies


Subcommittee Working Group Reports

2:15 - 2:20  Oncology Research Professionals Update: Jamie Myers, A.P.R.N., Ph.D.

2:20 - 2:25  Advocate Update: Rick Bangs and Anna Gottlieb.

Publications
The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts
No publication information for this cycle.

Submitted Manuscripts
■ Multiple Studies Association between body mass index (BMI) and cancer survival across multiple SWOG clinical trials. H Greenlee, J Unger, M LeBlanc, S Ramsey, D Hershman. Journal of the National Cancer Institute, under review.
PREVENTION & EPIDEMIOLOGY COMMITTEE

Prevention Committee Co-Chairs: Marian Neuhouser, Ph.D., R.D. Banu Arun, M.D.

Statistician: Patricia O’Kane

Oncology Research Professional: Patricia O’Kane

Protocol Coordinator: Patricia O’Kane

Time/Location

Thursday, October 8, 2015
Room: Michigan (Bronze Level, East Tower)
10:15 a.m. - 11:15 a.m.

Agenda

Introduction

Presentations

1. Welcome and Opening Comments - Marian Neuhouser, Ph.D., R.D.

2. Increased use of multigene panels for hereditary cancer testing and impact on cancer risk assessment, screening and prevention - Banu Arun, M.D.

3. Epidemiologic and Translational Research Opportunities Using PCPT and SELECT Data and Biorepositories - Cathy Tangen, Ph.D.

Active Studies


Closed Studies


New Business

Concepts under development

- Individualized Dosing of Omega-3 Fatty Acids for Prevention of Colorectal Cancer. Dr. Brenner.

Discussion

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts


PREVENTION & EPIDEMIOLOGY COMMITTEE


Multiple Studies: Ongoing use of data and specimens from NCI-sponsored Cancer Prevention Clinical Trials in the Community Clinical Oncology Program (CCOP). L Minasian, CM Tangen, DL Wickerham. Seminars in Oncology, in press. [special invited issue: Progress and Infrastructure for Clinical Research: The NCI National Clinical Trials Network; guest editor: CD Blanke].

Submitted Manuscripts


- **S1119** Clinical, epidemiologic and genomic studies (SWOG S1119) of Helicobacter pylori in Lima, Peru: The role of contaminated water. M Valdivieso, A Bussalleu, R Sexton, K Boehnke, S Osorio, S Novoa Reyes, JJ Crowley, GE Goodman, LH Baker, C Xi. [eBioMedicine, under review.]

- **S9217** Prostate cancer risk assessment by genetic risk score in men with or without family history. H Chen, X Liu, C. Brendler, DP Ankerst, RJ Leach, PJ Goodman, MS Lucia, CM Tangen, L Wang, F-C Hsu, J Sun, AK Kader, WB Isaacs, BT Helfand, SL Zheng, IM Thompson, EA Platz, J Xu. [European Urology, under review.]

- **S9217** Key genes involved in the immune response are generally not associated with intraprostatic inflammation in men without a prostate cancer diagnosis. DA Winchester, B Gurel, C Till, PJ Goodman, CM Tangen, RM Santella, T Paris-Johnson, RJ Leach, IM Thompson, J Xu, SL Zheng, MS Lucia, SM Lippmann, HL Parnes, WB Isaacs, CG Drake, AM DeMarzo, EA Platz. [International Journal of Cancer, under review.]

- **S9217** Inflammation in benign prostate tissue and prostate cancer in the finasteride arm of the Prostate Cancer Prevention Trial, TJ Murtola, B Gurel, M Umbehr, MS Lucia, IM Thompson, Jr., Pmj Goodman, AR Kristal, HL Parnes, SM Lippman, S Sutcliffe, SB Peskoe, JR Barber, CG Drake, WG Nelson, AM De Marzo, EA Platz. [Cancer Epidemiology, Biomarkers & Prevention, under review.]

- **S9217** Baseline serum androgens and prostate cancer risk: results from the placebo arm of the Prostate Cancer Prevention Trial. JM Schenk, C Till, AW Hsing, FZ Stanczyk, Z Gong, ML Neuhauser, JK Reichardt, AM Hoque, WD Figg, PJ Goodman, CM Tangen, IM Thompson. [Cancer Causes and Control, pending resubmission.]
SYMPTOM CONTROL & QUALITY OF LIFE COMMITTEE

Symptom Control and QOL Committee Co-Chairs:
Michael Fisch, M.D., M.PH.
James L. Wade, III, M.D.

Time/Location

Thursday, October 8, 2015
Room: Michigan (Bronze Level, East Tower)
8:00 a.m. - 10:00 a.m.

Agenda

Introductions

Presentations
1. SWOG SxQOL, Where we have been, where we are now, and what great road(s) are yet ahead!!! James L. Wade III, M.D.
2. Priority setting and new directions for SWOG SxQOL - Lynn Henry, M.D.

Active Studies

Closed Studies
- S1007, “A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone-responsive and Her2-Negative Breast Cancer According to Recurrence Score (RS).” Drs. Gonzales-Angulo, Meric-Bernstam, Hortobagyi, and Albain. Activated: 1/15/11 (Clinical study remains open to accrual); Quality of Life and Economic Substudy permanently closed to accrual: 12/1/12.

Other Active Studies with Symptom Control and QOL Component
- S1207, “Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer.” Dr. Chavez-MacGregor. Activated: 9/1/13.

- CTSU/A021202, “Prospective Randomized Phase II Trial of Pazopanib (NSC #737754, IND 75648) Versus Placebo in Patients with Progressive Carcinoid Tumors.” Dr. Phan. Activated: 1/15/14.
- CTSU/A041202, “A Randomized Phase III Study of Bendamustine Plus Rituximab versus Ibrutinib Plus Rituximab...
SYMPTOM CONTROL & QUALITY OF LIFE COMMITTEE

versus Ibrutinib Alone in Untreated Older Patients (>/= 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL).” Dr. Coutre. Activated: 12/15/13.

■ CTSU/B55, “A Randomised, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy.” Dr. Sharma. Activated: 7/3/14.


■ CTSU/E1411, “Intergroup Randomized Phase II Four Arm Study in Patients with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A = Rituximab + Bendamustine Followed by Rituximab Consolidation (RB --> R); Arm B = Rituximab + B endamustine + Bortezomib Followed by Rituximab Consolidation (RBV --> R), Arm C = Rituximab + Bendamustine Followed by Lenalidomide + Rituximab Consolidation (RB --> LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed by Lenalidomide + Rituximab Consolidation (RBV --> LR).” Dr. Till. Activated: 6/15/12.


■ CTSU/E1A11, “Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE).” Dr. Zonder. Activated: 2/1/14.


■ CTSU/E2906, “Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age >/= 60 Years).” Dr. Godwin. Activated: 8/15/12; Closed: 2/23/15.


SYMPTOM CONTROL & QUALITY OF LIFE COMMITTEE

- CTSU/R0848, “A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (Ph II-R) and Chemoradiation (Ph III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma.” Dr. Philip. Activated: 12/15/09.


Committee Process
Sign meeting attendance list
Communication issues

Announcements
NCORP Updates

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts


Submitted Manuscripts

- S0927 Uncontrolled lipid and triglycerides levels in breast cancer survivors on aromatase inhibitor therapy (SWOG S0927). DL Hershman, C Till, D Awad, KD Crew, H Greenlee, M Accordino, DL Lew, LM Minasian, JL Wade, III, CM Moinpour, JM Unger. Cancer Epidemiology, Biomarkers & Prevention, under review. [also under Breast Committee]
EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

Committee Leadership
Chair: Razelle Kurzrock, M.D.
Executive Officer: Christopher W. Ryan, M.D.
Statisticians: Megan Othus, Ph.D., Melissa Plets, M.S.

Designates
Data Coordinators: Laura Kingsbury, M.R.T., Christine McLeod

Oncology Research Professionals:
CRAs: Corrine Turrell, C.C.R.P.
Nurse: TBD
Pharmaceutical Science: Siu-Fun Wong, Pharm.D.
Protocol Coordinator: Cara Laubach

Early Therapeutics Liaisons
Breast Committee Liaison: George Somlo, M.D.
GU Committee Liaison: Neeraj Agarwal, M.D.
Lung Committee Liaison: Shirish M. Gadgeel, M.D.
Lymphoma Committee Liaison: Daruka Mahadevan, M.D., Ph.D.
Melanoma Committee Liaison: Jeffrey A. Sosman, M.D.
Myeloma Committee Liaison: Frits van Rhee, M.D., Ph.D.

Time/Location
Thursday, October 8, 2015
Room: Regency C (Gold Level, West Tower)
10:00 a.m. – 12:15 p.m.

Agenda

Introduction to Early Therapeutics - Razelle Kurzrock, M.D., Senior Deputy Center Director, UCSD Moores Cancer Center

Presentations
10:10 – 10:45 a.m. “New Developments in Early Therapeutics” Monica Mita, M.D.
10:45 – 11:05 a.m. “Jak1 inhibitor trial concept for pleomorphic and fibrosarcomas” Victor M. Villalobos, M.D., Ph.D., Rare Cancers Fellow: The Hope Foundation 2015
11:05 – 11:25 a.m. “EAY131 – NCI Match: Trial Overview” Victor M. Villalobos, M.D., Ph.D., Rare Cancers Fellow: The Hope Foundation 2015
11:25 – 11:45 a.m. “S1601: DART Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors” Sandip Patel, M.D.
11:45 – 12:05 p.m. “Brentuximab vedotin in CD30+ systemic mastocytosis and CMML trial concept” Marie Huong Nguyen, M.D. and Uma Borate, M.D.
12:05 – 12:15 p.m. Panel Questions and Answers/ Open Discussion and Other New Business Razelle Kurzrock, M.D. and Speakers

Proposed Studies
- SXXXX “A Trial Incorporating Upfront Targeted Therapy in Carcinoma of Unknown Primary.” Drs. Cobain and Baker.
- SXXXX “Brentuximab in mastocytosis and CMML.” Drs. Nguyen and Borate.
- CTSU/GOG-0286B, “A Randomized Phase II/III Study of Paclitaxel/Carboplatin/Metformin (NSC#91485) Versus Paclitaxel/Carboplatin/Placebo as Initial Therapy for Measurable Stage III or IVA, Stage IVB, or Recurrent Endometrial Cancer (NCT #0265687).” Dr. Verschraegen.
- SXXXX, “A Phase II Study of a Selective JAK1 Inhibitor in Subjects with Advanced Sarcomas.” Dr. Villalobos.

Active Studies
- CTSU/A071102, “A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed MGMT Promoter Hypermethylation.” Dr. Piccioni. Activated by Alliance: 1/28/14; Activated by SWOG: 4/1/15.
EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE


Closed Studies

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts


- The National Clinical Trials Network: conducting successful clinical trials of new therapies for rare cancers. AF Schott, JJ Welch, R Kurzrock. Seminars in Oncology, in press. [special invited issue: Progress and Infrastructure for Clinical Research: The NCI National Clinical Trials Network; guest editor: CD Blanke].

Submitted Manuscripts
GASTROINTESTINAL COMMITTEE

Committee Leadership
Chair: Howard S. Hochster, M.D.
Vice-Chair: Heinz-Josef Lenz, M.D.
Executive Officer: Christopher W. Ryan, M.D.
Statisticians: Katherine Guthrie, Ph.D.
Shannon McDonough, M.S.

Scientific Leadership
Gastroesophageal:
Syma Iqbal, M.D.
Lawrence P. Leichman, M.D.
Scott A. Hundahl, M.D. (Surgical representative)

Pancreatic:
Philip A. Philip, M.D., Ph.D.
Andrew M. Lowy, M.D. (Surgical representative)
Tanios Bekai-Saab, M.D. (Translational representative)

Hepatobiliary:
Anthony B. El-Khoueiry, M.D.
TBD
Syed Ahmad, M.D. (Surgical representative)

Colon:
Philip J. Gold, M.D.
Wells A. Messersmith M.D.
Kevin G. Billingsley, M.D. (Surgical representative)

Rectal:
Lisa A. Kachnic, M.D.
Cathy Eng, M.D.

Translational Medicine:
Wells A. Messersmith, M.D.
Heinz-Josef Lenz, M.D.

Drug Development:
Ramesh Ramanathan, M.D.
Sunil Sharma, M.D.

Imaging:
Anthony F. Shields, M.D., Ph.D.
David Shin-Kuo Lu, M.D.

Radiation Oncology:
Lisa A. Kachnic, M.D.

Designates
Cancer Control Liaison: Jason A. Zell, D.O.
Data Coordinators: Stephanie Edwards
Christine McLeod
Brian Zeller

Oncology Research Professionals:
CRAs: Sandy Annis, C.C.R.P.
Nurses: Rita Kaul, R.N., B.S.N.
Valerie A. Parks, R.N.

Patient Advocate (Pancreatic): Porsha James, M.P.H.
Patient Advocate (Colon): Florence Kurttila
Pharmaceutical Science: Craig Elg, Pharm.D.
Linda Lee-Gabel, Pharm.D.
Protocol Coordinator: Kimberly Kaberle

Time/Location
Friday, October 9, 2015
Room: Crystal A (Green Level, West Tower)
10:00 a.m. - 12:00 p.m.

Agenda
Introduction · Howard Hochster, M.D.

Active Studies
- CTSU/RTOG 1010, “A Phase II Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma.” Dr. L. Leichman. Activated: 9/1/11.

Closed Studies
- S1201, “A Randomized Phase II Pilot Study Prospectively Assigning Treatment for Patients Based on ERCC1 (Excision Repair Cross-Complementing 1) for Advanced/Metastatic Esophageal, Gastric or Gastroesophageal Junction (GEJ) Cancer.” Drs. Iqbal and Lenz. Activated: 2/8/12.

Proposed Studies
- S1508, “A Two-part Phase II Randomized Study of First and Second Line Therapy in HER2 Positive Metastatic/Locally Advanced (in-operable) Gastric Cancer.” Dr. Barzi.

Pancreatic

Active Studies

- S1505, “A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/nab-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma.” Dr. Sohal. Activated: TBD.


- CTSU/RTOG 0848, “A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with
**GASTROINTESTINAL COMMITTEE**

**Resected Head of Pancreas Adenocarcinoma.** Dr. Philip. Activated: 12/15/09.


**Proposed Studies**
- S1513, “Randomized Phase II Study of 2nd Line Therapy with FOLFIRI with or without PARP Inhibitor Veliparib (ABT-888) in Metastatic Pancreatic Cancer.” Dr. Chiorean.

**Hepatobiliary**

**Closed Studies**
- S1310, “Randomized Phase II Trial of Single Agent MEK Inhibitor GSK11200212 vs. 5-Fluorouracil or Capecitabine in Refractory Advanced Biliary Cancer.” Dr. Kim. Activated: 2/15/14; Closed: 5/15/15.

**Active Studies**
- S1406, “Randomized Phase II Study of Irinotecan and Cetuximab with or without Vemurafenib in BRAF Mutant Metastatic Colorectal Cancer.” Dr. Kopetz. Activated: 11/14/15.
- CTSU/C80702, “A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer.” Dr. Shields. Activated: 8/15/10.

**Proposed Studies**
- S1417, “Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer.” Dr. Shankaran.

**Rectal**

**Active Studies**

**Proposed Studies**

**Other**

**Active Studies**
- CTSU/A021202, “Prospective Randomized Phase II Trial of Pazopanib versus Placebo in Patients with Progressive Carcinoid Tumors.” Dr. Phan. Activated: 1/15/14.

**Correlative Studies**
- S9008A, “Trial of Adjuvant Chemoradiation after Gastric Resection Adenocarcinoma, Phase III.” Dr. Shridhar.
GASTROINTESTINAL COMMITTEE

Other Proposed Studies

- “Gemcitabine/nab-Paclitaxel Followed by SBRT +/- MK3475 as Neoadjuvant Therapy for Borderline Resectable Pancreatic Adenocarcinoma: A Randomized Phase II Study.” Dr. Bekaii-Saab.

- “Randomized Phase II Trial of SGI-110 with Gemcitabine and Cisplatin versus Gemcitabine and Cisplatin Alone in Advanced Biliary Cancer.” Dr. Siegel.

- “A Randomized Phase II/III Study of Gemcitabine and Cisplatin followed by Capecitabine/Radiation versus Gemcitabine and Cisplatin Alone.” Dr. El-Khoueiry.

- “Randomized Phase II Cooperative Group Study of Nivolumab Compared to FOLFI/R/OLFOX +/- Bevacizumab in 2nd Line Metastatic Microsatellite Instability High Colorectal Cancer (MRI-H CRC)” Dr. Overman.

- “Randomized Phase II Study of FOLFOXIRI vs FOLFOX for High Risk Rectal Cancer.” Dr. Kennecke.

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts


Submitted Manuscripts

No publication information for this cycle.
GENITOURINARY COMMITTEE

Committee Leadership
Chair: Ian M. Thompson, Jr., M.D.
Vice-Chair: Nicholas J. Vogelzang, M.D.
Executive Officer: Christopher W. Ryan, M.D.
Statisticians: Cathy M. Tangen, Dr.P.H.
Melissa Plets, M.S.

Scientific Leadership
Translational Medicine: David J. McConkey, Ph.D.
Radiation Oncology: David Raben, M.D.
Surgery: Daniel J. Culkin, M.D.
Imaging: Daniel W. Lin, M.D.
John D. Hazle, Ph.D.
Medical Oncology: Celestia S. Higano, M.D.
Pathology: M. Scott Lucia, M.D.
Liaison to the SPORES: Colin P.N. Dinney, M.D.
Early Therapeutics: Neeraj Agarwal, M.D.

Designates
Cancer Control: Peter J. Van Veldhuizen, M.D.
Data Coordinators: Jean Barce
Diana Heaney
Amy Johnson

Oncology Research Professionals:
CRAs: Debra W. Christie, M.B.A.
Nurses: Deborah A. Halk, R.N.
Patient Advocates: Rick Bangs (Bladder)
Tony Crispino (Prostate)
Pharmaceutical Science: Jorge G. Avila, Pharm.D.
Jesse Modlin, Pharm.D.
Protocol Coordinator: Jennifer Scott

Time/Location
Wednesday, October 7, 2015
Room: Regency A (Gold Level, West Tower)
2:00 p.m. - 5:00 p.m.

Agenda
“Update: PCORI, A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information.” Rick Bangs, Chair, SWOG Advocates Committee

Renal Cell
Organ Site Chairs: Drs. Primo N. Lara, Jr. (Advanced) and Edward M. Messing (Local)

Priority Studies
■ S1500, “A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors in Metastatic Papillary Renal Carcinoma (PAPMET).” Dr. Pal.

Active Studies

Bladder
Organ Site Chairs: Drs. Daniel P. Petrylak (Advanced) and Seth P. Lerner (Local)

Priority Studies

Active Studies

Prostate
Organ Site Chairs: Drs. David I. Quinn (Advanced) and Daniel W. Lin (Local)
GENITOURINARY COMMITTEE

Active Studies


Cancer Control

Organ Site Chair: Dr. Peter J. Van Veldhuizen

Active Studies


Closed Studies


Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.
GENITOURINARY COMMITTEE


Submitted Manuscripts


LEUKEMIA COMMITTEE

Committee Leadership
Chair: Harry P. Erba, M.D., Ph.D.
Vice-Chair: Steven E. Coutre, M.D.
Executive Officer: Susan M. O’Brien, M.D.
Statisticians: Megan Othus, Ph.D., Anna Moseley, M.S.

Scientific Leadership
Translational Medicine: Jerald P. Radich, M.D.
Pathology: David R. Head, M.D.
Cytogenetics Liaison: Diane Roulston, Ph.D., Min Fang, M.D., Ph.D.

Designates
Data Coordinators: Louise Highleyman, Laura Kingsbury, M.R.T., Tracy Maher, C.C.R.P.
Oncology Research Professionals:
CRAs: Mary Lynn Rush, R.N., B.S.N.
Nurses: Keisha C. Humphries, R.N., B.S.N.
Patient Advocate: Michelle J. Warman, L.V.N.
Pharmaceutical Science: Holly O. Chan, Pharm.D., Joyce Lee, Pharm.D.
Protocol Coordinator: Cara Laubach

Time/Location
Saturday, October 10, 2015
Room: Regency C (Gold Level, West Tower)
9:30 a.m. - 11:30 a.m.

Agenda

Introduction
Current Status of the Leukemia Committee – Harry Erba, M.D., Ph.D.

AML/MDS Studies

Active Studies


- S1203, “A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin (7 + 3) Therapy or Idarubicin with High Dose Cytarabine (IA) versus IA with Vorinostat (IA + V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia (AML).” Drs. Garcia-Manero, Pagel, Radich, and Fang. Activated: 12/15/12.

- CTSU/E2905, “Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with Lenalidomide (Revlimgid®) Alone and in Combination with Epoetin Alpha (Procrit®) in Subjects with Low-or Intermediate-1 Risk MDS and Symptomatic Anemia.” Dr. Schiffer. Activated by ECOG: 1/29/09; Activated by SWOG: 2/15/09.

Proposed Studies

- SXXXX, “A Randomized Phase II/III Trials of “Novel Therapeutic Regimens” versus Azacitidine in Newly Diagnosed Adult Patients Age 60 or Older with Previously untreated Acute Myeloid Leukemia.” Drs. Michaelis and Walter.

Closed Studies


- CTSU/E2906, “Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age ≥ 60 Years).” Dr. Godwin. Activated by ECOG: 12/28/10; Activated by SWOG: 8/15/12; Closed: 2/23/15.

ALL Studies

Active Studies

- S1318, “A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients > = 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients > = 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph +) ALL.” Drs. Advani and O’Dwyer. Activated: 1/12/15.

- S1312, “A Phase I Study of Inotuzumab Ozogamicin (NSC-772518) in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia and Burkitt’s Leukemia).” Drs. Advani and Liedtke. Activated: 4/1/14.
LEUKEMIA COMMITTEE


**Closed Studies**
- **S0805**, “Phase II Study of Combination of Hyper-CVAD and Dasatinib with or without allogenic stem cell transplant in Patients with Philadelphia (Ph) Chromosome Positive and/or BCR-ABL Positive Acute Lymphoblastic Leukemia (ALL) (A BMT Study).” Drs. Ravandi, O’Brien, Forman, Ha, Wong, and Radich. Activated: 9/1/09; Closed: 10/1/13.
- **CTSU/C10701**, “A Phase II Study of Dasatinib (Sprycel®) (IND #73969, NSC #732517) as Primary Therapy Followed by Transplantation for Adults >/= 18 Years with Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia by CALGB, ECOG, SWOG.” Dr. Liedtke. Activated by CALGB: 12/15/10; Activated by SWOG: 6/1/12; Closed: 11/14/14.

**CLL Studies**

**Active Studies**
- **CTSU/A041202**, “A Randomized Phase III Study of Bendamustine plus Rituximab versus Ibrutinib plus Rituximab versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL).” Dr. Coutre. Activated by Alliance: 12/9/13; Activated by SWOG: 12/15/13.

**CML Studies**

**Proposed Studies**
- **SXXXX**, “A Phase II Study of Ruxolitinib in Combination with Nilotinib in CML Patients with Evidence of Molecular Disease.” Dr. Sweet.

**Publications**

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**Published/Accepted Manuscripts**
LEUKEMIA COMMITTEE

Submitted Manuscripts


■ Multiple Studies* Relation between event-free survival and overall survival in acute myeloid leukemia: A report from SWOG, HOVN/SAKK, and MRC/NCRI. M Othus, W van Putten, B Lowenberg, SH Petersdorf, S Nand, H Erba, F Appelbaum, R Hills, N Russell, A Burnett, E Estey. Leukemia, under review. *includes other groups/institutions, as well as SWOG studies S0106, S0703.

LUNG COMMITTEE

Committee Leadership
Chair: David R. Gandara, M.D.
Vice-Chair: Stephen G. Swisher, M.D.
Executive Officer: Julie R. Gralow, M.D.
Statisticians: Mary Redman, Ph.D.
Jieling Miao, M.S. (Lung-MAP Protocol)
James Moon, M.S.
Shannon McDonough, M.S. (Lung-MAP Protocol)

Scientific Leadership
Translational Medicine: Philip C. Mack, Ph.D.
Fred R. Hirsch, M.D., Ph.D.
Radiation Oncology: Laurie E. Gaspar, M.D.
Surgery: Stephen G. Swisher, M.D.
Imaging: Anthony F. Shields, M.D., Ph.D.
Friedrich D. Knollmann, M.D., Ph.D.
Medical Oncology: Karen Kelly, M.D.
Pathology: Ignacio I. Wistuba, M.D.
Developmental Therapeutics: Roy S. Herbst, M.D., Ph.D.
Early Therapeutics: Shirish M. Gadgeel, M.D.
Designates
Cancer Control Liaison: Gary E. Goodman, M.D.
Community Affiliate: Paul J. Hesketh, M.D.
Data Coordinators: Kara Amber (Lung-MAP Protocol)
Louise Hightleyman (Lung-MAP Protocol)
Larry Kaye
Brian Zeller
Monica Yee

Oncology Research Professionals:
CRAs: Courtney L. Williamson
Ginny M. Keeling, M.S.
Nurses: Kimberly M. Belzer, M.S., P.A.-C
Rosalie Zablocki, R.N.
Patient Advocate: Bonnie J. Addario
Pharmaceutical Science: Joyce Lee, Pharm.D.
Daniel L. Hertz, Pharm.D.
Protocol Coordinator: Gretchen E. Goetz, M.B.A.
Crystal Miwa (Lung-MAP Protocol)

Agenda
Opening Remarks - Dr. Gandara
Translational Medicine Session
Surgery Session
Scientific Session - Karen Kelly, M.D.

Active Studies
- S1300, “A Randomized Phase II Trial of Crizotinib Plus Pemetrexed Versus Pemetrexed Monotherapy in ALK-Positive Non-Squamous NSCLC Patients Who Have Progressed Systemically After Previous Clinical Benefit From Crizotinib
LUNG COMMITTEE


■ S0905, “A Phase I / Randomized Phase II Study of Cediranib (NSC #732208) Versus Placebo in Combination with Cisplatin and Pemetrexed in Chemonaive Patients with Malignant Pleural Mesothelioma.” Drs. Tsao, Vogelzang and Wistuba. Activated: 3/15/10; Phase I Closed: 8/1/11; Phase II Activated: 10/1/11.


■ CTSU/A081105, “Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC).” Dr. Kelly. Activated: 8/18/14.


■ CTSU/CALGB 30610, “Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin or Carboplatin and Etoposide.” Drs. Gadgeel and Gaspar. Activated: 4/1/08.

Proposed Studies

■ S1400I, “A Phase III Randomized Study of Nivolumab plus Ipilimumab VERSUS Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (Lung-MAP Sub-study).” Drs. Gettinger and Bazhenova.

■ S1400G, “A Phase II Randomized Study of BMN 673 (Talazoparib) for Previously-Treated Homologous Recombination Repair Deficiency Positive Patients with Squamous Cell Lung Cancer (Lung-MAP Sub-study).” Drs. Gadgeel and Gaspar.

■ S1400F, “Nivolumab-exposed (3rd line): MEDI4736 plus tremelimumab (Lung-MAP Sub-study).” Drs. Leighl and Rizvi.

■ S1507, “A Phase II Trial of GSK1120212B (Trametinib Dimethyl Sulfoxide) with Docetaxel in Patients with Kras Mutation Positive Non-small Cell Lung Cancer (NSCLC) and Progressive Disease Following At Least One Prior Systemic Therapy.” Dr. Gadgeel.

■ S1604, “A Randomized, Phase III Study for Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) Patients Treated with Maintenance Therapy with Atezolizumab or
LUNG COMMITTEE

- Pemetrexed after Initial Chemotherapy with Immunosignature-Driven Analysis.” Dr. Chiang.

  - “A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Resectable Malignant Pleural Mesothelioma.” Dr. Tsao.

  - “A Randomized, Phase II Study Comparing AZD9291 alone versus AZD9291 plus MEDI4736 in Previously Treated Patients with Advanced Non-Small Cell Lung Cancer with EGFR driver mutation.” Dr. Arrieta.

  - “Strategies to Improve Lymph Node Examination of Non-Small Cell Lung Tumors (SILENT).” Dr. Osarogiagbon.

  - “Minimally Invasive Surgery vs. Surgery Including Open Lobectomy in Non-Small Cell Lung Cancer (MISSION).” Drs. Rice and Swisher.

  - “Randomized Phase II Study to Test the Efficacy of BIBF1120 in Combination with Cisplatin and Etoposide for Subjects with Previously Untreated Extensive Stage Small Cell Lung Cancer.” Drs. Heymach and Glisson.

  - “A Randomized Phase II Trial of Erlotinib with or without Ganetespib in 2nd Line EGFR, kRAS, and ALK Wild Type NSCLC Patients with Adenocarcinoma.” Dr. Kelly.

  - “Second Line Small Cell Lung Cancer Trial with BioMarin PARP Inhibitor.” Dr. Byers.

  - “A Phase II Trial of Carboplatin, Paclitaxel, and Ramucirumab in Patients with Locally Advanced, Meta-static, or Recurrent Thymic Epithelial Tumors (TET) not Amenable to Curative Intent Surgery.” Dr. Ferrarotto.


Closed Studies


Publications

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Published/Accepted Manuscripts

- S1400/other The master protocol concept. MW Redman, CJ Allegra. Seminars in Oncology, in press. [special invited issue: Progress and Infrastructure for Clinical Research: The NCI National Clinical Trials Network; guest editor: CD Blanke].


LUNG COMMITTEE


Submitted Manuscripts
LYMPHOMA COMMITTEE

Committee Leadership
Chair: Jonathan W. Friedberg, M.D.
Vice-Chair: Sonali M. Smith, M.D.
Executive Officer: Susan M. O’Brien, M.D.
Statisticians: Michael LeBlanc, Ph.D.
Hongli Li, M.S.

Scientific Leadership
Translational Medicine: Owen A. O’Connor, M.D., Ph.D.
Radiation Oncology: Louis S. Constine, M.D.
Imaging: Oliver W. Press, M.D., Ph.D.
Pathology: Lisa M. Rimsza, M.D.
Early Therapeutics: Daruka Mahadevan, M.D., Ph.D.

Designates
Cancer Control: TBD
Data Coordinators: Jeri Jardine, Iris Syquia

Oncology Research Professionals:
CRAs: Erin M. Cebula, M.P.H.
Nurse: TBD
Patient Advocate: Hildy Dillon, M.P.H.
Pharmaceutical Science: Lara M. Au, Pharm.D.
Holly O. Chan, Pharm.D.
Protocol Coordinator: Megan Hardin

Time/Location
Friday, October 9, 2015
Room: Regency D (Gold Level, West Tower)
8:00 a.m. - 11:00 a.m.

Agenda
2. Current landscape: How we treat NHL in 2015
   a. Follicular Lymphoma: Dr. Friedberg
   b. “Double hit” DLBCL: Dr. Smith
3. Upcoming Trials
   a. DLBCL: Dr. Smith
   b. Follicular lymphoma: Dr. Barr
   c. Mantle cell lymphoma: Dr. Till
   d. Alliance BMT nonGCB DLBCL: Dr. Stiff
4. ASH Preview
   a. RCHOP and Vorinostat for DLBCL: Dr. Persky
   b. Intergroup Mantle Cell Lymphoma: Dr. Chen
   c. S0816 HIV Cohort Analysis: Dr. Danilov
5. Correlative Science
   a. S0016 Genomic Alterations Analysis: Dr. Fang

Non-Hodgkin Lymphoma

- CTSU/E1411, “Intergroup Randomized Phase 2 Four Arm Study In Patients ≥ 60 With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab + Bendamustine Followed By Rituximab Consolidation (RB → R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV → R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB → LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR).” Dr. Till. Activated: 5/22/12.

- CTSU/E1412, “Randomized Phase II Open Label Study of Lenalidomide R-CHOP (R2CHOP) vs. RCOP (Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone) in Patients with Newly Diagnosed Diffuse Large B-Cell Lymphoma.” Dr. Amengual. Activated: 6/1/14.


LYMPHOMA COMMITTEE

Cancer Control Studies


New Proposals

- “Randomized Phase II Trial in High-Risk Relapsed Refractory Follicular Lymphoma.” Dr. Barr.

Publications

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Published/Accepted Manuscripts


Submitted Manuscripts


MELANOMA COMMITTEE

Committee Leadership
Chair: Antoni Ribas, M.D., Ph.D.
Vice-Chair: William E. Carson III, M.D.
Executive Officer: Christopher W. Ryan, M.D.
Statisticians: Megan Othus, Ph.D.; James Moon, M.S.; Michael Wu, Ph.D.

Scientific Leadership
Translational Medicine: William E. Carson III, M.D.
Radiation Oncology: Evan J. Wuthrick, M.D.
Surgery: Robert H.I. Andtbacka, M.D.
Imaging: Kenneth F. Grossman, M.D., Ph.D.
Pathology: Martin Allen-Auerbach, M.D.
Medical Oncology: Lawrence E. Flaherty, M.D.
Non-Melanoma Skin Cancer: Jane L. Messina, M.D.
Early Therapeutics: Sancy A. Leachman, M.D., Ph.D.

Designates
Cancer Control Liaison: Jeffrey A. Sosman, M.D.
Data Coordinator: Jennie Barrett
Oncology Research Professionals:
CRAs: TBD
Patient Advocate: Valerie Guild
Pharmaceutical Science: Linda Lee-Gabel, Pharm.D.; Ronald G. Kittson, Pharm.D.
Protocol Coordinator: Patricia O’Kane

Time/Location
Saturday, October 10, 2015
Room: Regency A (Gold Level, West Tower)
9:30 a.m. - 11:30 a.m.

Agenda

Scientific Presentation
“Translating the Molecular Biology of Melanoma into the Clinic”– Michael Davies, M.D., MD Anderson Cancer Center.

Active Studies
- S1221, “Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with the BRAF Inhibitor Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer.” Drs. Ribas, Algazi and Lo. Activated: 7/1/13.
- CTSU/E2607, “A Phase II Trial of Dasatinib in KIT-Positive Patients with Unresectable Locally Advanced or Stage IV Mucosal, Acral and Vulvovaginal Melanomas.” Dr. Margolin. Activated: 12/1/11.

Approved Study in Development

Closed Studies
MELANOMA COMMITTEE

Publications

The publications listed below were received by the Group Chair’s Office as published, accepted, and submitted or reflect change in publication status since the spring 2015 SWOG group meeting. Not included are submitted or accepted publications where posting is not permitted due to journal embargo policy (e.g., NEJM). Conference abstracts are also not included.

Published/Accepted Manuscripts
No publication information for this cycle.

Submitted Manuscripts

■ S0008 Does unknown primary melanoma have a better prognosis? Analysis from a randomized phase III adjuvant trial (SWOG S0008). VK Sondak, J Moon, WE Carson, JT Vetto, RJ Tuthill, M Othus, MB Atkins, JA Sosman, A Ribas, LE Flaherty. Cancer, pending resubmission.

Future Group Meeting Dates
Mark Your Calendar!

2016
— April 27-30 —  
San Francisco, CA

— Sep 14-17 —  
Chicago, IL

2017
— April 26-29 —  
San Francisco, CA

— Oct 11-14 —  
Chicago, IL

2018
— April 11-14 —  
San Francisco, CA

— Oct 3-6 —  
Chicago, IL

2019
— April 24-27 —  
San Francisco, CA

— Oct 2-5 —  
Chicago, IL

2020
— April 22-25 —  
San Francisco, CA

— Sep 23-26 —  
Chicago, IL

Check the SWOG website (swog.org) for updates!
Do you have a few minutes between meetings? Stop by the SWOG registration desk in the Regency Foyer to check your e-mail and/or print your boarding pass!
# FUNDING OPPORTUNITIES

## 2016 Funding Year

### Juried Grants & Fellowships

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<th>Program</th>
<th>Description</th>
<th>Deadlines</th>
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<tbody>
<tr>
<td>IMPACT AWARD PROGRAM</td>
<td>$250,000</td>
<td>Mechanism for translating scientific discovery to patient care</td>
</tr>
<tr>
<td>FELLOWSHIPS</td>
<td>Funding to ensure protected time for investigators developing research experience within the NCTN/NCORP</td>
<td>March &amp; Throughout 2016</td>
</tr>
<tr>
<td>HOPE FOUNDATION SEED FUND</td>
<td>Up to $50,000 for preliminary research that will translate to clinical trials or trial-associated projects</td>
<td>July &amp; December</td>
</tr>
<tr>
<td>SWOG TRIAL SUPPORT (STRS)</td>
<td>Up to $75,000/year to support trial components requiring additional funding</td>
<td>Rolling</td>
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<tr>
<td>NCORP PILOT GRANTS</td>
<td>One-year projects centered on use of integrated data within SWOG NCORP sites</td>
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### Workshops & Professional Development

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
<th>Deadlines</th>
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</thead>
<tbody>
<tr>
<td>YOUNG INVESTIGATOR TRAINING COURSE (YITC)</td>
<td>Educational intensive in trial development and mgmt, stats</td>
<td>July</td>
</tr>
<tr>
<td>CLINICAL TRIALS TRAINING COURSE</td>
<td>Essential skills for clinical research associates, etc., to work within SWOG</td>
<td></td>
</tr>
<tr>
<td>SWOG GRANT WORKSHOP</td>
<td>Virtual grant-writing program for those preparing future grant submissions</td>
<td>March</td>
</tr>
<tr>
<td>SWOG COMMITTEE &amp; TRAVEL FUNDS</td>
<td>Supports committee/working group needs at meetings, as well as funding for travelers not funded by NCTN/NCORP</td>
<td>March &amp; August</td>
</tr>
<tr>
<td>SWOG-VA INTEGRATION</td>
<td>Addresses the needs of VA Medical Centers challenged by trial participation</td>
<td></td>
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Learn more at thehopefoundation.org  |  @supportingSWOG