



Welcome

Silver Anniversary for The Hope Foundation

he Southwest Oncology Group Foundation, later Hope, was born 25 years ago, and we're celebrating here in San Francisco.

Hope President and CEO Jo Horn will speak at our general plenary on Friday about Hope's evolution, as well as its impact. We'll also hear from three recipients of Hope grants – Coltman fellowships, research awards, and ITSC funds for translational medicine studies. We will learn about how this financial support helped investigators launch important SWOG trials and advance their careers.

Hope's impact on SWOG is quite widespread. A number of SWOG initiatives, from our Young Investigator Training Course to our SWOG Latin America Initiative

to our VA Integration
Support Program to our new
Leadership Academy, were
started and continue to be
supported by Hope. Our
foundation also supports our
meetings, member travel,
training opportunities and
even infrastructure such as
our new website.



Here's another example of their impact. Here in San

Francisco, for the first time, our new palliative and end of life care committee in development will meet. That committee was supported from the outset by Hope, which covered the costs of the two-hour palliative care symposium held here last year.

I'm grateful that you've joined us here in San Francisco, and for your commitment to SWOG, our cancer trials, and our patients.





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Plenary Part I

The spring meeting's translational medicine plenary will take place Thursday, April 12, 3:00-4:30 p.m. in the Grand Ballroom. Speakers and topics include the following:



Welcome and Introduction

Lee M. Ellis, MD, FASCO

SWOG Vice-Chair for **Translational Medicine University of Texas** MD Anderson Cancer Center



Cancer Organoids as Predictive Models for PrecisionMedicine

David Tuveson, MD, PhD

Director, **Cold Spring Harbor Laboratory Cancer Center**



Cancer Immune Monitoring and Analysis Centers (CIMACs) and Cancer Immunologic Data Commons (CIDC) - A Systematic Approach to Enhancing Correlative Studies in NCI-Funded Immunotherapy Trials

Helen Chen, MD

Associate Chief, **Investigational Drug Branch Cancer Therapy Evaluation Program National Cancer Institute**



Correlative Science and Translational Medicine Studies in the Cooperative Groups: a 25 Year Journey

Daniel Hayes, MD, FASCO

Co-Director, **Breast Oncology Program** University of Michigan **Comprehensive Cancer Center** Chair, SWOG Translational Medicine Breast Committee

Plenary Part II

The spring meeting's general plenary will take place Friday, April 13, 12:00-2:00 p.m. in the Grand Ballroom. Speakers and topics include the following:



Chair's Welcome and Update

Charles D. Blanke, MD

SWOG Chair Oregon Health & Science University



Hope Turns 25 Johanna Horn **President & CEO** The Hope Foundation



Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University



Announcement of 2018 Dr. Charles A. Coltman, Jr. MD, Fellows

Jason Zell, DO

Associate Professor UC Irvine School of Medicine

Board Member, The Hope Foundation



Investment and Impact: Outcomes of Hope Foundation Funding

Siwen Hu-Lieskovan, MD, PhD

Assistant Professor of Medicine David Geffen School of Medicine at **UCLA and Jonsson Comprehensive Cancer Center**

Coltman Fellow and ITSC Grantee



Scott Kopetz, MD, PhD

Associate Professor University of Texas **MD Anderson Cancer Center**

Impact Award and SEED Fund Grantee



Veena Shankaran, MD, MS

Associate Professor, Division of Medical Oncology University of Washington School of Medicine

Associate Member, Clinical Research Division Fred Hutchinson Cancer Research Center

Coltman Fellow





SPECIAL EVENTS

You are invited to join the discussion! \$1600 Kickoff Meeting

Come hear about \$1600, a new SWOG nutrition trial for bladder cancer. The trial is testing a high-yield, low-risk, low-cost nutrition strategy to improve the outcome of patients with bladder cancer who undergo cystectomy.

Friday, April 13 from 6:30-7:30 p.m. | Seacliff ABC (Bay Level)

Open to All Members; Site Staff Encouraged

Study chairs **Jill Hamilton-Reeves**, **PhD**, **RD** and **Jeffrey Holzbeierlein**, **MD**, both of the University of Kansas, will discuss the trial goals and design, as well as eligibility and other requirements.

Attendance is encouraged for sites activating \$1600.

This Phase III trial will compare the impact of consuming Specialized IMmunonutrition (SIM) to standard oral nutritional support on postoperative complications after cystectomy. S1600 will determine if SIM, fortified with nutrients (L-arginine, omega-3 fatty acids, and dietary nucleotides), prevents complications after surgery. Two-thirds of patients undergoing

radical cystectomy experience a postoperative complication, including pain, infection, and poor wound healing. Using perioperative SIM may benefit patients undergoing cystectomy by reducing complications in a way that standard oral nutrition supplementation cannot.

Join Us for the First Group Meeting of SWOG's Palliative and End of Life Care Committee in Development

Friday, April 13 from 9:00-10:30 a.m. | Garden Room (Atrium Lobby Level) | All Members Welcome

Join committee co-chairs **Robert Krouse**, **MD** and **Mark O'Rourke**, **MD** for the first in-person meeting of this exciting committee in development – the first new SWOG NCORP committee in years.

Committee leadership, including Executive Officer Kathy Crew, MD and NCORP Vice Chair Dawn Hershman, MD, will provide a description of the committee and a status report on its formation. The meeting will also include a review of new and old trial concepts to consider for development and activation. Rebecca

Sudore, MD, a geriatrician, palliative medicine physician, and advance care planning researcher at the University of California San Francisco School of Medicine, will provide the keynote talk. Sudore is director of the Innovation & Implementation Center in Aging & Palliative Care (I-CAP) at UCSF.

Radiation Oncology Committee Group Meeting

AGENDA | Saturday, April 14, 2017

Industry Speaker:

Uri Weinberg, MD, PhD; (V.P. Research & Development for Novocure); presenting: "Tumor Treating Fields (TTFields): Going Beyond the Central Nervous System"

Committee Business:

Chair Update Drs. Okunieff & Kachnic

Approval of minutes – March 19, 2018 teleconference

Speakers:

Hesham Elhalawani, MD; (MD Anderson); presenting: "Prospective in-silico quality assurance study of contouring target volumes in thoracic tumors within a cooperative group setting"

David Fuller, MD; (MD Anderson); presenting: "LAMBDA-RAD head & neck data management/sharing platform"

Subcommittee Updates:

Breast	Dr. Reshma Jags
Gl	Dr. Lisa Kachnic
GU	Drs. Raben & Swansor
Lung	Dr. Roy Decker
Lymphoma	Dr. Louis Constine
Melanoma	Dr. Evan Wuthrick
Strategic	Dr. Steven Finkelsteir
IROC/QARC Update	Fran Laurie
IROC/RPC Update	Dr. Stephen Kry

April 13, 2018 | 9:00 - 11:00 AM.

Regional Therapies Educational Session: Surgery Committee

Hepatic transarterial and ablative therapies

Bruno C. Odisio, MD

Department of Interventional Radiology,
MD Anderson Cancer Center

Isolated limb regional chemotherapy: proven efficacy and opportunity to improve

Joshua M.V. Mammen, MD, PhD, FACS Associate Professor of Surgery, Department of Surgery, University of Kansas

HIPEC and Beyond: Surgery for Peritoneal Metastases in Patients with Colon Cancer

Andrew M. Lowy, MD
Professor of Surgery, Department of Surgery,
UC San Diego Health

Positive cytology on peritoneal washings: risk factor as stratification marker for HIPEC

Stacey Cohen, MD
Assistant Professor, Department of Medicine,
Division of Medical Oncology, Univ. Washington

Phase II Randomized Trial Comparing
Morbidity of Cytoreductive Surgery
(CRS) and Hyperthermic Intraperitoneal
Chemotherapy (HIPEC) with Mitomycin-C
versus Melphalan for Colorectal Peritoneal

Carcinomatosis

Mazin Al-Kasspooles, MD Professor of Surgery, Department of Surgery, University of Kansas Laparoscopic Hyperthermic Intraperitoneal Chemotherapy for Unresectable, High Volume Peritoneal Carcinomatosis of

Colorectal Origin

Jig Deneve, DO, FACS Assistant Professor of Surgery, UTHSC, Memphis, TN

Evaluating the Oncologic Safety of Laparoscopic vs. Open Liver Resection

Claudius Conrad, MD
Department of Surgical Oncology,
MD Anderson Cancer Center



Hope turns 25

A tradition of investment and impact



his year marks two and a half decades since our founding, and a number of celebratory projects are underway to honor our silver year.

Thanks, first and foremost, go to our donors.

Many of you have contributed to our growth, our successes, and the advancement of SWOG's mission to improve the lives of patients. Learn more about our donors and industry

supporters on page 10 of this agenda book.

The returns on your investment are incredibly high. Here on these two pages — and on banners and in plenary talks — you'll see evidence of those investment returns; who



we've partnered with, how we've supported them, and what impact we have made together since 1993.

The booklet included here pays tribute to another important milestone of 2018 — the 10th birthday of our Dr. Charles A. Coltman, Jr. Fellowship Program. Inspired by the legacy of past Chair Dr. Charles Coltman, this fellowship has advanced the careers of 18 of SWOG's best and brightest, many of whom are leading SWOG's research today. We've been here for a generation, and we've come full circle.

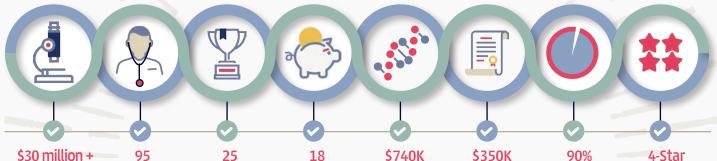
Thanks for celebrating with us, and for giving so generously.

Johanna Horn President & CEO





Our Impact



\$30 million + for SWOG members for research, education, and travel

Young Investigators supported 25 Impact Awards granted 18 Coltman Fellows funded \$740K in Integrated Translational Science Center grants funded \$350K in VA medical centers grants awarded

of every contribution directly invested in SWOG Charity
Navigator
rating 7
consecutive
years

SWOG Grant Writing Workshop

SWOG Executive Officer Dr. Katherine Crew leads this six-week, virtual grant writing course designed for new and early career investigators preparing future grant submissions.

Apply by May 1 for the next round! | tinyurl.com/SWOG-Grants



Dr. Katherine Crew

"I thought the course was outstanding and transformational in my academic development. Dr. Crew was an absolutely outstanding instructor, and I am so glad I participated."

- PAST WORKSHOP PARTICIPANT



Our Donors

The Hope Foundation would like to thank these exceptional donors who continue to make our work possible through repeated and generous giving.

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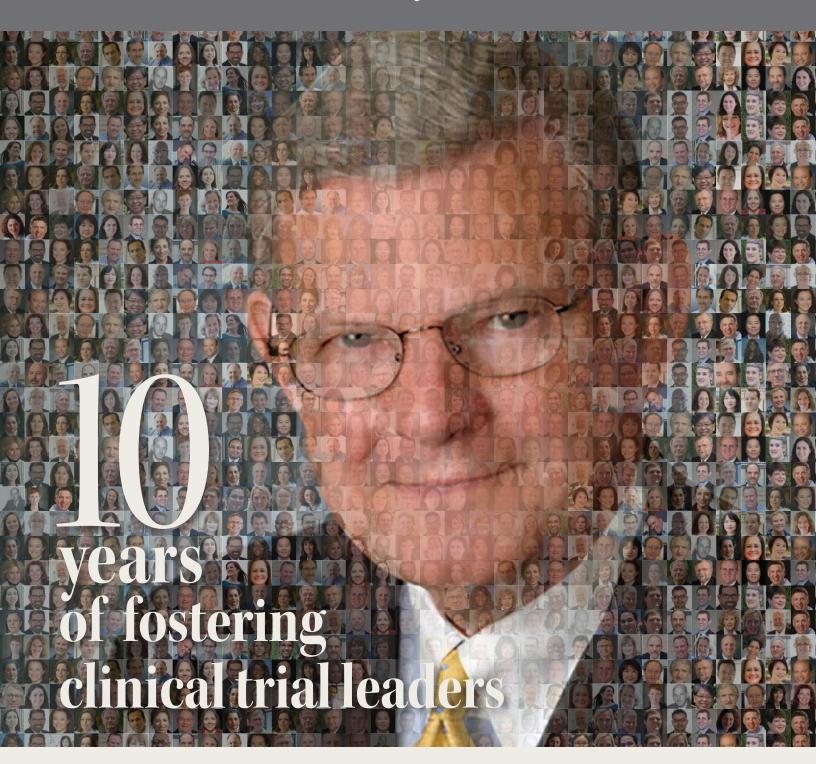
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Dr. Charles A. Coltman, Jr. Fellowship Program



DEVELOPING TOMORROW'S TALENT TODAY

ormer Group Chair Dr. Charles Coltman Jr. was a champion of SWOG early career researchers. In 1999, Coltman helped organize the first Young Investigator Training Course (YITC) to guide members through the intricacies of conducting National Cancer Institute network trials. In 2008, the Dr. Charles A. Coltman Jr. Fellowship Program was created for outstanding early career SWOG members. In 2017, the program expanded to include mid-career fellowships. Both provide two years of salary support ensuring protected time for research in the clinic or laboratory.

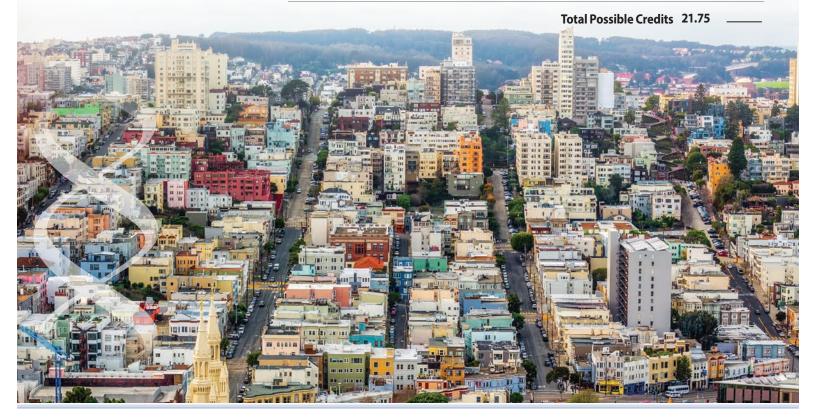
New Procedures for CME Credit

We've gone paperless! SWOG no longer requires members to submit paper forms to obtain CME credits. Getting your credits online is easy:

- Visit: https://www.swog.org/ hope-foundationswog-continuingmedical-education-certification
- Complete the evaluation questions
- Enter the credits being claimed
- Press "submit"

Your certificate will automatically be emailed to you. Problems or questions? Contact Courtney Wille in the SWOG operations office at cwille@swog.org. To keep track of your credits during the meeting, use the form on the right.

		Cred	its
Time	Session Title	Available	Actual
	THURSDAY, APRIL 12, 2018		
10:00 am — 12:15 pm	Early Therapeutics & Rare Cancers Committee	2.25	
10:00 am — 12:15 pm	Cancer Care Delivery Committee	2.0	
12:30 pm — 2:30 pm	Symptom Control and Quality of Life Committee	2.0	
3:00 pm — 4:30 pm	Plenary I (Translational Medicine)	1.5	
4:45 pm — 6:45 pm	Prevention and Epidemiology Committee	2.0	
	FRIDAY, APRIL 13, 2018		
7:30 am — 9:00 am	Cancer Survivorship Committee	1.5	
7:30 am — 9:30 am	Barlogie-Salmon Myeloma Committee	2.0	
9:00 am — 11:00 am	Surgery Committee	2.0	
12:00 pm — 2:00 pm	Plenary II (General)	2.0	
3:00 pm — 6:00 pm	Breast Committee	3.0	
5:00 pm — 7:00 pm	GI Committee	2.0	
	SATURDAY, APRIL 14, 2018		
9:30 am — 11:30 am	Radiation Oncology Committee	1.75	
9:30 am — 12:30 pm	Lymphoma Committee	3.0	
9:30 am — 12:30 pm	GU Committee	3.0	
9:30 am — 12:30 pm	Lung Committee	3.0	
9:30 am — 11:30 am	Leukemia Committee	2.0	
9:30 am — 11:30 am	Melanoma Committee	2.0	



Procedures for CME Credit

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; 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 21.75 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

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.

SWOG gratefully acknowledges the support of our CME Commercial Supporters

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As of 3/15/18

We've gone paperless!

SWOG no longer requires members to submit paper forms to obtain CME credits.

Getting your credits online is easy:

- Visit: https://www.swog.org/ hope-foundationswog-continuingmedical-education-certification
- Complete the evaluation questions
 - Enter the credits being claimed
 - Press "submit"

Your certificate will automatically be emailed to you. Problems or questions? Contact Courtney Wille in the SWOG operations office at cwille@swog.org.

To keep track of your credits during the meeting, use the form on the next page.





Jack Aiello, MS, EE



Rick Bangs, MBA, PMP



Tony Crispino



Hildy Dillon, MPH



Amy Geschwender, PhD



Valerie Guild, MBA, CPA



Sandra Hamilton, RN, BSN, MEd



Marcia K. Horn, JD



Our Advocates

Advocates serve as the voice of the patient in the development and execution of our trials.



Cheryl Jernigan, CPA, FACHE



Judy Johnson, MBA



Lee Jones, MBA



Florence Kurttila, MS



Ginny Mason, RN



Elda Railey



Barbara Segarra-Vazquez, DHSc



Carole Seigel, MBA



Gail Sperling, MPH



Peggy Zuckerman, M.Ed.



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:

- Eclipse Restaurant specializes in a variety of cuisines and offers guests a relaxing atmosphere to enjoy breakfast, lunch and dinner.
- Eclipse Lounge specializes in a wide variety of cocktails, wines, beers and cognacs.
- In-room dining is available from 6:00 a.m. 12:00 a.m. daily.

Business Center:

The Business Center is located on the Atrium Lobby level 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 photo-copying.

Ground Transportation:

- A taxi ride from San Francisco airport to the hotel is approximately \$35.00 one-way.
- Valet parking at the hotel is \$50.00 per day for hotel guests.

Temperature:

The average high for April is 65 degrees and the average low is 50 degrees.

Area Attractions:

- Alcatraz and Angel Island
- Aquarium of the Bay
- Bay Ferry Tours
- Boudin Bakery
- Cable Car Museum
- Coit Tower
- Embarcadero Center
- Farmer's Market
- Ferry Building Marketplace
- Fisherman's Wharf (Pier 39)
- Ghirardelli Square
- Golden Gate Bridge and Park
- Lombard Street
- Napa/Sonoma Wine Country
- San Francisco Maritime National Historical Park
- Sausalito Island
- The Exploratorium
- Yerba Buena Center for the Arts
- Yerba Buena Gardens

Local Restaurants:

(The hotel concierge can assist with reservations and suggestions)

- · Alioto's Seafood
- Barney's Gourmet Hamburgers Burgers
- Boudin at the Wharf Deli Cuisine
- Caffe Macaroni Italian
- E'Angelo Restaurant Italian
- Harris' Steaks/Chops
- Michael Mina American
- One Market American Regional
- Plump Jack Cafe Eclectic
- Tadich Grill Steak and Seafood
- The Waterfront Seafood



Hyatt Regency San Francisco Floor Levels

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Hyatt Regency San Francisco Meeting Rooms

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WEDNESDAY, APRIL 11, 2018

Group Meeting Registration & Information Desk 1:00 p.m. - 5:00 p.m. - Grand Foyer (Street Level)

7:00 A.M. - 7:30 A.M.

Grand B Foyer, Street Level CRA Clinical Trials Training Course

Check-In

7:30 A.M. - 12:00 P.M.

Grand A, Street Level CRA Clinical Trials Training Course

12:00 P.M. - 2:00 P.M.

Regency B, Street Level Core Office Staff Meeting (Invitation Only)

1:00 P.M. - 3:00 P.M.

Plaza Room, Street Level Nursing Research Subcommittee

1:30 P.M. - 5:00 P.M.

Grand B, Street Level CRA Clinical Trials Training Course

Practicum

2:00 P.M. - 3:00 P.M.

Seacliff B, Bay Level ORP Liaison Subcommittee (Formerly

Disease & Discipline & Research)

3:00 P.M. - 5:30 P.M.

Pacific G, Pacific Con Level ORP Executive Committee

(Committee Members Only)

3:30 P.M. - 5:00 P.M.

Regency B, Street Level Hope Foundation Board Meeting

(Board Members Only)

5:30 P.M. - 7:30 P.M.

Seacliff CD, Bay Level Site Operations (Formerly Head CRA –

Open Session)

5:30 P.M. – 8:00 P.M.

Seacliff A, Bay Level NCORP Research Base Executive

Committee Meeting (Committee

Members Only)

6:30 P.M. - 8:30 P.M.

Pacific L, Pacific Con Level ITSC Steering Committee

(Committee Members Only)

THURSDAY, APRIL 12, 2018

Group Meeting Registration & Information Desk 7:00 a.m. - 5:00 p.m. – Grand Foyer (Street Level)

Hope Foundation Information Desk 8:00 a.m. - 5:00 p.m. – Grand Foyer (Street Level)

Exhibits & Complimentary Coffee Service 7:00 a.m. - 4:00 p.m. – Grand Foyer (Street Level)

6:00 A.M. - 7:30 A.M.

Grand Foyer, Street Level Conference Kick-Off Fun Run and Walk

7:00 A.M. - 10:00 A.M.

Seacliff D, Bay Level Advocates Committee Meeting

(Committee Members Only)

7:30 A.M. - 8:00 A.M.

Grand B Foyer, Street Level Jeri & Noboru Oishi Symposium Check-In

8:00 A.M. - 12:00 P.M

Grand BC, Street Level Jeri & Noboru Oishi Symposium (Open

Session)

10:00 A.M. – 12:00 P.M.

Pacific K, Pacific Con Level Digital Engagement Committee

(Committee Members Only)

10:00 A.M. – 12:00 P.M.

Plaza Room, Street Level Quality Initiative Meeting (Committee

Members Only)

10:00 A.M. - 12:15 P.M.

Seacliff A-C, Bay Level EARLY THERAPEUTICS AND RARE

CANCERS COMMITTEE

10:00 A.M. - 12:15 P.M.

Bayview B, Bay Level CANCER CARE DELIVERY COMMITTEE



12:00 P.M. - 2:00 P.M.

Pacific I, Pacific Con Level Lung-MAP Site Coordinators Committee

Meeting (Committee Members Only)

12:00 P.M. - 2:00 P.M.

Bayview A, Bay Level Adolescent and Young Adult (AYA

Committee

12:30 P.M. - 2:00 P.M.

Pacific M, Pacific Con Level ORP Open Forum

12:30 P.M. - 2:30 P.M.

Bayview B, Bay Level SYMPTOM CONTROL AND QUALITY OF

LIFE COMMITTEE

2:00 P.M. - 3:00 P.M.

Pacific BC, Pacific Con Level SWOG Tissue Banking Meeting

(Invitation Only)

2:00 P.M. - 3:00 P.M.

Grand Foyer, Street Level Plenary Reception (Light Hors D'oeuvres)

2:00 P.M. - 3:00 P.M.

Seacliff B, Bay Level ORP Education Subcommittee (Formerly

Education & Program)

3:00 P.M. - 4:30 P.M.

Grand Ballrm, Street Level PLENARY I (TRANSLATIONAL MEDICINE)

4:30 P.M. - 7:30 P.M.

Pacific BC, Pacific Con Level Myeloma Working Group Meeting

(Working Group Members Only)

4:45 P.M. - 6:45 P.M.

Bayview B, Bay Level PREVENTION AND EPIDEMIOLOGY

COMMITTEE

5:00 P.M. - 7:00 P.M.

Boardroom C, Atrium Level Conflict Management Committee

(Committee Members Only)

5:30 P.M. - 6:30 P.M.

Waterfront AB, Atrium Level S1316 Protocol Update Meeting

7:00 P.M. – 9:00 P.M.

Waterfront C-E, Atrium Level S0777 Reception (Invitation Only)

7:00 P.M. - 9:00 P.M.

Garden A, Atrium Level Latin American Symposium (Invitation

Only)

7:30 P.M. - 9:30 P.M.

Boardroom B, Atrium Level Coltman Fellowship Committee

(Committee Members Only)

7:30 P.M. - 9:30 P.M.

Marina, Bay Level Early Therapeutics Working Group

(Invitation Only)

FRIDAY, APRIL 13, 2018

Group Meeting Registration & Information Desk 7:00 a.m. - 5:00 p.m. - Grand Foyer (Street Level)

Hope Foundation Information Desk

8:00 a.m. - 5:00 p.m. - Grand Foyer (Street Level)

Exhibits & Complimentary Coffee Service

7:00 a.m.- 4:00 p.m. – Grand Foyer (Street Level)

7:30 A.M. - 9:00 A.M.

Garden Room, Atrium Level CANCER SURVIVORSHIP COMMITTEE

7:30 A.M. - 9:30 A.M.

Seacliff A-C, Bay Level BARLOGIE-SALMON MYELOMA

COMMITTEE

7:30 A.M. - 9:30 A.M.

Plaza Room, Street Level Imaging Committee (Committee

Members Only)

7:30 A.M. – 9:30 A.M.

Boardroom B, Atrium Level SWOG Data and Safety Monitoring

Committee (Cmte Members Only)

8:00 A.M. - 9:00 A.M.

Boardroom A, Atrium Level Professional Review Committee

(Committee Members Only)



8:00 A.M. - 10:00 A.M.

Waterfront A, Atrium Level Drug Information Subcommittee and

Pharmacy Working Group (Working

Group Members Only)

8:00 A.M. - 10:00 A.M.

Pacific LM, Pacific Con Level Breast Translational Medicine Working

Group (Working Group Members Only)

9:00 A.M. - 11:00 A.M.

Bayview A, Bay Level SURGERY COMMITTEE

9:00 A.M. - 10:30 A.M.

Garden Room, Atrium Level Palliative and End of Life Care Committee

in Development

10:00 A.M. - 11:30 A.M.

Pacific DE, Pacific Con Level S1602 and S1605 Joint Protocol Meeting

10:00 A.M. - 11:30 A.M.

Pacific F, Pacific Con Level Quality Assurance Committee Meeting

(Committee Members Only)

10:00 A.M. - 12:00 P.M.

Seacliff A-C, Bay Level Breast Working Group Meeting

(Working Group Members Only)

10:30 A.M. - 12:00 P.M.

Pacific J, Pacific Con Level Bone Marrow & Stem Cell

Transplantation Committee

11:00 A.M. - 12:00 P.M.

Plaza Room, Street Level Publications Committee

(Committee Members Only)

11:00 A.M. - 12:00 P.M.

Grand Foyer, Street Level Plenary Reception (Light Hors D'oeuvres)

11:00 A.M. - 12:00 P.M.

Pacific F, Pacific Con Level Lung Surgery Subcommittee

(Committee Members Only)

11:00 A.M. - 12:00 P.M.

Pacific NO, Pacific Con Level GI Translational Medicine Working Group

(Working Group Members Only)

12:00 P.M. - 2:00 P.M.

Grand Ballrm, Street Level PLENARY II (GENERAL)

2:00 P.M. - 3:00 P.M.

Pacific NO, Pacific Con Level Lung Radiation Subcommittee

(Committee Members Only)

2:00 P.M. - 3:00 P.M.

Waterfront AB, Atrium Level Lung Translational Medicine

Subcommittee (Cmte Members Only)

2:15 P.M. - 3:15 P.M.

Pacific J, Pacific Con Level NCORP/MU-NCORP Site PI Meeting

2:30 P.M. - 4:00 P.M.

Pacific A, Pacific Con Level VA Working Group (Invitation Only)

2:30 P.M. - 4:00 P.M.

Seacliff Room, Bay Level S1400 Lung-MAP Update Meeting

2:30 P.M. – 4:30 P.M.

Marina, Bay Level GI Working Group Meeting (Working

Group Members Only)

2:30 P.M. - 6:30 P.M.

Waterfront C-E, Atrium Level GU Organ Site Meeting

(Working Group Members Only)

3:00 P.M. - 5:00 P.M.

Golden Gate, Bay Level ORP Planning Meeting (Committee

Members Only)

3:00 P.M. - 6:00 P.M.

BREAST COMMITTEE



4:00 P.M. - 6:00 P.M.

Pacific BC, Pacific Con Level Recruitment and Retention Committee

4:00 P.M. - 6:00 P.M.

Pacific NO, Pacific Con Level Lymphoma Working Group

(Working Group Members Only)

4:15 P.M. - 6:15 P.M.

Pacific HI, Pacific Con Level Lung Working Group

(Working Group Members Only)

4:30 P.M. - 6:30 P.M.

Plaza Room, Street Level Pharmaceutical Sciences Committee

5:00 P.M. - 7:00 P.M.

Grand C, Street Level GI COMMITTEE

6:00 P.M. - 7:00 P.M.

Executive Reception (Invitation Only)

6:30 P.M. - 7:30 P.M.

Seacliff A-C, Bay Level S1600 Kick-Off Meeting

6:45 P.M. - 8:00 P.M.

Atrium, Atrium Level Reception

Saturday, April 14, 2018

Group Meeting Registration & Information Desk 7:00 a.m. - 11:00 a.m. - Grand Foyer (Street Level)

Hope Foundation Information Desk 8:00 a.m. - 11:00 a.m. - Grand Foyer (Street Level)

7:15 A.M. – 8:00 A.M.

Grand B, Street Level Board of Governors

(Board Members Only)

8:15 A.M. - 9:15 A.M.

Grand B, Street Level Committee Chairs

(Committee Chairs Only)

9:30 A.M. - 11:30 A.M.

Marina, Bay Level RADIATION ONCOLOGY COMMITTEE

9:30 A.M. - 12:30 P.M.

Grand C, Street Level LYMPHOMA COMMITTEE

9:30 A.M. - 12:30 P.M.

Grand A, Street Level GU COMMITTEE

9:30 A.M. - 12:30 P.M.

Bayview B, Bay Level LUNG COMMITTEE

9:30 A.M. - 11:30 A.M.

Garden Room, Atrium Level LEUKEMIA COMMITTEE

9:30 A.M. - 11:30 A.M.

Seacliff A-C, Bay Level MELANOMA COMMITTEE

11:30 A.M. - 12:30 P.M.

Pacific EF, Pacific Con Level Leukemia Working Group

(Working Group Members Only)

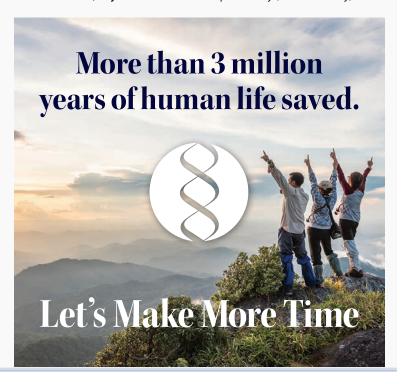
11:30 A.M. - 12:30 P.M.

Bayview A, Bay Level Melanoma Working Group

(Working Group Members Only)

12:30 P.M. - 3:30 P.M.

Golden Gate, Bay Level Leadership Academy (Invitation Only)





SWOG Administrative Committees

Conflict Management
Paul Okunieff, MD

Data and Safety Monitoring

Lawrence E. Flaherty, MD

Publications

Hagen Kennecke, MD

Professional ReviewPrimo N. Lara, Jr., MD

Adolescents and Young
Adults

Mark A. Lewis, MD

Digital Engagement

Don S. Dizon, MD

ImagingLawrence H. Schwartz, MD

Oncology Research Professionals

SWOG

Research Support Committees

Keisha Humphries, RN, RSN

Patient Advocates

Rick Bangs, MBA

Pharmaceutical Sciences

Co-Chair Siu-Fun Wong, MD

Co-Chair Susan Kadlubar, MD

Radiation Oncology

Paul Okunieff, MD

Recruitment and Retention

Elise Cook, MD

Surgery

George H. Yoo, MD

Future Meeting Dates

2018

April 11-14 San Francisco, CA

> October 3-6 Chicago, IL

2019

April 24-27 San Francisco, CA

> October 2-5 Chicago, IL

2020

April 22-25 San Francisco, CA

September 23-26 Chicago, IL

2021

April 21-24 San Francisco, CA

October 13-16 Chicago, IL



Join the Conversation on Facebook

SWOG Oncology is a private Facebook group just for members.

Join the group and you'll get news from SWOG and funding alerts from The Hope Foundation. You can also get introduced to key staff and researchers, meet SWOG patient advocates, and get tips and tricks on study challenges.

This year, we've launched new features to help you meet members from across the country, and learn how to run great trials.

It's easy to sign up.

Log onto Facebook, search for SWOG Oncology, and hit the green "Join Group" button. You'll get a notification when your access is approved.

See you online!



Tweet the meeting

Our Twitterverse is expanding fast!

We've got more than 4,000 followers of @SWOG.

Be one of them. Follow us!

And post your meeting tweets with the hashtag





Barlogie—Salmon Myeloma Committee

Leadership

Chair:	Robert Z. Orlowski, MD, PhD
Vice-Chair:	Brian G.M. Durie, MD
Executive Officer	Susan M. O'Brien, MD
Statisticians:	Antje Hoering, PhD
	Rachael Sexton, MS
	Kari Chansky, MS

Scientific Leadership

Translational Medicine:	Brian A. Walker, B.Sc., PhD
Radiation:	TBD
Surgery:	J. Sybil Biermann, MD
Imaging:	Saad Z. Usmani, MD
	Eric M. Rohren, MD, PhD
Pathology:	Robert B. Lorsbach, MD, PhD
Early Therapeutics:	Frits van Rhee, MD, PhD

Designates

NCORP Representative:	-
	. Laura Kingsbury, MRT
	Sean O'Bryan
	Joanna Dur
Oncology Research Professionals:	
CRA:	TBD
Nurses:	Deborah A. Shaw, RN
	Teresa Wtcher, BSN, RN
Patient Advocate:	Jack Aiello, MS
Pharmaceutical Science:	Lara M. Au, PharmD
	Craig Elg, PharmD
Protocol Coordinator:	TBD

Time/Location

Friday, April 13, 2018 7:30 a.m. - 9:30 a.m.

Room: Seacliff A-C (Bay Level)

Active Studies

S1211, "A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone and Lenalidomide with or Without Elotuzumab (NSC-764479) for Newly Diagnosed High Risk Multiple Myeloma (HRMM)." Drs. S. Usmani, S. Ailawadhi, and B. Lipe. Activated: 10/12/2012. Temporarily closed to accrual: 6/2/2016.

Barlogie—Salmon Myeloma Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018
Includes studies that are currently open, or that closed since 7/1/16.

	E1A11	E3A06
Arkansas, U of	1	_
Baylor College	7	_
Beaumont NCORP	4	_
CORA NCORP	1	_
Cookeville Reg MC	4	_
Davis, U of CA	15	_
Dayton NCORP	2	_
Greenville NCORP	_	6
Hawaii MU-NCORP	1	_
Henry Ford Hospital	10	1
Irvine, U of CA	5	1
Kaiser Perm NCORP	23	_
Kansas, U of	1	15
Loyola University	6	_
Michigan, U of	4	_
Montana NCORP	3	2
Oregon Hlth Sci Univ	3	_
Ozarks NCORP	6	1
PCRC NCORP	_	1
Providence Hosp	9	2
San Antonio, U of TX	7	_
Southeast COR NCORP	6	_
Sutter Cancer RC	6	_
Tennessee, U of	_	1
Tulane University	_	2
VAMC Kansas City	2	_
Wayne State Univ	12	_
Yale University	32	3
Total	170	35

CTSU/E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Ver-sus Carfilzomib, Lenalidomide, Dexamethasone (CRd) Followed by Limited or Indefinite DURation Le-nalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDUR-ANCE)." Dr. J. Zonder. Activated: 11/13/2013.



Barlogie—Salmon Myeloma Committee

CTSU/A061402, "Solitary Plasmacytoma of Bone: Randomized Phase III Trial to Evaluate Treatment with Adjuvant Systemic Treatment and Zoledronic Acid Versus Zoledronic Acid After Definite Radiation Ther-apy." Dr. E. Manasanch. Activated: 12/23/2015.

Closed Studies

<u>\$1304</u>, "A Phase II Randomized Study Comparing Two Doses of Carfilzomib (NSC-756640) with Dexame-thasone for Multiple Myeloma Patients with Relapsed or Refractory Disease." Drs. S. Ailawadhi, M. Abidi, S. Lentzsch, et al. Activated: 10/18/2013. Closed: 5/15/2016.

CTSU/E3A06, "Randomized Phase III Trial of Lenalidomide Versus

Observation Alone in Patients with Asymptomatic High-Risk Smoldering

Multiple Myeloma." Dr. M. Dhodapkar. Activated: 10/5/2010; Closed:
7/27/2017.

Proposed Studies

<u>S1611</u>, "A Phase II Non-Randomized Study of 11-1F4 Chimeric Monoclonal Ab Added to Standard Induction Therapy in Untreated Subjects with Light Chain (AL) Amyloidosis." Dr. S. Lentzsch.

51702, "A Phase II Study of Isatuximab (SAR650984) for Patients with Previously Treated AL Amyloido-sis." Drs. E. Scott, V. Sanchorawala, and B. Walker.

S1803, "Phase III Study of Daratumumab (NSC- 791647) + Lenalidomide (LD) or Lenalidomide (L) as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Us-ing Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. A. Krishnan, P. Hari, P. Wallace, et al.

"Randomized Phase II Multicenter Non-Inferiority Trial of Rivaroxaban 10 mg Daily Versus Low Molecular Weight Heparin for Prevention of Thromboembolism in Patients Being Treated with an Immunomodulatory-Based Regimen for Multiple Myeloma." Drs. D. Calverley, J. Meyers, and E. Scott.

Open Forum Discussion

Working Groups

Amyloidosis Working Group update

Waldenström's Working Group update

Myeloma Translational Medicine Subcommittee update

Patient Voice



As a physician, I've seen patients benefit from treatments tested through clinical trials. And now, as a cancer patient, I've benefited from clinical trials, too, so I wanted to do my part.



Leadership	
Chair:	Lajos Pusztai, MD DPhil
Vice-Chair:	Priyanka Sharma, MD
Executive Officer:	Julie R. Gralow, MD
Statisticians:	
	Danika Lew, MA
	•
	<i>3</i> ,
Scientific Leadership	
Translational Medicine:	•
Radiation Oncology:	•
Surgery:	
Imaging:	Anne F. Schott, MD
	Wei Tse Yang, MBBS
Pathology:	David Rimm MD
Early Therapeutics:	George Somlo, MD
Designates	
3	
Cancer Control Liaisons:Melinda	L. Irwin, Ph.D. MPH (Survivorship)
Cancer Control Liaisons:Melinda Dawn L. Hers	•
Dawn L. Hers	hman, MD (Cancer Care Delivery)
Dawn L. Hers	hman, MD (Cancer Care Delivery) Banu Arun, MD (Prevention)
Dawn L. Hers	hman, MD (Cancer Care Delivery) Banu Arun, MD (Prevention) w, MD (Symptom Control & QOL)
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Dawn L. Hers	hman, MD (Cancer Care Delivery)Banu Arun, MD (Prevention) w, MD (Symptom Control & QOL)TBDIris SyquiaLarry Kaye
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	hman, MD (Cancer Care Delivery)Banu Arun, MD (Prevention) w, MD (Symptom Control & QOL)TBDIris SyquiaLarry KayeJacqueline ScurlockKaryn N. Hart, CCRPDorothy Coleman, RN, MSGinny MasonElda Railey, RN, BSNJessie Modlin, PharmD
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Time/Location

Friday, April 13, 2018 3:00 p.m. - 6:00 p.m. Room: Bayview Room (Bay Level)

Agenda

3:00 – 3:05 pm Welcome and Introductions – Lajos Pusztai, MD D.Phil and Priyanka Sharma, MD

3:05 – 3:45 pm 1st Annual Robert B. Livingston Translational Breast and Lung Cancer Lecture: "New strategies for targeted therapy of HER2+ breast cancer" - C. Kent Osborne, MD*

3:45 – 4:35 Breast Committee Mini-Symposium

"Potentials of Artificial Intelligence in Pathology Image Analysis."

3:45 – 4:05pm "The Deep Learning Revolution and Implications in Cancer Pathology Diagnostics" - Scooter Willis, PhD

<u>4:05 – 4:25pm</u> "Computational Pathology: Opportunities in Precision Oncology" - Anant Madabushi PhD

4:25 – 4:35 pm Panel discussion and audience Q & A
4:35 – 4:45 pm Publications update - Bill Barlow, PhD

4:45 – 5:15 pm Update of open SWOG and CTSU trials - All

5:15 - 5:30 pm Studies in Development - All

<u>5:30 – 5:45 pm</u> Reports from Committee Liaisons

Patient Advocate – Ginny Mason and Elda Railey

Radiotherapy - Reshma Jagsi, MD

Surgery - Christine Lee, MD

Cancer Survivorship - Melinda L. Irwin, PhD, MPH

Cancer Care Delivery - Dawn Hershman, MD

Prevention - Banu Arun, MD

Symptom Control & QOL- Helen K. Chew, MD

NCORP (NCI Community Oncology Research Program)

<u>5:45 – 5:55 pm</u> Translational Medicine Sub-Committee – Alastair

Thompson, MD and Andrew K. Godwin, PhD

5:55 – 6:00 pm New Business – All

6:00 pm Closing Comments and Adjourn

*Supported in part by a generous gift from the Breast Cancer Research Foundation



Active Studies

- 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." Drs. Chavez-MacGregor, Rastogi, Pusztai. Activated: 9/3/13.
- <u>S1416</u>, "Phase II Randomized Placebo-Controlled Trial of Cisplatin with or without ABT-888 (Veliparib) in Metastatic Triple Negative Breast Cancer (TNBC) and BRCA Mutation-Associated Breast Cancer." Drs. Rodler and Sharma. Activated: 7/7/16.
- <u>S1418</u>, "A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy." Drs. Pusztai and Mammen. Activated: 11/15/16.
- CTSU/A011106, "Alternate Approaches for Clinical Stage II or III Estrogen Receptor Positive Breast Cancer Neoadjuvant Treatment (ALTERNATE) in Postmenopausal Women: A Phase III Study." Dr. Mata. SWOG Champion: Dr. Forero. Activated: 12/13/13.
- CTSU/A011202, "A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy." Dr. Boughey. SWOG Champion: Dr. Mammen. Activated: 2/7/14.
- CTSU/A011502, "A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial." Dr. Chen. SWOG Champion: Dr. Symington. Activated: 12/8/16.

- CTSU/A221405, "A Study Evaluating the Pregnancy Outcomes and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer who Desire Pregnancy." Dr. Pagani, SWOG champion Dr. Halle Moore. Activated: 10/15/15.
- CTSU/EA1131, "A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy." Dr. Mayer. SWOG Champion: Dr. Rodler. Activated 4/29/15.
- CTSU/E2112, "A Randomized Phase III Trial of Endocrine Therapy plus Entinostat/Placebo in Patients with Hormone Receptor-Positive Advanced Breast Cancer." Dr. Connolly. SWOG Champion: Dr. Royce. Activated: 3/29/14.
- CTSU/NRG-BR002, "A Phase IIR/III Trial of Standard of Care Therapy with or without Stereotactic Body Radiotherapy (SBRT) and/or Surgical Ablation for Newly Oligometastatic Breast Cancer." Drs. Chmura and White. SWOG Champion: Dr. Jagsi. Activated: 12/24/14.
- CTSU/NRG-BR003, "A Randomized Phase III Trial of Adjuvant Therapy
 Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly
 Paclitaxel with or without Carboplatin for Node-Positive or High-Risk
 Node-Negative Triple-Negative Invasive Breast Cancer." Dr. Valero. SWOG
 Champion: Dr. Makhoul. Activated: 6/26/15.
- CTSU/NSABP-51, "A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy." Drs. Mamounas and White. Activated: 08/22/13.

Help us honor the IOth anniversary of SWOG's Coltman Fellowship program.

Because answers to cancers come from clinical trials.

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Melissa K. Accordino, MD 2016 Coltman Fellow



Paul M. Barr, MD 2017 Coltman Fellow

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

Active and Developing Cancer Control Studies

- Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia Trial Assessing CSF Prescribing Effectiveness and Risk (TRACER)". Drs. Ramsey, Hershman, Lyman and Sullivan. Activated: 10/7/16.
- <u>S1501</u>, "Prospective Evaluation of Carvedilol vs No Treatment in Prevention of Cardiac Dysfunction in Women with Metastatic HER2+ Breast Cancer." Drs. Floyd and Leja. Activation: 9/15/17.
- <u>\$1703</u>, "Randomized Non-Inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) Versus Usual Care in Patients with Metastatic Hormone Receptor Positive Breast Cancer – Melissa Accordino, MD
- CTSU/A011401, "Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer." Drs. Ligibel and Hershman. Activated: 8/29/16.

<u>CTSU/E1Z11,</u> "A Cohort Study to Evaluate Genetic Predictors for Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)." Dr. Stearns. Activated: 5/21/13.

Active Studies

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." Drs. Chavez-MacGregor, Rastogi, Pusztai. Activated: 9/3/13.

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. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer." Drs. Kalinsky, Gralow, Meric-Bernstam, Hortobagyi, Albain and Barlow. Activated: 1/15/11. Closed: 10/1/15.

Closed Cancer Control Studies

<u>S1200</u>, "Randomized Blinded Sham- and Waitlist-Controlled Trial of Acupuncture for Joint Symptoms Related to Aromatase Inhibitors in Women with Early Stage Breast Cancer." Drs. Hershman and Crew. Activated: 3/27/12. Closed 2/15/17.

Rare Cancers Active Studies

S1609, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 1/13/17.

Studies in Development

- <u>\$1706</u>, "A Phase II Randomized, Double-Blinded, Placebo-Controlled Trial of Olaparib Administered Concurrently with Radiotherapy for Inflammatory Breast Cancer." Dr. Jagsi.
- <u>\$1807</u>, "A Phase II Randomized Double-Blinded, Placebo-Controlled Study of Tucatinib (ONT-380) Following Stereotactic Radiosurgery (SRS) in HER2-Positive Breast Cancer Brain Metastases." Dr. Tsien
- **S1817**, "BIOmarker driven immune CHECKpoint inhibitor therapy in metastatic breast cancer (BIO-CHECK)." Drs. Cobain, Hayes and Adams
- Phase II, Multi-arm, Randomized Umbrella Study to Evaluate the Therapeutic Efficacy and Safety of Immune-Oncology Drug Combinations in Metastatic Breast Cancer (RUSTIC). Drs Pusztai and Sharma
- Phase II Randomized Trial to Evaluate the Safety and Efficacy of Pertuzumab and Trastuzumab Plus Ribociclib and an Aromatase Inhibitor or Fulvestrant as Therapy for HER2-positive and HR-positive Metastatic Breast Cancer (PETRA). Drs. Giordano and Lu.



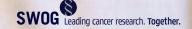
What We Do

SWOG's mission is to significantly improve lives through cancer clinical trials and translational research.

What We Believe

- Patients are our absolute highest priority
- We ensure that the best science drives our research
- We embrace and encourage diversity in leadership and membership to effectively solve problems in cancer
- We demand integrity, accountability, and ethical behavior
- We foster and mentor young investigators to ensure strong leadership and excellent clinical research for future generations

Michael LeBlanc, PhD
Group Statistician
Fred Hutchinson Cancer
Research Center



Cumulative Accrual by Institution and Study
Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1007	S1207	S1416	S1418	A011106	A011202	A011203	A011401	A011502	A221405	B51	B55	E1Z11	E2112	EA1131	EA1151	NRGBROO	NRGBR003	3 Z1110
Arizona MC, U of	_	10	_	_	19	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Arkansas, U of	22	16	_	5	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Atlanta Reg CCOP	11	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baptist MU-NCORP	1	5	1	_	10	1	1	5	_	_	_	_	1	1	_	_	_	1	_
Bay Area NCORP	3	1	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baylor Univ Med Ctr	_	2	_	_	_	1	_	_	_	_	2	_	_	_	_	_	_	_	_
Beaumont NCORP	30	7	2	_	_	4	_	2	_	_	1	_	3	_	_	_	1	_	1
Boston Medical Ctr	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Brooke Army Med Ctr	2	_	_	2	_	_	_	_	_	_	_	1	_	_	2	_	_	1	-
CORA NCORP	16	17	1	4	1	_	_	_	_	_	2	_	1	3	_	_	_	_	_
CRC West MI NCORP	7	8	3	7	_	_	_	1	_	_	_	_	2	_	_	_	_	_	-
Carle CC NCORP	_	4	1	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Cedars-Sinai Med Ctr	8	9	_	_	_	_	_	_	_	_	_	6	_	_	_	_	_	_	_
Cincinnati MC, U of	3	9	_	_	_	_	_	_	_	_	1	_	4	_	_	_	_	_	_
City of Hope Med Ctr	45	19	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Cleveland Clinic OH	27	12	7	_	_	_	_	_	_	_	1	2	_	14	_	_	_	6	-
Colorado, U of	29	15	4	2	11	24	_	9	2	7	1	2	2	_	_	_	_	_	6
Columbia MU-NCORP	16	5	_	2	_	_	_	_	_	_	_	_	17	2	_	_	_	_	_
Columbia University	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Columbus NCORP	18	14	7	3	_	_	_	_	_	_	_	_	2	_	_	_	_	_	_
Cookeville Reg MC	7	_	_	_	_	_	_	_	6	_	_	_	_	_	_	_	_	_	_
Davis, U of CA	8	7	7	2	_	1	_	_	7	_	_	_	1	_	_	_	_	_	_
Dayton NCORP	6	6	4	_	2	_	_	1	_	_	_	_	2	_	_	_	_	_	_
Desert Hospital	2	1	_	_	_	2	_	_	_	_	3	_	_	_	_	_	_	_	_
Essentia Hlth NCORP	_	2	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	6	19	8	2	_	_	_	2	_	1	_	1	_	1	_	_	_	_	_
Georgia NCORP	_	1	_	3	_	_	_	1	_	_	_	_	8	_	_	_	_	_	_
Greenville NCORP	4	_	2	1	_	_	_	_	_	_	_	_	12	_	_	_	_	_	-
Gulf Coast MBCCOP	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Gulf South MU-NCORP	6	17	_	2	_	_	_	_	_	_	_	_	5	_	_	_	_	1	-
H Lee Moffitt CC	2	5	_	_	_	1	_	2	2	_	_	_	_	_	_	_	_	_	-
Harrington CC	2	1	_	_	_	4	_	1	_	_	_	_	_	_	_	_	_	_	_
Harrison Medical Ctr	9	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Hawaii MU-NCORP	12	10	_	_	_	_	_	_	_	_	_	_	20	_	_	_	_	_	-
Heartland NCORP	12	20	4	5	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Henry Ford Hospital	11	6	_	_	_	_	_	_	_	_	_	_	_	1	1	_	_	_	-
INC, Bogota	11	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
INCan	96	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Intermountain MC	5	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Irvine, U of CA	21	8	_	1	2	_	_	2	_	_	_	_	_	_	_	_	_	_	-
Kaiser Perm NCORP	89	39	5	5	_	1	2	17	_	_	_	2	30	_	_	_	_	9	-
Kansas City NCORP	11	7	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	33	41	_	3	_	4	_	7	_	_	_	1	_	8	_	_	_	1	-
Kentucky, U of	21	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
King Faisal Spec Hos	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	-
Lahey Hosp & Med Ctr	19	4	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_



Breast Committee, cont.

Cumulative Accrual by Institution and Study
Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1007	S1207	S1416	S1418	A011106	A011202	A011203	A011401	A011502	A221405	B51	B55	E1Z11	E2112	EA1131	EA1151	NRGBROO	NRGBR003	Z11102
Loma Linda Univ	5	10	_	_	_	2	_	_	_	_	2	_	_	_	_	_	_	_	_
Loyola University	30	13	2	1	_	_	_	3	_	_	1	_	_	_	_	_	_	_	_
MD Anderson CC	147	69	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
MUSC MU-NCORP	21	8	5	_	1	_	_	_	_	_	_	_	5	_	_	_	_	_	_
Madigan Army Med Ctr	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Methodist Hospital	7	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	3
Michigan CRC NCORP	44	18	8	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Michigan, U of	29	17	4	2	_	_	_	2	1	_	_	1	11	_	_	_	_	3	_
Mississippi, Univ of	4	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Montana NCORP	9	6	2	_	_	_	_	_	_	_	_	_	4	_	_	_	_	_	_
National Cancer Ctr	143	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	1	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	27	20	8	1	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	28	8	_	_	_	_	_	_	_	_	_	1	_	_	_	_	_	_	_
Northwestern Univ	3	11	_	_	_	_	4	_	_	_	_	_	_	2	_	_	_	1	_
Oklahoma, Univ of	8	9	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Oregon HIth Sci Univ	4	21	3	1	_	_	_	_	_	_	1	_	_	_	_	_	_	_	_
Ozarks NCORP	9	14	4	_	_	_	_	_	_	_	_	_	9	_	_	_	_	3	_
PCRC NCORP	31	17	2	2	_	_	_	1	_	_	_	_	6	_	_	_	_	1	_
Providence Hosp	8	8	1	1	_	2	_	5	1	_	4	1	2	_	_	_	_	3	_
Rochester, Univ of	7	4	<u>.</u>	_	_	_	_	_	<u>.</u>	_	_	_	_	_	_	_	_	2	_
San Antonio, U of TX	25	19	_	_	1	_	_	_	_	_	1	1	_	4	_	_	_	3	_
San Diego, U of CA	9	_	_	_	_	_	_	_	_	_	_		_	_	_	_	_	1	1
So Calif, U of	15	11	_	_	_	2	_	_	_	_	_	1	_	_	_	_	_	_	_
Southeast COR NCORP	31	26	4	7	_	_	_	1	_	_	_		_	_	_	4	_	_	_
St Louis CCOP	3	_	_	_	_		_	_	_	_	_		_	_	_		_	_	_
St Louis University	1	1	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	_	10	1	_	4		_	2	1	_	1				_	_	_	2	_
Tennessee, U of	5	6	_	_	_	5	_	_	_	_	4	_	_	_	_	_	_	_	_
Tulane Univ MBCCOP	3	_	_	_	_	_	_	_	_	_	_				_	_	_	_	_
Tulane University	6	2	_	_	_		_	_	_	_	_				_	_	_	_	_
Univ of Louisville	8	_	_		_	_	_		_		_		_	_	_		_		_
Upstate Carolina	3		_								_								_
Utah, U of	18	_	3		_		_	_	_		_						_		
Wayne State Univ	23	13	_			7		2			_	3		3	1			5	3
Wichita NCORP	57	29	2	3	_		_	_	_		_			_	_		_	_	_
Wisconsin NCORP	_	1	1	_					_		_						_		_
Yale University	24	40	_		_		_	39	6				2	6	4		_	5	_
Alliance	526	223	43	8					_		_		_		_			_	_
CCTG	328		4 3				_										_		
ECOG-ACRIN	713	 209	<u></u>	14			_		_		_							_	_
GEICAM	792																		
NRG	265	— 307	38	 28	_						_	_							_
	1,022		20																
UNICANCER		 1,500	<u></u>	_ 126	 53	62	7	106	 26		 25	23	149	45	8	4	1	48	14



Cancer Control & Prevention Committee

Patient Voice After being on a SWOG trial, I am still cancer-free. And I've got confidence I'm done with cancer for good. I am optimistic and hopeful. Jean Cowan, SWOG trial participant

Leadership
Vice-Chair NCORP:
Cancer Care Delivery Cmte Co-Chairs: Dawn L. Hershman, MD, MS
Scott D. Ramsey, MD, PhD
Cancer Survivorship Cmte Co-Chairs: Halle C.F. Moore, MD
Melinda L. Irwin, PhD, MPH
Palliative & End of Life Cmte Co-Chairs:Robert S. Krouse, MD, FACS
Prevention and Epidemiology Cmte Co-Chairs: Banu Arun, MD
Symptom Control & QOL Cmte Co-Chairs: Michael Fisch, MD, MPH
Norah Lynn Henry, MD, PhD
Executive Officers: Katherine D. Crew, MD (Prevention, Survivorship)
Gary Lyman, MD (CCD, Symptom Control & QOL)
Senior Advisor:Frank L. Meyskens, Jr., MD
Statisticians:
William E. Barlow, PhD
Cathy Tangen, DR PH
Joseph M. Unger, PhD
Riha Vaidya, PhD
Kathryn B. Arnold, MS
Phyllis J. Goodman, MS
Danika Lew, MA
Anna Moseley, MS
Administrative Lead
Statistics & Data Management Center (SDMC): Monica Yee, CCRP
Scientific Leadership
NCORP Representative: Mark A. O'Rourke, MD
Radiation Oncology Committee:Louis "Sandy" Constine, MD
Surgery Committee:
Translational Medicine:James (Jimmy) Rae, PhD
Liaisons:
Breast Committee: Melinda L. Irwin, PhD, MPH (Survivorship)
Norah Lynn Henry, MD, PhD(Symptom Control & QOL)
Banu Arun, MD (Prevention)



Cancer Control & Prevention Committee

International Liaison:
Designates
Oncology Research Professionals
Clinical Research Associates:
Susan A. Kadlubar, PhD
SDMC Data Coordinators and Staff:
Sam Dzingle
Diane Liggett, CCRP
Jennifer Patterson
Roxanne Topacio, CCRP
Monica Yee, CCRP
SDMC Recruitment and Retention Specialist: Jennifer Maeser, MS
Patient Advocates: Barbara Segarra-Vazquez, D.H.Sc. (CCD)
Amy Geschwender, PhD (Symptom Control & QOL)
Hartley "Lee" M. Jones, MBA (Survivorship)
Sandra Jean Hamilton, RN, M.E.D. (Recruitment & Retention)
Cheryl Jernigan, CPA (Prevention & Epidemiology)
Protocol Coordinator (Cancer Care Delivery;
Prevention and Epidemiology Committees): Patricia O'Kane
Protocol Coordinator (Cancer Survivorship
Committee): Nicki Trevino
Protocol Coordinator (Symptom Control and
Quality of Life Committee):



Cancer Care Delivery (CCD) Committee

Leadership

Co-Chairs: Dawn L. Hershman, MD, MS Scott D. Ramsey, MD, PhD

Time/Location

Thursday, April 12, 2018 10:00 a.m. - 12:15 p.m. Room: Bayview B (Bay Level)

Agenda

Presentations/Concepts:

- "Advancing Cancer Care Delivery through Implementation Science," Bryan Weiner, PhD, University of Washington
- "Building the Case for Connected Health: How Digital Medicines Could Optimize Cancer Care Delivery," Dr. George Savage, Founder, CMO Proteus Digital Health
- "Patient-Centricity is More Than a Buzzword: Redefining the Patient Experience with Trial Sites to Accelerate Recruitment," Lilly Stairs, Head of Patient Advocacy Clara Health; Evan Ehrenberg, PhD Co-founder, CEO Clara Health
- <u>S1711</u>, "Decision Support to Increase Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma in Situ," Kathy Crew, MD, MS, Columbia University

Protocols in Development

<u>S1703</u>, "Randomized Non-inferiority Trial Comparing Overall Survival of Patients Monitored with Serum Tumor Marker Directed Disease Monitoring (STMDDM) versus Usual Care in Patients with Metastatic Hormone Receptor Positive Breast Cancer." Dr. M. Accordino.

Active Studies

Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia - Trial Assessing CSF Prescribing, Effectiveness and Risk (TrACER)." Drs. S. Ramsey, D. Hershman, G. Lyman, et al. Activated: 10/7/16.

- <u>S1417CD</u>, "Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer." Dr. V. Shankaran. Activated: 4/15/16.
- <u>S1400 (Genomics)</u>, "Ancillary Study to Evaluate Patient & Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in SWOG 1400 (Lung-MAP)." Dr. J. Roth and M. Trivedi. Activated: 2/5/18.

Concepts Submitted to DCP

S1705, "Post Marketing Utilization and Effectiveness of Nivolumab and Palbociclib in General Population." Drs. A. Barzi and A. Lyss.

Concepts Approved by Triage

<u>\$1808</u>, "Health Insurance Coverage as a Potential Barrier to Enrollment in Cancer Clinical Trials." J. Roth, PhD, MHA.

Concepts in Development

- Randomized Trial of a Proactive Financial Navigation Intervention for Cancer Patients and Caregivers. Veena Shankaran, MD, University of Washington
- The Breast Cancer Endocrine Therapy Adherence (BETA) Feasibility Study:
 A Text-Messaging Application to Increase Adherence to Adjuvant
 Endocrine Therapy in Stage I-III Hormone Receptor Positive Breast
 Cancer. Sarah Mougalian, MD, Yale University (Primary committee is
 Symptom Control/QOL)
- A Pilot Project to Identify Techniques to Raise Awareness about SWOG Clinical Trials on an Online Oncologist Q&A Network. Nadine Housri, MD Yale Cancer Center (SEED Funded Pilot Trial).
- Optimizing Clinical Work Intensity Among Medical Oncologists. Matthew Hudson, PhD, MPH, Greenville Health System

Substudies (Economic Analyses / Cost Effectiveness from NCTN trials)

<u>\$1007</u>, Update on Quality of Life and Economic Analysis Sub-study of Breast protocol \$1007. Bill Barlow, PhD



Cancer Care Delivery Committee

S1207, Cost Effectiveness Analysis of "Phase III Randomized, Placebocontrolled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-risk, Hormone Receptor-positive and HER2 Negative Breast Cancer." Dr. Chavez-MacGregor.

Updates on Closed Studies and Projects

<u>S1204</u>, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B (HBV) and Hepatitis C (HCV) Among Newly Diagnosed Cancer Patients." Drs. S. Ramsey, R. Loomba, R. Chugh, et al. Activated: 8/29/13. Closed: 2/15/17.

PCORI Project: A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information (VOI). Dr. Ramsey and Dr. J. Carlson.

Newly Funded and Ongoing Database/Grant Funded Projects

Long-term Consequences of Intervention Following Receipt of Finasteride or Placebo in the Prostate Cancer Prevention Trial. Joseph Unger, PhD

Newly Funded Database Studies

- Development of Prognostic Risk Models for Response to Treatment and Placebo for Aromatase Inhibitor-Associated Musculoskeletal Symptoms. Lynn Henry, MD, PhD
- Secondary Data Analysis of Adolescent & Young Adult Oncology (AYA) Patients in Relation to their Body Mass Index (BMI) and Cancer Outcomes. Mark Lewis, MD

Ongoing Database Pilot Studies

- 1. Ethnic disparities among participants in SWOG randomized clinical trials. Mariana Chavez, MD (Manuscript submitted)
- Osteoporosis in Patients with Colorectal Cancer Enrolled on SWOG Trials. Afsaneh Barzi, MD (Manuscript submitted)
- Evaluating the role of geographic location on outcomes among patients enrolled in SWOG trials. Banu Symington, MD (Manuscript in preparation)

Cancer Care Delivery Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.
Includes studies that are currently open, or that closed since 7/1/16.

	S1204	S1415CD	S1417CD	A011104	A191402C
Baptist MU-NCORP	_	35	_	1	_
Bay Area NCORP	92	12	_	_	_
Beaumont NCORP	_	2	_	_	_
Boston MC MBCCOP	33	_	_	_	_
Boston Medical Ctr	69	_	_	_	_
Brooke Army Med Ctr	_	_	_	2	_
CORA NCORP	_	16	10	_	_
CRC West MI NCORP	_	2	12	_	_
Carle CC NCORP	_	42	_	_	_
Columbia MU-NCORP	266	62	9	_	_
Columbus NCORP	_	8	14	_	_
Cookeville Reg MC	_	_	_	2	_
Dayton NCORP	_	11	3	_	_
Desert Hospital	77	_	_	_	_
Essentia HIth NCORP	_	33	_	_	_
GRU MU-NCORP	_	4	_	_	_
Georgia NCORP	_	18	5	_	_
Greenville NCORP	542	61	9	_	_
Gulf South MU-NCORP	426	35	_	_	_
Harrington CC	147	_	_	_	_
Hawaii MU-NCORP	86	29	2	_	_
Heartland NCORP	_	167	17	_	_
Kaiser Perm NCORP	624	_	23	_	4
Loyola University	74	_	_	_	,
MD Anderson CC	354	_	_	_	_
Michigan CRC NCORP		49	4	_	_
Montana NCORP	33	38	1		_
Nevada CRF NCORP	_	_	1	_	_
New Mexico MU-NCORP	_	63	3	_	
Northwest NCORP	_	28	3	_	_
Ozarks NCORP	_	87	_	_	_
PCRC NCORP	6	115	3		_
Providence Hosp	_	_	_	7	
San Antonio, U of TX	146	_	_	_	_
Southeast COR NCORP	_	82	7		_
Sutter Cancer RC	10	_	_		_
VAMC Kansas City	107	_		_	_
Wayne State Univ	_			1	_
Wichita NCORP		60	4	,	_
Wisconsin NCORP	_	33	_	_	_
Alliance	_	145	10	_	_
ECOG-ACRIN	_	90	22	_	_
NRG	_		9	_	_
	2 002	48		- 13	_
Total	3,092	1,375	171	13	4



Cancer Survivorship Committee

Leadership

Co-Chairs:	Halle C.F. Moore, MD
	Melinda L. Irwin, PhD, MPH
Executive Officer:	Katherine Crew, MD
Statisticians:	Katherine A. Guthrie, PhD
	Garnet Anderson, PhD
	Kathryn Arnold, MS
	Amy Darke, MS
	Danika Lew, MS
Data Coordinators:	Monica Yee
	Roxanne Topacio
Patient Advocate:	Lee Jones
Nurse/CRA:	Connie Szczepanek
Protocol Coordinator:	Nicki Trevino

Time/Location

Friday, April 13, 2018 7:30 a.m. - 9:00 a.m. Room: Garden Room (Atrium Lobby Level)

Agenda

Introduction of new co-chairs and committee changes:

Melinda L. Irwin, PhD, MPH

Halle C.F. Moore, MD

Advocate Update: Lee Jones

Active Study

<u>S1501</u>, "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer." Justin Floyd, DO and Monika Leja, MD

-Discussion of accrual barriers and O&A session

Triage Approved Studies

<u>\$1812</u>, "A Fractional Factorial Trial to Identify the Most Effective Method to Increase Physical Activity Among Colorectal Cancer Survivors." Heather Greenlee N.D., PhD.

<u>\$1713,</u> "Text Intervention to Improve Cardiovascular Health In Breast Cancer Survivors." Dawn Hershman, MD

Update of Concepts Previously Proposed

"A Phase II Trial of Flibanserin to Improve Desire in Women with Cancer."

Don Dizon, MD

"Physical Function in Sarcoma Survivors." Lara Davis, MD, Kerri Winters-Stone, PhD, FACSM., Kim Templeton, MD

Cancer Survivorship Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.
Includes studies that are currently open, or that closed since 7/1/16.

	S1316	S1501	E1Q11	EA9131
Arizona MC, U of	9	_	_	_
Arkansas, U of	5	_	_	_
Baylor College	1	_	_	_
City of Hope Med Ctr	4	_	_	_
Columbia MU-NCORP	1	_	_	_
Essentia Hlth NCORP	1	_	_	_
H Lee Moffitt CC	1	_	_	_
Hawaii MU-NCORP	_	_	9	_
Heartland NCORP	_	4	_	_
Kaiser Perm NCORP	_	_	_	3
Kansas, U of	14	_	_	_
Lahey Hosp & Med Ctr	_	1	_	_
MD Anderson CC	1	_	_	_
MUSC MU-NCORP	5	_	_	_
Michigan, U of	7	_	_	_
Oklahoma, Univ of	2	_	_	_
Tennessee, U of	26	_	_	_
Alliance	17	_	_	_
NRG	41	_	_	_
Total	135	5	9	3

"Cardiovascular Toxicity in Renal Cell Carcinoma." Kerryn Reding, PhD, MPH, RN

Subcommittee Updates

GU Survivorship: Peter Van Veldhuizen, MD

Sarcoma Survivorship

New Ideas

"Risks of Cardiovascular Disease in Testicular Cancer Survivors." Chunkit Fung, MD

"Cardiac Evaluation and Monitoring in Oncology Patients Receiving Immunotherapy." Krishna Guntur, MD

"Tele-psychiatry for Women with Breast Cancer and Major Depression." John Markowitz, MD, David Hellerstein, MD, and Jon Levenson, MD

Oncology Research Professionals Update:

Other Business



Palliative & End of Life Care Committee

Leadership

Co-Chairs:	Robert S. Krouse, MD
Executive Officer:	Katherine Crew, MD
Senior Advisor:	Frank L. Meyskens, Jr. MD
Statisticians:	Katherine A. Guthrie, PhD
	Garnet Anderson, PhD
	Kathryn Arnold, MS
	Amy Darke, MS
	Danika Lew, MS
Data Coordinators:	Monica Yee
	Roxanne Topacio
Patient Advocate:	
Nurse/CRA:	Connie Szczepanek
Protocol Coordinator:	Nicki Trevino

Time/Location

Friday, April 13, 2018 9:00 a.m. - 10:30 a.m. Room: Garden Room (Atrium Lobby Level)

Agenda

Introduction

Description and status of "Committee in Development": Frank Meyskens, MD

Mission and Future Goals: Krouse/O'Rourke, MD

Presentation

Palliative Care Research Cooperative (PCRC) Group and Opportunities for Collaboration with SWOG - Rebecca Sudore MD

Advocate Update: Rick Bangs, MBA

Introduction of new Advocate - TBD

Activated Study

S1316, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Robert Krouse, MD Activated: 3/9/15.

Update of Concepts Previously Proposed

"A Personalized Dietary Intervention to Manage Bowel Dysfunction in Rectal Cancer Survivors." Virginia Sun, PhD, RN

"Intervention to Improve Physician Communication in EOL Care." Mark O'Rourke, MD "A Cluster Randomized Phase II Trial of a Palliative Care Planning Intervention in Pancreatic Cancer." Virginia Sun, PhD

"An Intervention to Reduce Cardiovascular Complications of TKI Use in metastatic Renal Cell Cancer Patients." Kerryn Reding, PhD

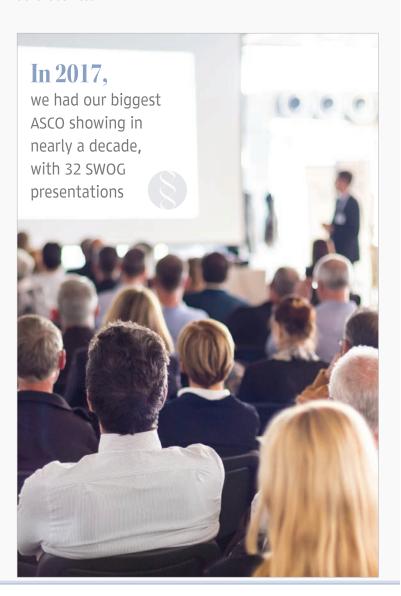
New study ideas

"Hyperthermic Intraperitoneal Chemotherapy for High Volume Peritoneal Carcinomatosis of Colorectal and Appendiceal Adenocarcinoma Origin."

Jiq Deneve, DO

"Description of Palliative Care Research Program at Kaiser Permanente: Potential future research collaborations within SWOG." Piyush Srivastava, MD

Other Business



Prevention & Epidemiology Committee

Leadership

Time/Location

Thursday, April 12, 2018 4:45 p.m. - 6:45 p.m. Room: Bayview B (Bay Level)

Agenda

Introduction

Welcome and Opening Comments: Dr. Marian Neuhouser & Dr. Banu Arun

Presentation:

eLearning Tobacco Program for the Oncology Practice in South America
 – Dr. Irene Tami-Maury, The University of Texas MD Anderson Cancer
 Center, Department of Behavioral Science

Biomarkers of breast cancer risk following benign biopsy – Dr. Deidre Hill, University of New Mexico

Active Studies

S0820, "A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients With Stage 0-III Colon or Rectal Cancer, Phase III." Drs. J. Zell, P. Brown, M.P. Lance, et al. Activated: 3/1/13.

NHLBI-MDS, The National Myelodysplastic Syndromes Natural History Study. D. Hill, MPH, PhD, Study Champion. Activated: 4/5/16.

Closed Studies

50812, "A Randomized Double-Blind Placebo-Controlled Biomarker Modulation Study of High Dose Vitamin D in Premenopausal Women at High Risk for Breast Cancer, Phase IIB." Dr. K. Crew. Activated 11/1/11; Closed 8/15/14.

New Business

Concepts approved by Triage

<u>S1711</u>, "Decision Support to Increase Informed Choice Among Women with Atypical Hyperplasia or Lobular Carcinoma in Situ." Dr. Katherine Crew, MD, MS

Assessment of Microbiota Composition Among Patients from S1119. Chuanwu Xi, PhD

Concepts Approved By NCORP Executive Committee

A Randomized Biomarker Study of Aspirin in Addition to Non-Steroidal Aromatase Inhibitors in Women of High BMI (≥ 30 kg/m2) with Breast Cancer. Andrew Brenner, MD, PhD

Phase II Study of Intraoperative Radiotherapy (IORT) for DCIS after Breast Conserving Surgery. Eileen Connolly, MD

Biology-Based Care in Testicular Cancer. Lucia Nappi, MD and Craig Nichols, MD

Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab in S1418. Banu Arun, MD

Concepts in Development

Project STOP (SWOG Tobacco Program for Oncology Practice). Irene Tami-Maury, DMD, M.Sc., DPH

Bazedoxefine + Conjugated Estrogen for Cancer Prevention in Women with Hot Flashes. Carol Fabian, MD and Lauren Nye, MD

Melanoma Chemoprevention. Sancy Leachman, MD

Other Concepts to discuss:

Open discussion





Prevention & Epidemiology Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.

Includes studies that are currently open, or that closed since 7/1/16.

	S0820	A211102	A211201	A1141
Baptist MU-NCORP	1	_	_	_
Brooke Army Med Ctr	2	_	_	_
CORA NCORP	2	_	_	_
City of Hope Med Ctr	1	2	_	_
Colorado, U of	3	_	_	_
Columbia MU-NCORP	1	1	2	_
Columbus NCORP	4	_	_	_
Dayton NCORP	1	_	_	_
Essentia HIth NCORP	4	_	_	_
Georgia NCORP	2	_	_	_
Hawaii MU-NCORP	6	_	_	_
Heartland NCORP	2	_	_	_
Irvine, U of CA	17	_	_	_
Kaiser Perm NCORP	23	_	9	_
Kansas, U of	3	_	_	_
Lahey Hosp & Med Ctr	_	_	1	44
Loma Linda Univ	1	_	_	_
Loyola University	1	_	_	_
MAVERIC	3	_	_	_
MD Anderson CC	9	_	_	_
Michigan CRC NCORP	4	_	_	_
Michigan, U of	_	_	2	_
Mississippi, Univ of	1	_	_	_
Nevada CRF NCORP	1	_	_	_
Northwest NCORP	5	_	_	_
Oklahoma, Univ of	1	_	_	_
Providence Hosp	1	_	_	_
San Antonio, U of TX	6	_	_	_
So Calif, U of	5	_	_	_
Southeast COR NCORP	1	_	_	_
Wayne State Univ	2	_	_	_
Wichita NCORP	11	_	_	_
Yale University	9	_	_	_
Alliance	19	_	_	_
ECOG-ACRIN	12	_	_	_
NRG	19	_	_	_
Total	183	3	14	44



Leadership

Time/Location

Thursday, April 12, 2018 12:30 p.m. - 2:30 p.m.

Room: Bayview B (Bay Level)

Agenda

Feature Presentations (90 minutes):

Deborah Bruner, RN, PhD, FAAN, "Overview of symptom research: past, present, and future"

Deborah Barton, RN, PhD, AOCN, FAAN, "Management of fatigue in patients with cancer: current options and future directions"

Discussion

Updates on Trials under development (20 minutes)

Siu-Fun Wong, Pharm D.: "A phase II randomized, placebo-controlled study to evaluate the use of vitamin K1 topical cream in patients with cutaneous toxicity caused by EGFR inhibitors."

Jamie Myers, PhD, RN, AOCNS and Arash Asher, MD: "Cognitive Rehabilitation Intervention during Cancer Treatment: Emerging from the Haze."

Other Discussion Topics (10 minutes)

Approved Trials (not yet active)

<u>\$1600</u>, "Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. J. Hamilton-Reeves and J. Holzbeierlein.

S1614, "A Phase III Randomized Trial of Prophylactic Antiviral Therapy in Patients with Current or Past Hepatitis B Virus (HBV) Infection Receiving Anti-Cancer Therapy for Solid Tumors." Drs. J. Hwang, A. Lok, A. Ghering, et al.

<u>S1714</u>, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. M. Trivedi, D. Hershman, T. Brannagan, et al.

Closed Studies

<u>S1200</u>, "Randomized Blinded Sham- and Waitlist-Controlled Trial of Acupuncture for Joint Symptoms Related to Aromatase Inhibitors in Women with Early Stage Breast Cancer." Drs. D. Hershman and K. Crew. Activated: 3/27/2012. Closed: 2/15/2017.

S1202, "A Randomized Placebo-Controlled Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor(AI)-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer." Drs. N. Henry and A. Schott. Activated: 5/15/2013. Closed to accrual 10/1/2015.

Other Concepts in Development

"The Breast Cancer Endocrine Therapy Adherence (BETA) Feasibility Study: A Text Messaging Application to Increase Adherence to Adjuvant Endocrine Therapy in Stage I-III Hormone Receptor Positive Breast Cancer." Dr. S. Mougalian.

"A Phase II Randomized Placebo-Controlled Study to Evaluate the Use of Vitamin K1 Topical Cream in Patients with Cutaneous Toxicity Caused by Epidermal Growth Factor Receptor (HER1/EGFR) Inhibitors."

Drs. S. Wong, C. Ryan, C. Moinpour, et al.

Other Studies with Symptom Control and QOL Component

Breast

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. E^3 Breast Cancer Study Evaluating Everolimus with Endocrine Therapy" Dr.M. Chavez-MacGregor. Activated: 9/3/2013.

51418, "A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy." Drs. L. Pusztai J. Mammen, N. Henry, et al. Activated: 11/15/2016.

<u>S1706</u>, "A Phase II Randomized, Double-Blinded, Placebo-Controlled Trial of Olaparib Administered Concurrently with Radiotherapy for Inflammatory Breast Cancer." R. Jagsi.



<u>\$1807</u>, "A Phase II Randomized Double-Blinded, Controlled Study of Tucatinib (ONT-380) Following Stereotactic Radiosurgery (SRS) HER2-Positive Breast Cancer Brain Metastases." Dr. C. Tsien.

S1817, "BIOmarker Driven Immune CHECKpoint Inhibitor Therapy in Metastatic Breast Cancer." Dr. E. Cobain.

GI

S1717. "Randomized Phase III Trial of the CancerTYPE ID Test in the Evaluation of Patients with Cancer of Unknown Primary (CUP)." Drs. S. Yentz and L. Baker.

GU

<u>\$1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST)
Versus Standard Systemic Therapy plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer."
Dr. B. Chapin.

<u>S1806</u>, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. P. Singh.

Leukemia

S1612, "A Randomized Phase II/III Trial of Novel Therapeutics Versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia (AML) or High-Risk Myelodysplastic Syndrome (MDS), Age 60 or Older (LEAP: Intergroup Less Intense AML Platform Trial)." Drs. L. Michaelis, R. Walter, S. Assouline, et al. Activated 12/22/2017.

Lung

<u>S1400I</u>, "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. S. Gettinger and L. Bazhenova. Activated 12/18, 2015.

<u>S1400GEN</u>, "Ancillary Study to Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in S1400." Drs. S. Ramsey and D. Hershman. Activated 2/5/2018.

"PCI vs Active MRI Surveillance in Small-Cell Lung Cancer." Dr. C. Rusthoven, MD

"A Randomized Phase II Study of Irinotecan Alone Versus Combined Irinotecan with Atezolizumab in Patients with Relapsed or Refractory UGTA1*1 or UGTA1*28 Small Cell Lung Cancer (SCLC)." Dr. N. Karim.

Lymphoma

S1818, "A Phase II/III Randomized Study of R-miniCHOP with or Without Oral Azacitidine in Elderly Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma (DLBCL)." Drs. Elizabeth Brem and Sonali Smith.

Melanoma

<u>S1404</u>, "A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma." Drs. K. Grossmann, S. Patel, M. Knopp, et al. Activated: 10/15/2015. Closed: 11/2/2017.

Mveloma

S1803, "Phase III Study of Daratumumab (NSC-791647) + Lenalidomide (LD) or Lenalidomide (L) as Post-Autologous Stem Cell Transplant Maintenance Therapy in Patients with Multiple Myeloma (MM) Using Minimal Residual Disease to Direct Therapy Duration (DRAMMATIC Study)." Drs. A. Krishnan, P. Hari, P. Wallace, et al.

NCTN Studies

CTSU/NRG-GI004, "Colorectal Cancer Metastatic dMMR Immunotherapy (COMMIT) Study: A Randomized Phase III Study of mFOLFOX6/
Bevacizumab Combination Chemotherapy with or Without
Atezolizumab or Atezolizumab Monotherapy in the First Line Treatment of Patients with Deficient DNA Mismatch Repair (dMMR) Metastatic Colorectal Cancer." Dr. M. Overman. Activated 11/7/2017.

CTSU/A021202, "Prospective Randomized Phase II Trial of Pazopanib (NSC #737754, IND 75648) Versus Placebo in Patients with Progressive Carcinoid Tumors." Dr. Phan. Activated: 6/21/2013. Closed: 10/7/2016.

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. S. Coutre. Activated: 12/9/2013. Closed: 5/16/2016.



CTSU/C30610, "Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin or Carboplatin and Etoposide." Drs. S. Gadgeel and L. Gaspar. Activated: 3/15/2008. Closed: 8/30/2017.

CTSU/C51101, "A Randomized Phase II Trial of Myeloablative Versus Non-Myeloablative Consolidation Chemotherapy for Newly Diagnosed Primary CNS B-Cell Lymphoma." Dr. N. Mohile. Activated: 6/15/2012. Closed 5/2/2017.

CTSU/C90203, "A Randomized Phase III Study of Neo-Adjuvant Docetaxel and Androgen Deprivation Prior to Radical Prostatectomy Versus Immediate Radical Prostatectomy in Patients with High-Risk, Clinically Localized Prostate Cancer." Dr. F. Kim. Activated: 12/15/2006. Closed:10/2/2015.

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. B. Till. Activated
5/22/2012. Closed: 9/9/2016.

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 =

CTSU/E1609, "A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon a-2b for Resected High-Risk Melanoma." Dr. Flaherty. Activated: 5/25/2011. Closed: 7/26/2016.

CTSU/E1912, "A Randomized Phase III Study of Ibrutinib (PCI-32765)-Based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. S. O'Brien. Activated 2/20/2014. Closed: 6/9/2016.

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. J. Zonder. Activated: 12/2/2013.

Symptom Control & Quality of Life Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.
Includes studies that are currently open, or that closed since 7/1/16.

	S1013	S1200	A221101	A221102
Arkansas, U of	_	_	1	_
CORA NCORP	_	_	_	7
CRC West MI NCORP	_	68	_	_
City of Hope Med Ctr	20	_	_	_
Columbia MU-NCORP	3	29	_	_
Fred Hutchinson CRC	_	11	_	_
Greenville NCORP	_	15	_	_
Gulf South MU-NCORP	12	_	_	_
Heartland NCORP	61	_	_	_
Irvine, U of CA	_	_	7	_
Kaiser Perm NCORP	_	56	_	_
Kansas City NCORP	1	_	_	_
Kansas, U of	_	_	1	_
Kentucky, U of	_	_	1	_
Lahey Hosp & Med Ctr	_	10	_	_
Loma Linda Univ	1	_	2	_
Northwest NCORP	_	_	1	_
Oregon Hlth Sci Univ	_	9	_	_
PCRC NCORP	_	20	_	1
Providence Hosp	_	_	2	_
San Antonio, U of TX	_	_	1	_
So Calif, U of	26	5	_	_
Southeast COR NCORP	5	_	_	_
Sutter Cancer RC	_	_	1	2
Upstate Carolina	_	_	1	_
Utah, U of	_	3	_	_
Wayne State Univ	3	_	_	_
Wichita NCORP	14	_	_	_
Total	146	226	18	10



CTSU/E2810, "Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy." Dr. S. Pal. Activated: 8/8/2012. Closed 7/25/2017.

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. J. Godwin. Activated: 12/28/2010. Temporarily closed: 2/23/2015.

CTSU/E3A06, "Randomized Phase III Trial of Lenalidomide Versus
Observation Alone in Patients with Asymptomatic High-Risk Smoldering
Multiple Myeloma." Drs. M. Dhodapkar and J. Epstein. Activated:
10/5/2010. Closed: 7/14/2017.

CTSU/EA6134, "A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab Followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma." Dr. B. Chmielowski. Activated: 7/13/2015.

CTSU/N1048, "A Phase II/III Trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation Versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision." Dr. C. Eng. Activated: 1/13/2012.

CTSU/N107C, "A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease." Dr. L. Gaspar. Activated: 7/8/2011. Closed: 12/18/2015.

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. P. Philip. Activated: 11/17/2009.

CTSU/R1010, "A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma." Dr. L. Leichman. Activated: 12/30/2010. Closed 11/10/2015.

Committee Process

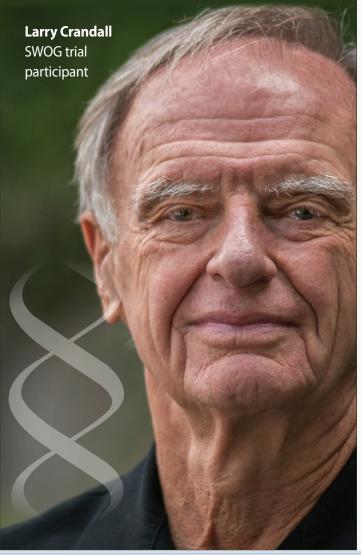
Sign and/or correct the meeting attendance/contact list

Patient Voice



I cared enough about the community to join a SWOG trial. As a volunteer, I believe in giving back. And I'm not alone. There are a lot of great folks out there joining clinical trials.







Early Therapeutics & Rare Cancers Committee

Leadership

Chair:	Razelle Kurzrock MD
Vice-Chair:	
Executive Officer:	· · · ·
Statisticians:	•
	Melissa Plets, MS
	Edward Mayerson, MS
Designates	
Data Coordinators:	Christine McLeod
	Jourdain Havward
Oncology Research Professionals:	,,
CRA:	Corring Turrell CCPP
Nurse:	
Pharmaceutical Science:	3 3 .
	Sun "Coco" Yang, PharmD
Patient Advocate:	Marcia K. Horn, JD
Protocol Coordinator:	Dion Holmes
Early Therapeutics Liaisons	
Breast Committee Liaison:	George Somlo, MD
Genitourinary Committee Liaison:	Neeraj Agarwal, MD
Imaging:	
Lung Committee Liaison:	Shirish M. Gadgeel, MD
Lymphoma Committee Liaison:	Daruka Mahadevan, MD, PhD
Melanoma Committee Liaison :	Jeffrey A. Sosman, MD
Myeloma Committee Liaison:	Frits van Rhee, MD, PhD

Time/Location

Thursday, April 12, 2018 10:00 a.m. — 12:15 p.m.

Room: Seacliff A-C (Bay Level)

Agenda

Introduction

10:00 a.m. -10:05 a.m.: Razelle Kurzrock, MD, Chief, Division of Hematology and Oncology, UCSD School of Medicine, Senior Deputy Center Director, Director, Center for Personalized Cancer Therapy, Director Clinical Trials Office, Chair, Early Therapeutics and Rare Cancer Committee (SWOG), UCSD Moores Comprehensive Cancer Center, San Diego, CA

Presentations

10:05 a.m. – 10:35 a.m.: "Innovative Developments in Early Therapeutics: What is New?" Monica Mita, MD, Associate Professor, Department of Medicine; Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center

Early Therapeutics & Rare Cancers Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.
Includes studies that are currently open, or that closed since 7/1/16.

	1609	A071102	A071401	ARST1321	EAY131
Arizona MC, U of	_	_	_	_	2
Arkansas, U of	_	_	_	_	3
Baptist MU-NCORP	2	_	_	_	_
Baylor College	_	2	_	_	_
Brooke Army Med Ctr	_	2	_	_	_
CORA NCORP	3	1	1	_	1
Carle CC NCORP	2	_	_	_	_
Cedars-Sinai Med Ctr	3	_	_	_	3
City of Hope Med Ctr	_	_	_	_	3
Cleveland Clinic OH	_	_	_	_	4
Colorado, U of	2	2	1	_	9
Columbus NCORP	2	_	_	_	_
Davis, U of CA	7	_	_	_	7
Dayton NCORP	1	_	_	_	1
Essentia Hlth NCORP	2	_	_	_	_
Fred Hutchinson CRC	5	_	_	_	2
Georgia NCORP	3	_	_	_	_
Gulf South MU-NCORP	1	_	_	_	_
H Lee Moffitt CC	6	_	_	_	_
Hawaii MU-NCORP	_	_	_	_	1
Heartland NCORP	9	_	_	_	1
Henry Ford Hospital	10	_	_	_	9
Irvine, U of CA	3	2	1	_	7
Kaiser Perm NCORP	13	3	_	_	5
Kansas City NCORP	_	_	_	_	1
Kansas, U of	15	_	_	1	4
Kentucky, U of	_	_	_	_	9
Lahey Hosp & Med Ctr	_	3	_	_	_
Loma Linda Univ	_	_	_	_	1

10:35 a.m. – 10:55 a.m.: "Dual Anti-CTLA-4 and Anti-PD-1 blockage in Rare Tumors (DART)." Sandip Pa-tel MD, Assistant Professor, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA

<u>10:55am – 11:15am:</u> "DART Translational Initiative." Young Kwang Chae, MD, Assistant Professor Co-Director, Early Therapeutics, Northwestern University, Robert H. Lurie Comprehensive Cancer Center



Early Therapeutics & Rare Cancers Committee

Early Therapeutics & Rare Cancers Committee, cont.

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.
Includes studies that are currently open, or that closed since 7/1/16.

	1609	A071102	A071401	ARST1321	EAY131
Loyola University	1	_	_	_	_
MAVERIC	2	_	_	_	_
MD Anderson CC	1	_	_	_	_
MUSC MU-NCORP	2	_	_	_	_
Methodist Hospital	_	_	_	_	1
Michigan CRC NCORP	12	_	_	_	_
Michigan, U of	17	_	_	_	6
Mississippi, Univ of	3	1	_	_	_
Montana NCORP	5	_	_	_	_
Nevada CRF NCORP	7	_	_	_	_
New Mexico MU-NCORP	10	_	_	_	_
Northwest NCORP	2	_	_	_	_
Northwestern Univ	3	1	_	1	_
Oregon Hlth Sci Univ	_	_	_	1	_
Ozarks NCORP	1	2	_	_	_
PCRC NCORP	9	3	_	_	_
Providence Hosp	1	_	_	_	2
Rochester, Univ of	_	8	_	_	_
San Antonio, U of TX	2	_	_	3	4
San Diego, U of CA	7	7	2	_	_
Southeast COR NCORP	4	_	_	_	6
Sutter Cancer RC	1	_	_	_	4
Tulane University	_	_	_	_	1
Wayne State Univ	_	_	_	_	1
Wisconsin NCORP	3	_	_	_	_
Yale University	2	1	_	_	7
Alliance	46	_	_	_	_
ECOG-ACRIN	27	_	_	_	_
NRG	54	_	_	_	_
Total	311	38	5	6	105

<u>11:15 a.m. – 11:45 a.m.:</u> "Genomic Analysis for Rare Cancers." Jeff Chuang, PhD, Associate Professor, The Jackson Laboratory for Genomic Medicine, Farmington, CT

11:45 a.m. – 12:05 p.m.: "Brain Tumor Initiative." Manmeet Ahluwalia, MD, F.A.C.P., Professor of Medicine, Miller Family Endowed Chair in Neuro-Oncology, Head of Operations, Burkhardt Brain Tumor Center, Cleveland Clinic

12:05 p.m. – 12:15 p.m.: Wrap Up and Open Discussion. Razelle Kurzrock, MD, Chief, Division of Hematology and Oncology, UCSD School of Medicine, Senior Deputy Center Director, Director, Center for Personalized Cancer Therapy, Director Clinical Trials Office, Chair, Early Therapeutics and Rare Cancer Committee (SWOG), UCSD Moores Comprehensive Cancer Center, San Diego, CA

Active Studies

<u>\$1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. P. Patel, Y. Chae, F. Giles, and R. Kurzrock. Activated: 1/13/17.

CTSU/A071102, "A Phase II/III Randomized Trial of Veliparib or Placebo in Combination with Adjuvant Te-mozolomide in Newly Diagnosed Glioblastoma with MGMT Promoter Hypermethylation." Dr. D.E. Piccioni. Activated by Alliance 12/15/2014. Activated by SWOG: 4/1/2015. Temporarily closed: 10/21/16.

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas with SMO/AKT/ NF2 Mutations." Dr. D.E. Piccioni. Activated by Alliance 8/28/2015. Activated by SWOG: 1/1/2016.

CTSU/ARST1321, "Pazopanib Neoadjuvant Trial in Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III

Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)." Dr. V.M. Villalobos. Activated by COG 1/27/2014. Activated by SWOG: 3/15/2016.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. V.M. Villalobos. Activated: 8/12/2015.

Proposed Studies

<u>\$1618</u>, "A Phase II Study of a selective JAK1 Inhibitor (INCB9110) in Subjects with Advanced Sarcomas." Dr. V.M. Villalobos.

S1716, "A Phase I/II study of Brentuximab Vedotin in CD30 + Systemic Mastocytosis and CMML." Drs. U. Borate and A. Gerds.

S1720, "Efficacy and Safety of Laparoscopic Extraperitoneal Para-aortic Lymphadenectomy vs. PET/CT as a Classificatory Method for the Treatment of Locally Advanced Cervical Cancer, a Phase III Randomized Clinical Trial." Dr. J. Acosta.



Gastrointestinal Committee

Leadership	
Chair:	.Howard S. Hochster, MD
Vice-Chair:	Heinz-Josef Lenz, MD
Executive Officer:	Christopher W. Ryan, MD
Statisticians:	Katherine A. Guthrie, PhD
S	hannon McDonough, MS
Scientific Leadership	
Gastroesophageal:	
Li	•
Scott A. Hundahl, MD	
Pancreatic:	
Andrew M. Lowy, MD	•
Hepatobiliary: An	
Syed Ahmad, MD	
Colon:	•
Kevin G. Billingsley, MD	
Rectal:	
To all developed the Peters	, ,
Translational Medicine:	
Drug Development:	•
brug Development:	
lmaging:An	
illagiligAli	•
Radiation Oncology:	
Designates	Lisa A. Nacilille, IND
Cancer Control Liaison:	lason A. Zell, DO
Data Coordinators:	•
	•
Oncology Research Professionals:	
CRA:	Sandy Annis, CCRP
Nurses:	
Patient Advocate (Pancreatic):	Carole Seigel, MBA
Patient Advocate (Colon):	Florence Kurttila, MS
Pharmaceutical Science:	inda Lee-Gabel, PharmD
	Jessie Modlin, PharmD
Protocol Coordinator:	Danae Campos

Time/Location

Friday, April 13, 2018 5:00 p.m. - 7:00 p.m.

Room: Grand C (Street Level)

Agenda

Introduction. Howard Hochster, MD, Rutgers University.

"Treatment resistance to anti-EGFR therapy and ctDNA." Scott Kopetz, MD, PhD, MD Anderson Cancer Center.

Presentation of S1417, "Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer." Veena Shankaran, MD, Fred Hutchinson Cancer Research Center.

Gastroesophageal

No studies

Pancreatic

Active Studies

<u>\$1505</u>, "A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/nab-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma." Dr. Sohal. Activated: 10/12/15.

CTSU/RTOG 0848, "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.

CTSU/A021501, "Preoperative Extended Chemotherapy vs Chemotherapy Plus Hypofractionated Radiation Therapy for Borderline Resectable Adenocarcinoma of the Head of the Pancreas." Dr. Lieu. Activated: 12/1/16

EA2142, "Randomized Phase II Study of Platinum and Etoposide Versus Temozolomide and Capecitabine in Patients with Advanced G3 Non-Small Cell Gastroenteropancreatic Neuroendocrine Carcinomas." Activated 11/06/2015.

Proposed Studies

<u>\$1819, "</u>A randomized phase II study of FOLFIRINOX with or without CCR2 Inhibition in Locally Advanced Pancreatic Cancer." Dr. Marcus Noel

Closed Studies

S1313, "A Phase IB/II Randomized Study of Modified FOLFIRINOX + Pegylated Recombinant Human Hyaluronidase (PEGPH20) versus Modified FOLFIRINOX Alone in Patients with Good Performance Status Metastatic Pancreatic Adenocarcinoma." Dr. Ramanathan. Activated: 1/15/14. Closed: 7/1/17.



Gastrointestinal Committee

<u>S1513</u>, "Randomized Phase II Study of 2nd Line FOLFIRI versus Modified FOLFIRI with PARP Inhibitor ABT-888 (Veliparib) (NSC-737664) in Metastatic Pancreatic Cancer." Dr. Chiorean. Activated: 9/1/16. Closed 12/13/2017.

Hepatobiliary

Active Studies

CTSU/RTOG-1112, "Randomized Phase III Study of Sorafenib versus Stereotactic Body Radiation Therapy Followed by Sorafenib in Hepatocellular Carcinoma." Activated: 4/24/13.

Proposed Studies

<u>\$1815</u>, Gemcitabine, cisplatin, and nab-paclitaxel versus gemcitabine and cisplatin in advanced biliary cancers: a randomized Phase II/III study. Dr. Rachna Shroff.

Colon

Active Studies

- **50820**, "A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon or Rectal Cancer, Phase III." Dr. Zell. Activated: 3/1/13.
- <u>S1417CD</u>, "Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer." Dr. Shankaran. Activated: 4/15/16.
- S1415CD, "A Pragmatic Trial to Evaluate a Guideline-Based Colony
 Stimulating Factor Standing Order Intervention and to Determine
 the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for
 Patients Receiving Chemotherapy with Intermediate Risk for Febrile
 Neutropenia Trial Assessing CSF Prescribing Effectiveness and Risk
 (TrACER)." Drs. Ramsey and Hershman. Activated: 10/7/16.
- <u>\$1613</u>, "A Randomized Phase II study of Trastuzumab and Pertuzumab (TP) compared to Cetuximab and Irinotecan (CETIRI) in HER2 Amplified Irinotecan-refractory Metastatic Colorectal Cancer (mCRC)." Dr. Raghav. Activated: 10/9/17

Closed Studies

Proposed Studies

Rectal

Active Studies

- CTSU/N1048, "A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision." Dr. Eng. Activated: 1/13/12.
- CTSU/NRG-GI002, "A Phase II Clinical Trial Platform of Sensitization Utilizing Total Neoadjuvant Therapy (TNT) in Rectal Cancer." Dr. Kachnic. Activated: 10/12/2016.

Closed Studies

CTSU/EA2133, "InterAACT – An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin Plus 5-Fluorouracil Versus Carboplatin Plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease." Dr. Morris. Activated: 2/15/16. Closed 09/27/2017

Other

Active Studies

- <u>\$1316</u>, "Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15.
- <u>\$1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Dr. Patel. Activated: 1/13/17.
- **EAY131**, "NCI-MATCH: Molecular Analysis for Therapy Choice." Dr. Villalobos. Activated: 8/12/15.

Closed

<u>S1204</u>, "A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Among Newly Diagnosed Cancer Patients." Drs. Ramsey, Loomba, Chugh, Hershman and Hwang. Activated: 8/29/13 Closed: 2/15/17.

Correlative Studies

- S9008A, "Trial of Adjuvant Chemoradiation after Gastric Resection Adenocarcinoma, Phase III." Dr. Shridhar.
- <u>S-C80405-A</u>, "Analysis of EGFR and ERCC1 Markers and Progression-Free Survival in Patients with Advanced Colorectal Cancer Enrolled on C80405." Drs. Shields and Lenz.



Gastrointestinal Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1313	S1505	S1513	A021202	A021501	E7208	EA2133	EA2142	EA214	N1048 2	NRGGI002	R0848
Arizona MC, U of	4	1	_	_	_	_	_	_	_	4	_	_
Baptist MU-NCORP	_	1	_	_	_	_	_	_	_	_	_	_
Baylor College	_	_	_	_	_	_	_	_	_	17	_	_
Baylor Univ Med Ctr	_	_	_	2	_	_	_	_	_	_	_	_
Beaumont NCORP	_	_	2	_	_	_	_	_	_	_	_	_
Boston Medical Ctr	_	_	_	_	_	_	_	_	_	2	_	_
CORA NCORP	_	_	2	_	_	1	_	_	_	2	_	_
CRC West MI NCORP	_	_	1	_	_	_	_	_	_	_	_	_
Carle CC NCORP	_	2	1	_	_	_	_	_	_	_	_	_
Cedars-Sinai Med Ctr	_	_	_	4	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	2	_	_	2	_	_	_	_	_	_	_
City of Hope Med Ctr	3	_	2	_	_	_	_	_	_	_	_	_
Cleveland Clinic OH	_	5	_	_	_	_	_	_	_	_	_	_
Colorado, U of	_	_	2	1	_	_	_	_	_	1	_	_
Columbia MU-NCORP	_	_	2	_	_	_	_	_	_	_	_	2
Columbia University	_	_	_	_	_	_	_	_	_	_	_	1
Columbus NCORP	_	1	_	_	_	_	_	_	_	_	_	_
Davis, U of CA	1	_	_	_	_	_	_	_	_	2	_	_
Dayton NCORP	_	3	2	_	_	_	_	_	_	2	2	_
Fred Hutchinson CRC	14	_	2	_	_	_	_	_	_	16	2	_
Greenville NCORP	_	3	_	_	_	_	_	_	_	_	_	1
Gulf South MU-NCORP	_	_	1	_	_	_	_	_	_	_	_	_
H Lee Moffitt CC	_	_	_	22	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	_	_	_	_	_	_	_	_	_	_	_	1
Heartland NCORP	8	6	5	_	_	_	_	_	_	_	_	_
Irvine, U of CA	7	_	_	_	3	_	_	_	_	13	_	6
Kaiser Perm NCORP	_	5	8	1	_	_	_	_	1	20	_	_
Kansas City NCORP	7	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	_	2	2	1	_	_	1	_	_	_	_	1
Kentucky, U of	_	3	_	_	_	_	_	_	_	_	_	_
Lahey Hosp & Med Ctr	_	_	_	_	_	_	_	_	_	11	_	_













Since 1956,

we've conducted more than 1,400 cancer clinical trials.

Our research has made life longer, or better, for thousands of people.

We expanded our patient advocate committee to 19 members, making it one of the largest, and the most experienced, groups in the NCTN.



Gastrointestinal Committee, cont.

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1313	\$1505	\$1513	A021202	A021501	E7208	EA2133	EA2142	EA214	N1048 2	NRGGI002	R0848
Loyola University	_	_	_	_	_	_	_	_	_	_	_	4
MUSC MU-NCORP	5	3	1	_	_	_	_	_	_	_	_	_
Methodist Hospital	_	_	_	1	_	_	_	_	_	11	_	_
Michigan CRC NCORP	_	1	2	_	_	_	_	_	_	_	_	_
Michigan, U of	_	6	2	_	5	1	_	_	3	4	_	_
Montana NCORP	_	_	1	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	1	5	_	_	_	_	_	_	1	_	_
Northwest NCORP	_	_	_	_	_	_	_	_	_	_	_	3
Northwestern Univ	_	_	_	_	_	1	_	_	_	1	_	_
Oklahoma, Univ of	_	1	_	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	1	_	_	_	_	_	_	_	_	1	_
Oregon HIth Sci Univ	_	1	_	_	_	_	_	_	_	_	_	_
Ozarks NCORP	_	1	_	_	_	_	_	_	_	1	_	_
PCRC NCORP	6	4	_	_	_	_	_	_	_	1	_	_
Providence Hosp	_	_	_	_	_	1	_	_	_	_	_	_
Rochester, Univ of	_	4	11	1	1	_	_	_	_	21	_	_
San Antonio, U of TX	_	_	_	2	_	_	_	_	_	_	_	_
San Diego, U of CA	_	4	_	_	_	_	_	_	_	4	_	_
Scott & White Mem	_	2	_	_	_	1	_	_	_	1	_	_
So Calif, U of	6	_	_	_	_	6	_	_	_	1	_	_
Southeast COR NCORP	5	2	4	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	9	_	_	_	1	_	_	_	_	_	_	_
Utah, U of	_	_	7	_	_	_	_	_	_	3	_	_
Wayne State Univ	11	_	2	_	_	1	_	_	_	_	_	_
Wichita NCORP	_	_	_	_	_	_	_	_	_	_	_	1
Wisconsin NCORP	_	3	1	_	_	_	_	_	_	_	_	_
Yale University	40	_	3	_	_	11	_	_	_	_	_	_
Alliance	_	13	17	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	_	22	18	_	_	_	_	_	_	_	_	_
NRG	_	18	17	_	_	_	_	_	_	_	_	_
Total	126	118	123	35	12	23	1	1	4	139	5	20

We registered over 1,500 patients to Lung-MAP, our precision medicine trial

Thanks, team!















Genitourinary Committee

Leadership

	lan M. Thompson, Jr., MD
	Nicholas J. Vogelzang, MD Christopher W. Ryan, MD
	Cathy M. Tangen, DR PH
	Melissa Plets, MS
	Eddie Mayerson, MS
Scientific Leadership	Ladie Mayerson, M3
•	David J. McConkey, PhD (GU Chair)
	Joshua J. Meeks, MD, PhD (Bladder)
	Amir Goldkorn, MD (Prostate)
	Brian Shuch, MD (Renal)
	David Raben, MD
= -	David Raberi, MD
• •	John D. Hazle, PhD
	M. Scott Lucia, MD
•	Colin P.N. Dinney, MD
	Neeraj Agarwal, MD
	Seth P. Lerner, MD (Localized)
	Daniel P. Petrylak, MD (Advanced)
	Daniel W. Lin, MD (Localized)
_	David I. Quinn, MD, PhD (Advanced)
	Edward M. Messing, MD (Localized)
<u> </u>	Primo N. Lara, Jr., MD (Advanced)
Designates	
Cancer Control:	Peter J. Van Veldhuizen, Jr., MD
Data Coordinators:	Sean O'Bryan
	Joseph Sanchez
	Vicky Kim
Oncology Research Professionals:	
CRA:	TBD
Nurses:	Deborah A. Shaw, RN
	Cheryl Kefauver, RN
	Rick Bangs, MBA (Bladder)
	Tony Crispino (Prostate)
_	aret "Peggy" Zuckerman, M.Ed. (Renal)
Pharmaceutical Science:	Joyce Lee, PharmD
	Rivka Siden, PharmD
Protocol Coordinator:	Nicki Trevino

Time/Location

Saturday, April 14, 2018 9:30 a.m. - 12:30 p.m.

Room: Grand A (Street Level)

Agenda

Introductions and Announcements: Ian M. Thompson, Jr., MD

The GU Committee and the 2018 SWOG Grant Renewal: Continuing High-Impact: Christopher W. Ryan, MD

The near-final report from the Prostate Cancer Prevention Trial: Ian M. Thompson, Jr, MD and Cathy M. Tangen, DR PH

Cancer Control

Liaison: Dr. Peter J. Van Veldhuizen

Active Studies

<u>\$1316,</u> "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Drs. Krouse, Badgwell, and Sun. Activated: 3/9/15.

<u>\$1600</u>, "A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. Hamilton-Reeves and Holzbeierlein.

Renal

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

Active Studies

S1500, "A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)." Drs. Pal, Lara, and Shuch. Activated: 4/5/16.

CTSU/EA8143, "A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)." Drs. Lara and Shuch. Activated: 2/2/17.

Closed Studies

<u>\$0931</u>, "EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study." Drs. Ryan, Heath, Lara, et al. Activated: 4/1/11. Closed: 9/15/16.

CTSU/E2810, "Randomized, Double-Blind Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatec-tomy." Dr. Pal. Activated 4/17/12. Closed 7/25/17.



Genitourinary Committee

Prostate

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

Priority Study

S1802, "Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (surgery or radiation) of the Primary Tumor in Metastatic Prostate Cancer." Drs. Brian Chapin and Ana Aparicio.

Active Studies

- CTSU/NRG-GU003, "A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Ra-diation Therapy (HYPORT) Versus Conventional Post-Prostatectomy Radiation Therapy (COPORT)." Dr. David Raben. Activated: 7/28/2017.
- CTSU/NRG-GU002, "Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Follow-ing Radical Prostatectomy with or without Adjuvant Docetaxel." Dr. David Raben. Activated: 12/30/2016.
- CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Ex-tensive Disease Following Docetaxel: The CHAARTED2 Trial." Dr. Paul Corn. Activated 2/8/18.
- CTSU/ A031102, "A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Us-ing Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors." Dr. David Quinn. Activated: 7/1/15.
- RTOG-0924, "Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial. Dr. David Marshall. Activated: 7/7/2011.

Closed Study

S1216, "A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hor-mone Sensitive Prostate Cancer." Drs. Agarwal, Goldkorn, Gupta, et al. Activated: 3/1/13. Closed 7/15/2017.

SWOG Champions needed: EA8173

Bladder

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

Priority Study

- **S1806**, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without
- Atezolizumab in Localized Muscle Invasive Bladder Cancer." Drs. Singh, Lerner, Efstathiou, et al.

Active Studies

- <u>S1602</u>, "A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG Naïve High-Grade Non-Muscle Invasive Bladder Cancer." Dr. Svatek, Activated: 2/7/17.
- <u>\$1605</u>, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Can-cer." Drs. Black and Singh. Activated: 2/7/17.

Closed Studies

- **S1011**, "A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pel-vic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer." Drs. Lerner, Alva, Koppie, et al. R. Bangs. Activated: 8/1/11. Closed: 2/15/2017.
- **<u>\$1314</u>**, "A Randomized Phase II Study of CO-eXpression ExtrapolatioN (COXEN) Directed Neo-adjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer." Drs. Flaig, Alva, Daneshmand, et al. Activated: 7/9/14. Closed 12/1/17.
- CTSU/EA8141, "A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma." Drs. Go-doy and Alva. Activated 4/10/15. Closed 1/5/18.

Diverse Studies of Interest

- <u>\$1609:</u> "DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors." Drs. Patel, Chae, Kur-zrock, et al. Activated: 1/13/17.
- CTSU/EAY 131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.



Genitourinary Committee

Cumulative Accrual by Institution and StudyIncludes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S0931	S1011	S1216	S1314	S150	S1602	S1605	A031102	A03120	E2810	EA8141	EA8143	NRGGU002	R0924
Arizona MC, U of	13	_	10	3	_	_	_	_	10	_	_	2	_	_
Arkansas, U of	10	_	6	_	1	_	_	_	4	_	_	_	_	_
Atlanta Reg CCOP	7	_	_	_	<i>.</i>	_	_	_	_	_	_	_	_	_
BC Cancer Agency	_	22	_	_	_	_	_	_	_	_	_	_	_	_
Baptist MU-NCORP	3	_	1	_	_	_	_	_	_	_	_	_	_	_
Bay Area NCORP	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Baylor College	21	51	16	3	_	_	_	_	3	_	_	_	_	_
Beaumont NCORP	8	_	3	_	_	_	_	_	_	_	_	_	_	_
Birmingham, U of AL	_	_	_	1	_	_	_	_	11	_	1	_	_	_
Boston MC MBCCOP	1	_	3	_	_	_	_	_	_	_	_	_	_	_
Boston Medical Ctr	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Brooke Army Med Ctr	2	_	_	_	_	_	_	_	_	_	_	_	_	_
CORA NCORP	7	_	2	_	_	_	_	_	3	_	_	_	_	1
CRC West MI NCORP	15	_	4	_	_	_	_	_	_	_		_	_	
Carle CC NCORP	—	_	2	_	_	_	_	_	_	_		_	_	_
Cedars-Sinai Med Ctr	13	_	_	_	1	_	_	_	_	_		_	_	
Cincinnati MC, U of	6	_	1	_	<i>.</i>	_	_	_	3	_	_	_	_	_
City of Hope Med Ctr	41	_	49	8	14	_	_	_	22	16	_	_	_	_
Cleveland Clinic OH	_	7	_	12	_	_	_	_	38	_	_	_	_	3
Colorado, U of	27	3	4	11	_	2	2	_	5	_	5	_	1	_
Columbia MU-NCORP	6	_	2	_	_	_	_	_	_	1	_	_	_	_
Columbia University	3	_	_	_	_	_	_	_	_	_	_	_	_	_
Columbus NCORP	17	_	6	_	_	_	_	_	_	_	_	_	_	_
Davis, U of CA	13	12	37	4	2	_	1	_	10	_	_	_	_	_
Dayton NCORP	16	_	9	_	_	_	_	_	_	_	_	_	_	_
Desert Hospital	_	_	_	_	_	_	_	_	_	_	_	_	_	7
Essentia HIth NCORP	_	_	_	_	_	_	1	_	_	_	_	_	_	_
Fred Hutchinson CRC	2	_	28	_	_	_	_	_	_	_	_	_	_	_
Galveston, U of TX	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Georgia NCORP	2	_	2	_	_	_	_	_	1	1	_	_	_	_
Greenville NCORP	6	_	_	3	_	_	_	_	_			_	_	_
Gulf Coast MBCCOP	1	_		_		_	_	_		_		_	_	
Gulf South MU-NCORP	17	4	2	3	_	12	1	_	_	_	_	_	_	_
H Lee Moffitt CC	_	2	32	_	_	_	_	_	_	_	_	1	_	_
Harrison Medical Ctr	_	_		_	_	_	_	_	2	_	_		_	_
Hawaii MU-NCORP	13	_	_	_	_	_	_	_	1	_	_	_	_	_
Heartland NCORP	37	_	38	18	2	1	1	_	3	_		_	_	_
Henry Ford Hospital	8	_	_	_	_	_	_	_	14	1			_	
Irvine, U of CA	8	_	6	_	_	_	_	_	2	_				_
Kaiser Perm NCORP	14	_	83	_	_	_	_	_	97	_	_	_	_	
Kansas City NCORP	7	_	6	_		_		_	_	_	_			_
Kansas, U of	29	_	29	10	_	_	_	_	9	6	1	_	_	3
Kentucky, U of		_	16	_	_	_		_		_	_	2	_	_
remucky, o oi	_		10				_		_			2		



Genitourinary Committee, cont.

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S0931	S1011	S1216	S1314	\$150	S1602	S1605	A031102	A03120	E2810	EA8141	EA8143	NRGGU002	R0924
Lahey Hosp & Med Ctr	2	_	3	_	_	_	_	_	_	_	_	_	_	_
Loma Linda Univ	_	_	11	6	_	_	_	_	3	_	_	_	_	_
Loyola University	32	15	6	2	_	_	_	_	2	1	_	_	_	_
MAVERIC	_	_	2	_	_	_	_	_	5	_	_	_	_	_
MD Anderson CC	_	49	4	2	_	1	_	_	_	_	1	_	_	_
MUSC MU-NCORP	1	_	12	1	1	_	_	_	_	_	_	_	_	2
Madigan Army Med Ctr	3	_	2	_	_	_	_	_	_	_	_	_	_	_
Michigan CRC NCORP	20	_	17	6	1	_	_	_	_	_	_	_	_	_
Michigan, U of	34	_	17	_	4	7	_	_	_	1	_	_	_	_
Mississippi, Univ of	3	_	1	_	_	_	_	_	_	_	_	_	_	_
Montana NCORP	10	_	3	2	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	11	_	45	10	2	_	1	_	_	_	_	_	_	_
New Mexico MU-NCORP	2	_	26	_	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	15	_	4	_	_	_	_	_	_	_	_	_	_	_
Northwestern Univ	_	_	3	_	_	5	_	_	_	_	_	_	_	_
Oklahoma, Univ of	6	_	16	5	1	5	1	_	_	_	_	_	_	_
Orange Reg Med Ctr	1	_	1	_	_	_	_	_	_	_	_	_	_	_
Oregon HIth Sci Univ	22	19	21	4	3	_	2	_	_	6	_	_	_	_
Ozarks NCORP	13	_	5	3	_	_	_	_	_	_	_	_	_	_
PCRC NCORP	32	_	7	_	2	8	_	_	_	_	_	_	_	_
Rochester, Univ of	14	1	7	5	_	_	_	_	6	_	_	_	_	18
San Antonio, U of TX	27	50	3	8	_	4	_	_	_	_	_	_	_	_
San Diego, U of CA	_	_	6	1	_	_	1	_	_	_	_	_	_	_
Scott & White CCOP	3	_	_	_	_	_	_	_	_	_	_	_	_	_
Scott & White Mem	2	_	_	_	_	_	_	_	_	_	_	_	_	_
So Calif, U of	9	153	34	11	_	_	_	2	11	1	_	_	_	_
Southeast COR NCORP	32	_	6	2	_	_	_	_	_	1	_	_	_	_
St Louis CCOP	4	_	_	_	_	_	_	_	_	_	_	_	_	_
St Louis University	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	23	_	5	_	_	_	_	_	1	_	_	_	_	1
Tennessee, U of	5	_	_	_	_	_	_	_	12	1	_	_	_	_
Upstate Carolina	1	_	1	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	25	_	106	5	1	11	2	_	_	12	_	1	_	_
VAMC Kansas City	_	_	2	_	_	_	_	_	1	_	_	_	_	30
Wayne State Univ	15	_	_	1	2	_	_	_	8	_	_	_	_	_
Wichita NCORP	23	_	12	1	1	_	_	_	_	_	_	_	_	_
Wisconsin NCORP	1	_	2	2	_	_	_	_	_	_	_	_	_	_
Yale University	6	_	7	1	_	_	1	_	_	_	_	_	_	_
Alliance	297	105	239	45	9	3	11	_	_	_	_	_	_	_
CCTG	_	38	_	_	5	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	396	87	240	20	10	_	5	_	_	_	_	_	_	_
NRG	78	_	40	18	7	7	4	_	_	_	_	_	_	_
Total	1,545	618	1,313	237	69	66	34	2	287	48	8	6	1	65



Leukemia Committee

Leadership

Chair:	Harry P. Erba, MD, PhD
Vice-Chair:	Steven E. Coutre, MD
Executive Officer:	Susan M. O'Brien, MD
Statisticians:	Megan Othus, PhD
	Anna Moseley, MS
Scientific Leadership	
Translational Medicine:	Jerald P. Radich, MD
Pathology:	TBD
Cytogenetics Liaison:	
	Min Fang, MD, PhD
Designates	
Data Coordinators:	Louise Highleyman
	Tracy Maher, CCRP
Oncology Research Professionals:	
CRA:	TBD
Nurses:	Keisha C. Humphries, RN, BSN
Patient Advocate:	Gail Sperling, MPH
Pharmaceutical Science:	Mai T. Nguyen, PharmD
	Holly O. Chan, PharmD
Protocol Coordinator:	Dion Holmes

Time/Location

Saturday, April 14, 2018 9:30 a.m. - 11:30 a.m. Room: Garden Room (Atrium Lobby Level)

Agenda

Introduction

Leukemia Committee Updates - Dr. Harry Erba

AML/MDS Studies

Active Studies

<u>\$1612</u>, "A Randomized Phase II/III Trials of "Novel Therapeutic Regimens" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia Age 60 or Older." Drs. L. Michaelis and R. Walter. Activated by SWOG 12/22/17.

Proposed Studies

None

Closed Studies

S0919, "A Phase II Study of Idarubicin and Ara-C in Combination with Pravastatin for Poor-Risk Acute Myelogenous Leukemia (AML)." Drs. A.S. Advani and L.C. Michaelis. Activated: 8/15/09. Closed: 9/15/17

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

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. A.S. Advani and K. O'Dwyer. Activated: 1/12/2015.

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. A.S. Advani and M. Liedtke. Activated: 4/1/14.

CTSU/E1910, "A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-Negative B Lineage Acute Lymphoblastic Leukemia in Adults." Dr. M. Liedtke. Activated by ECOG: 12/17/13. Activated by SWOG: 1/15/14.



Leukemia Committee

Proposed Studies

S1811, "A Phase I/II Study of Glasdegib in Combination with Inotuzumab Ozogamicin for Patients with Relapsed/Refractory CD22+ Acute Lymphoblastic Leukemia (ALL)." Drs. A.S. Advani and C. Yeung.

A041501, "A Phase III Trial to Evaluate the Efficacy of the Addition of Inotuzumab Ozogamicin (a Conjugated Anti-CD22 Monoclonal Antibody) to Frontline Therapy in Young Adults (Ages 16-39 years) with Newly Diagnosed Precursor B-Cell ALL." Dr. A.S. Advani.

CTSU/EXXXX, "A Phase II Randomized Trial of Steroids + TKI Induction with Chemotherapy or Blinatumomab and Allo-HCT for Newly Diagnosed BCR-ABL-Positive ALL in Adults." Drs. Kathleen Phelan, Yishai Ofran, and Katarzyna Jamieson.

CLL Studies

Closed Studies

CTSU/E1912, "A Randomized Phase III Study of Ibrutinib (PCI-32765)-Based Therapy vs. Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. S. O'Brien. Activated by ECOG: 1/31/14; Activated by SWOG: 2/15/14.

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. S.E. Coutre. Activated by Alliance: 12/9/13; Activated by SWOG: 12/15/13.

Proposed Studies

EA9161, "A Randomized Phase III Study of a Targeted Therapy Combination vs. Ibrutinib and Obinutuzumab in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)." Dr. T. Shanafelt.

<u>A041702</u>, "Ibrutinib vs. Ibrutinib/Obinotuzumab/Venetoclax in MRD-Negative Patients." Dr. J. Woyach.

CML Studies

Proposed Studies

S1712, "A Randomized Phase II Study of Ruxolitinib (NSC-752295) in Combination with BCR-ABL Tyrosine Kinase Inhibitors Chronic Myeloid Leukemia (CML) Patients with Molecular Evidence of Disease." Drs. K. Sweet and J. Radich. (Formerly S1615)



Leukemia Committee

Cumulative Accrual by Institution and Study
Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S0919	S1312	\$1318	E1910	E2906	NHLBIMDS
Arizona MC, U of	_	_	_	4	7	_
Arkansas, U of	_	_	1	3	_	_
Baylor College	5	4	_	_	_	_
Birmingham, U of AL	3	_	1	7	_	_
CRC West MI NCORP	_	_	_	_	4	_
Cincinnati MC, U of	_	_	_	_	3	_
City of Hope Med Ctr	_	14	4	_	_	_
Cleveland Clinic OH	23	10	4	4	_	3
Colorado, U of	6	_	_	_	_	_
Columbia MU-NCORP	_	_	_	_	3	_
Dayton NCORP	_	_	_	1	5	_
Greenville NCORP	_	_	1	1	_	_
Gulf South MU-NCORP	1	_	_	_	_	_
H Lee Moffitt CC	11	_	_	_	_	_
Heartland NCORP	_	_	1	_	_	_
Irvine, U of CA	_	_	_	3	_	_
Henry Ford Hospital	_	_	3	7	_	_
Kaiser Perm NCORP	_	_	_		_	2
Kansas, U of	_	_	_	9	_	_
Kentucky, U of	_	_	_	_	7	_
Loma Linda Univ	_	_	1	_	_	_
Loyola University	4	_	<u>,</u>	1	9	_
Michigan, U of	_	_	2	_	_	_
Mississippi, Univ of	1	_	_	_	1	_
New Mexico MU-NCORP	5	_	1	_	1	_
Northwest NCORP	_	_	_	7		
Northwestern Univ				1	_	_
Oregon HIth Sci Unv	6	_		_	_	2
PCRC NCORP	2		_	_	_	_
Rochester, Univ of	15	7	<u> </u>	4	27	_
San Diego, U of CA	15	,	1	3	21	_
So Calif, U of	_	_		3	_	_
Stanford University		2	3	<u> </u>	_	_
Tulane Univ MBCCOP	24	2	_	8	_	_
	1	_	_	_	_	_
Tulane University	2	_	_	_	_	_
Upstate Carolina	_	_	_	_	3	_
Wayne State Univ	_	_	_	1	_	_
Wichita NCORP	6	_	1	_	_	_
Yale University	_	_	1	13	5	_
Alliance	_	_	15	_	_	_
ECOG-ACRIN	_	_	6	_	_	_
Total	115	37	47	77	<i>75</i>	7



Leadership	Agenda						
Chair:	9:30 a.m.	Opening Remarks – Dr. Kelly					
Vice-Chair: Roy S. Herbst, MD, PhD		, ,					
Executive Officer: Julie R. Gralow, MD Statisticians: Mary Redman, PhD		General Update					
Statisticians:		Patient Advocate Judy Johnson					
	9:45 a.m.	Thoracic Surgery Session – Dr. Hofstetter					
		- ,					
James Moon, MS		Update on Current Trials					
Scientific Leadership		Review of Trials in Development					
Translational Medicine:	10:00 a.m.	Thoracic Radiation Session – Dr. Decker					
Biology/PathologyPhilip C. Mack, PhDFred R. Hirsch, MD, PhD		Update on Current Trials					
		opuate off current mais					
Imaging:		Review of Trials in Development					
Myrna Godoy, MD	10:15 a.m.	Translational Medicine Session – Biology/Pathology - Dr.					
Radiation Oncology:		Mack					
Surgery:Wayne L. Hofstetter, MD		Scientific Presentation: The Role of Tumor Mutational					
Subcommittee Chairs:		Burden as a Predictive Biomarker for Immunotherapy					
Early Stage Disease:		- David Gandara, MD Professor of Medicine, UC Davis					
	9:30 a.m. 9:30 a.m. 9:30 a.m. 9:30 a.m. 9:45 a.m. 10:00 a.m. 10:00 a.m. 10:15 a.m. 10:45 a.m.	Comprehensive Cancer Center					
Shirish Gadgeel, MD		Updates					
Metastatic Disease: Ross Camidge, MD	10.45	·					
	10:45 a.m.	Translational Medicine Session – Imaging – Dr. Wright					
Community Engagement:		Scientific Presentation: Current Utilization and					
Suzanne Cole, MD		Opportunities for Imaging in SWOG Lung Cancer Trials					
	PhD PhD PhD MS PhD MS PhD MS PhD MS MS MS 10:00 a.m. PhD MD	- Chadwick Wright, MD, PhD. Assistant Professor, Division					
Data Coordinators:Krystle PagariganLouise Highleyman		of Molecular Imaging and Nuclear Medicine, Department of Radiology, The Ohio State University Wexner Medical					
Larry Kaye		Center					
Oncology Research Professionals:		H. bro					
CRAs:Courtney L. Williamson		Updates					
Ginny M. Keeling, MS	11:15 a.m.	Community Engagement Core – Dr. Hesketh					
Nurses: Kimberly M. Belzer, MS, PAC		Updates					
	11.20	·					
Patient Advocate:	11:30 a.m.	Thoracic Oncology Session					
Linda Lee-Gabel, PharmD		Scientific Presentation: What's next for Patients with EGFR					
Protocol Coordinator:TBD		Mutated Tumors? - Trever G. Bivona, MD, PhD, Associate					
		Professor, Division of Hematology Oncology, University of California San Francisco					
Time/Location		Camornia San Fiancisco					
Saturday, April 14, 2018 9:30 a.m 12:30 p.m.							



Room: Bayview B (Bay Level)

Active Studies

- S1619, "A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma." Drs. A. Tsao, J. Cetnar, B. Sepesi, et al. Activated 11/3/17.
- **S1403**, "A Randomized Phase II/III Trial of Afatinib Plus Cetuximab versus Afatinib Alone in Treatment-Naïve Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC)." Drs. S. Goldberg, R. Lilenbaum, and K. Politi. Activated: 3/25/15.
- <u>S1400</u>, "A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer." Drs. V. Papadimitrakopoulou, F. Hirsch, R. Herbst, et al. Activated: 6/16/14.
- <u>S1400F</u>, "A Phase II Study of MEDI4736 and Tremelimumab as Therapy for Checkpoint Inhibitor Refractory Squamous Patients (Lung-MAP Substudy)." Drs. N. Leighl and N. Rizvi. Activated 10/2/17.
- **S1400G**, "A Phase II Study of Talazoparib (BMN 673) in Patients with Homologous Recombination Repair Deficiency Positive Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-study)." Drs. T. Owonikoko and L. Byers. Activated: 2/7/17.
- <u>S1400I</u>, "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. S. Gettinger and L. Bazhenova. Activated: 12/18/15.

- <u>S1400K</u>, "A Phase II Study of ABBV-399 (Process II) in Patients with c-MET Positive Stage IV or Recur-rent Squamous Cell Lung Cancer (Lung-MAP Sub-study)." Drs. S. Waqar and S. Arnold. Activated 2/5/18.
- <u>S1400GEN</u>, "Ancillary Study to Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in S1400." Drs. S. Ramsey and J. Roth. Activated 2/5/18.
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.
- <u>CTSU/A151216</u>, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHE-MIST)." Dr. Gandara. Activated: 8/18/14.
- CTSU/A081105, "Randomized Study of Erlotinib versus Observation in Patients with Completely Resect-ed Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)." Dr. Kelly. Activated: 8/18/14.
- CTSU/EA5142, "Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) A Randomized Phase III Study of Nivolumab after Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers." Ac-tivated: 5/6/16.
- CTSU/NRGCC003, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hippo-campal Avoidance For Small Cell Lung Cancer." Activated: 12/7/2015.
- CTSU/E4512, "A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein." Dr. T. Li. 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. S. Gadgeel and L. Gaspar. Activated: 3/15/08.

Closed Studies

S1507, "A Phase II Trial of Trametinib with Docetaxel in Patients with Kras Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies." Drs. Gadgeel, Riess and Mack. Activated: 7/17/16. Closed: 3/15/18.

NCI Approved Concepts

<u>S1701</u>, "A Phase II Trial of Carboplatin, Paclitaxel, and Ramucirumab in Patients with Locally Advanced, Metastatic, or Recurrent Thymic Epithelial Tumors (TET) not Amenable to Curative Intent Surgery." Dr. A. Tsao.

<u>\$1800A</u>, "A Phase II/III Randomized Study of Ramucirumab plus MK3475 (Pembrolizumab) versus Stand-ard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-Map Non-Matched Sub-Study)." Drs. K. Reckamp and K. Dragnev.

EA5163/S1709, "A Randomized Phase III Study for PD-L1 Positive Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) Patients Treated with Pembrolizumab in Induction or Maintenance Therapy with Immunosignature-Driven Analysis." Dr. A. Chiang.

A081702, "A Randomized Phase III Study of Pembrolizumab versus Investigator's Choice Chemotherapy in Patients with Previously-treated Malignant Pleural Mesothlioma." Dr. L. Garland.

Concepts in Development

<u>S1400L</u>, "A Phase II Study of Rucaparib in Patients with Genomic LOH-Positive Stage IV Non-Small Cell Lung Cancer (Lung-MAP Sub-study)." Drs. J. Riess and Wheatley-Price

<u>S1814</u>, "A Randomized Phase II Trial of SBRT with or without Atezolizumab in Medically Inoperable Stage I NSCLC." Drs. M. Daly, A. Monjazeb, and K. Kelly.

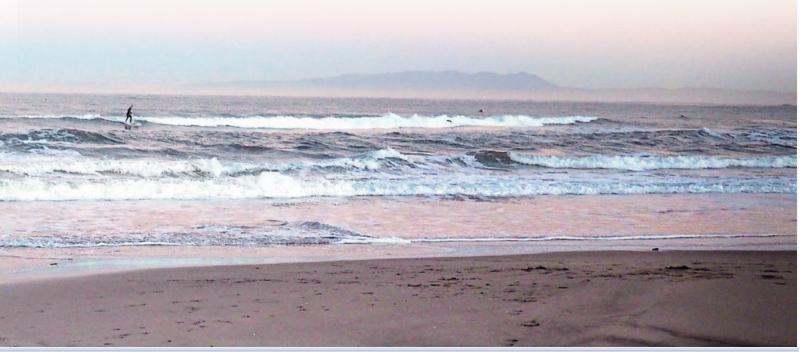
S1813, "Phase II Selection Design Study of Pembrolizumab with Hypo vs. Conventional Fractionated Thoracic Radiotherapy in Patients with Stage II or III NSCLC with Borderline Performance Status." Dr. R. Aljumaily.

<u>\$1810</u>, "Randomized Phase II Trial to Test the Efficacy of Nintedanib (BIBF1120) in Combination with Cisplatin and Etoposide for Subjects with Previously Untreated Extensive Stage Small Cell Lung Cancer." Drs. J. Heymach and Y. Chae.

PCI vs. Active MRI Surveillance in Small-Cell Lung Cancer. Dr. C. Rusthoven.

Neoadjuvant immunotherapy Phase II study platform. Dr. T. Cascone.

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





Cumulative Accrual by Institution and StudyIncludes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1206	S1300	S1400	S1400B	S1400C	S1400D	S1400F	S1400G	S1400I	S1403	S1507	A081105	A151216	C140503	C30610	C30901	E4512	EA5142	NRGCC003	R130
Arizona MC, U of	3	_	1	_	_	_	_	_	_	_	_	_	1	_	_	_	_	_	_	_
Arkansas, U of	_	_	3	_	_	1	_	_	_	_	_	_	_	1	2	_	_	_	_	_
Baptist MU-NCORP	_	_	11	_	1	_	_	_	5	2	1	_	16	_	2	_	_	_	_	_
Baylor College	_	_	1	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Beaumont NCORP	_	_	2	_	1	_	_	_	_	_	_	_	2	_	_	_	_	_	_	_
Boston Medical Ctr	_	_	4	_	_	_	_	_	2	_	_	_	2	_	_	_	_	_	_	_
Brooke Army Med Ctr	_	_	6	_	_	_	_	_	2	_	_	_	7	_	_	_	_	_	_	_
CORA NCORP	_	_	9	1	1	_	_	_	3	_	_	_	2	_	_	_	_	_	_	_
CRC West MI NCORP	_	_	9	_	_	_	_	_	1	2	_	_	1	_	_	_	_	_	_	_
Carle CC NCORP	1	_	4	_	_	1	_	_	3	_	_	_	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	_	5	_	_	_	_	_	2	_	_	1	10	_	3	_	1	1	_	_
City of Hope Med Ctr	2	_	14	_	1	_	_	_	2	_	_	1	4	_	_	_	_	<u> </u>	_	
Cleveland Clinic OH	_	_	10	_		_	_	_	_	_	1	3	20	_	_	1	_	4	_	
Colorado, U of	_	1	2		1		_	_	1		_	2	16	12	_		1	_	_	1
Columbia MU-NCORP	_		2		_				_			_	_	12			_			
Columbia MO-NCORP			12	2	1				1	3	2				1					
			12	_	_	2		1	2		_				_					
Cookeville Reg MC	10			_	2	2	_			4	2	1	 25	6	— 13	_	1	2		
Davis, U of CA	10		18			_		2	3		_	1		O	13		1	2		
Dayton NCORP	1		5 7		2	_	_		1	1			2	_	_		_	2	_	_
Essentia HIth NCORP	_	_		_		_	_	1	2	_	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	_	_	18	1	1	_	_	1	4	_		1	8	_	_	_	_	_	_	_
Georgia NCORP	_	_	10	_	_	_	1	_	4	_	1	_	_	_	1	_	_	_	_	_
Greenville NCORP	_	_	14	1	_	1	_	1	6	2	_	_	_	_	_	_	_	_	_	_
Gulf South MU-NCORP	_	_	6	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_
H Lee Moffitt CC	_	_	10	_	_	_	_	_	_	_	_	2	43	_	_	_	_	2	_	_
Harrington CC	_	_	7	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	4	_	6	_	_	_	_	_	1	5	_	_	_	_	_	_	_	_	_	_
Heartland NCORP	7	_	46	_	2	1	2	_	8	1	6	_	_	_	7	_	_	_	_	_
Henry Ford Hospital	2	_	7	1	_	_	_	_	_	_	_	1	16	_	_	_	_	3	_	_
Irvine, U of CA	_	_	8	_	_	_	_	_	2	_	1	2	6	_	_	_	_	1	_	_
Kaiser Perm NCORP	_	_	42	_	4	1	_	_	5	26	_	11	112	_	3	_	1	3	_	_
Kansas City NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	1	_	36	_	_	_	_	_	12	1	_	_	22	_	1	_	_	5	_	_
Kentucky, U of	_	_	8	_	_	1	_	_	4	_	_	_	_	_	_	_	_	_	_	_
Lahey Hosp & Med Ctr	1	_	9	_	1	_	_	1	1	3	1	_	13	_	_	_	_	2	_	2
Loma Linda Univ	_	_	6	_	_	_	_	1	1	_	1	1	1	_	_	_	_	_	_	_
Loyola University	4	_	9	_	1	_	_	_	3	_	_	_	6	_	_	_	_	2	_	_
MAVERIC	_	_	15	1	2	_	1	_	7	_	_	_	1	_	_	_	_	_	_	_
MD Anderson CC	3	_	20	_	_	1	_	_	1	_	_	_	_	_	_	_	_	_	_	5
MUSC MU-NCORP	_	_	1	_	_	_	_	_	_	_	2	_	_	_	1	_	_	_	_	_
Methodist Hospital	_	_	5	_	_	_	_	_	_	_	_	1	4	_	_	_	_	_	_	_
Michigan CRC NCORP	_	_	30	2	_	1	_	3	3	7	3	_	_	_	_	_	_	_	_	_
Michigan, U of	_	_	12	1	2	_	_	_	3	3	1	_	37	_	1	_	_	_	_	_
Mississippi, Univ of	_	_	6	1	_	_	_	_	3	_	_	_	6		1	_	_	_	_	_
Montana NCORP	_	_	15	1	2	_	_	_	2	2	1	_	_	_	_	_	_	_	_	_
Mt Sinai Med Ctr	_		1		_	_	_	_	_	_	_	_	_		_	_	_	_	_	
Nevada CRF NCORP	_	_	4	_	_	_	_	_	3		_		_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_		6	_	_		_		_	1					_					
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Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1206	S1300	S1400	S1400B	S1400C	S1400D	S1400F	S1400G	S1400I	S1403	S1507	A081105	A151216	C140503	C30610	C30901	E4512	EA5142	NRGCC003	R1306
Northwestern Univ	_	_	1	_	_	_	_	_	_	_	3	_	_	_	_	_	_	_	_	_
Oklahoma, Univ of	_	_	8	_	_	1	_	1	2	4	_	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	1	_	_	_	_
Oregon Hlth Sci Univ	_	_	10	_	_	_	_	2	6	_	_	_	2	_	_	_	_	1	_	_
Ozarks NCORP	_	_	16	_	1	1	_	_	2	3	1	1	1	_	_	_	_	_	_	_
PCRC NCORP	_	_	15	1	_	_	_	_	_	_	_	_	4	6	_	_	_	_	_	_
Providence Hosp	_	_	11	_	_	_	_	_	_	_	_	_	9	_	2	_	1	1	_	_
Rochester, Univ of	_	_	17	_	1	_	_	1	1	2	1	_	_	_	_	_	_	_	4	_
San Antonio, U of TX	_	_	12	1	1	3	_	_	2	5	_	_	_	_	3	_	_	_	_	_
San Diego, U of CA	_	_	10	_	_	_	_	_	1	7	_	1	3	_	_	_	_	_	_	_
So Calif, U of	_	_	_	_	_	_	_	_	_	_	_	1	5	_	_	_	_	_	_	_
Southeast COR NCORP	1	_	49	1	_	1	1	1	11	2	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	_	_	4	_	_	_	_	_	1	_	_	1	4	_	_	_	_	2	_	_
Tennessee, U of	_	_	_	_	_	_	_	_	_	_	_	_	_	2	_	_	_	_	_	_
Tulane Univ MBCCOP	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Univ of Louisville	_	_	_	_	_	_	_	_	_	_	_	_	5	_	_	_	_	_	_	_
Upstate Carolina	_	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	_	_	1	_	1	_	_	_	_	_	3	_	_	_	_	_	_	_	_	_
VAMC Kansas City	_	_	4	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Wayne State Univ	_	_	10	_	_	_	_	1	_	1	1	_	1	_	1	_	_	_	_	_
Wichita NCORP	_	_	19	_	_	_	_	1	3	7	_	_	_	_	13	_	_	_	_	_
Wisconsin NCORP	_	_	5	_	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_
Yale University	12	_	26	_	1	1	_	_	4	22	_	2	21	_	_	_	2	5	_	_
Alliance	_	_	324	12	12	10	2	10	38	23	9	_	_	_	_	_	_	_	_	_
CCTG	_	_	14	_	_	_	_	_	3	_	_	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	_	_	285	6	5	10	_	6	58	9	9	_	_	_	_	_	_	_	_	_
NRG	1	_	159	6	5	6	2	2	22	13	5	_	_	_	_	_	_	_	_	_
Total	53	1	1,505	39	53	43	9	37	259	162	55	33	438	27	55	2	7	36	4	8

Helping SWOG Do More

SWOG formally invited patient advocates into its research activities in 1993, the same year The Hope Foundation was established.

Since that time, Hope has continually funded travel and professional development to further advocates' important work.

Text "SWOG" to 41444 to give today.

25 Years of Supporting SWOG



THE HOPE FOUNDATION



Lymphoma Committee

Leadership

Chair: Jonathan W. Friedberg, MD Vice-Chair:Sonali M. Smith, MD Statisticians:Michael LeBlanc, PhD Hongli Li, MS **Scientific Leadership** Translational Medicine: Lisa M. Rimsza, MD Radiation Oncology: Louis S. Constine, MD Imaging:.....Oliver W. Press, MD, PhDLawrence H. Schwartz, MD Pathology: Lisa M. Rimsza, MD Early Therapeutics:...... Daruka Mahadevan, MD, PhD **Designates** Cancer Control: TBD Data Coordinators: Jeri Jardine Iris Syquia Oncology Research Professionals: CRA: Erin M. Cebula, MPH Nurse: TBD Pharmaceutical Science: Lara M. Au, PharmDHolly Chan, PharmD

Time/Location

Saturday, April 14, 2018 9:30 a.m. - 12:30 p.m.

Room: Grand C (Street Level)

Agenda

- 1. Open Studies:
 - a. 51301: Dr. Stiff
 - b. S1608: Dr. Barr
 - c. EA4151: Dr. Till
- 2. Studies in Development
 - a. S1818: Dr. Brem
 - b. DLBCL: Dr. S. Smith
 - c. MCL: Dr. S. Spurgeon
- 3. Focus on Hodgkin lymphoma
 - a. Treatment landscape for advanced stages: Dr. Friedberg
 - b. SWOG-led North American Intergroup concept: Dr. Herrera
- 4. Mantle cell lymphoma: Update of S1106: Dr. Kamdar
- 5. Other Business





Active Studies

\$1608, "Randomized Phase II Trial in High-Risk Relapsed Refractory

Follicular Lymphoma." Dr. Barr. Ac-tivated: 8/10/17

CTSU/A051301, "A Randomized Double-Blind Phase III Study of Ibrutinib During and Following Autologous Stem Cell Transplantation Versus Placebo in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma of the Activated B-Cell Subtype." Dr. Stiff. Activated: 7/6/16.

CTSU/EA4151, "A Randomized Phase III Trial of Consolidation with Autologous Hematopoietic Cell Transplantation Followed by Maintenance Rituximab vs. Maintenance Rituximab Alone for Patients with Mantle Cell Lymphoma in Minimal Residual Disease-Negative First Complete Remission. Drs. Fenske, Till, Blum, Crump, Scott, and Kostakoglu. Activated: 8/29/17

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Drs. Chen, Flaherty, Conley, et al. Activated: 8/12/15.

Closed Studies

SO801, "A Phase II Study of Iodine-131 Labeled Tositumomab in Combination With Cyclophosphamide, Doxorubicin, Vincristine, Prednisone and Rituximab Therapy for Patients with Advanced Stage Follicular Non-Hodgkin's Lymphoma." Drs. Paul M. Barr, J.W. Friedberg, O.W. Press, and L.M. Rimsza. Activated: 4/1/09. Closed 12/15/10.

<u>S0816</u>, "A Phase II Trial of Response-Adapted Therapy of Stage III-IV Hodgkin Lymphoma using Interim FDG-PET Imaging." Dr. Ha. Activated: 701/09. Closed: 1201/12.

CTSU/CALGB 51101, "A Randomized Phase II Trial of Myeloablative versus Non-Myeloablative Consoli-dation Chemotherapy for Newly Diagnosed Primary CNS B-Cell Lymphoma." Dr. Mohile. Activated: 6/15/12. Closed 5/2/17.

Lymphoma Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018.

Includes studies that are currently open, or that closed since 7/1/16.

	\$1608	A051301	C51101	E141	E1412	_9177
Arizona MC, U of	_	_	_	1	1	_
Arkansas, U of	_	_	_	1	_	_
Baylor College	_	1	_	_	_	_
Brooke Army Med Ctr	_	_	_	_	2	_
CRC West MI NCORP	1	_	_	3	_	_
Cincinnati MC, U of	_	_	_	_	3	_
City of Hope Med Ctr	_	1	_	_	_	_
Cleveland Clinic OH	_	_	_	9	_	4
Colorado, U of	_	1	_	4	_	_
Columbia MU-NCORP	_	_	_	1	3	_
Davis, U of CA	_	_	1	_	_	_
Dayton NCORP	_	_	_	2	_	_
Fred Hutchinson CRC	_	_	2	4	_	_
Hawaii MU-NCORP	_	_	_	4	1	_
Kaiser Perm NCORP	_	_	_	14	7	_
Kansas City NCORP	_	_	_	3	1	1
Kansas, U of	_	_	2	_	_	_
Kentucky, U of	_	_	_	_	_	4
King Faisal Spec Hos	_	1	_	_	_	_
Montana NCORP	_	_	_	3	4	_
Oregon Hlth Sci Univ	_	_	_	6	_	_
PCRC NCORP	_	_	_	3	_	_
Rochester, Univ of	_	2	3	25	16	9
Southeast COR NCORP	_	_	_	1	_	_
Tennessee, U of	_	_	_	_	_	1
Tulane University	_	_	1	_	_	_
Upstate Carolina	_	_	_	1	_	_
Wayne State Univ	_	_	_	1	1	_
Alliance	1	_	_	_	_	_
Total	2	6	9	86	39	19





Melanoma Committee

Leadership



Rare cancers

In 2017, we activated S1609, known as DART, the first federally-funded immunotherapy trial for rare cancers. The trial is open at more than 750 sites and already is more than halfway to its enrollment goal.









Vice-Chair:Kenneth F. Grossmann, MD, PhD Statisticians: Michael Wu, PhD Megan Othus, PhD James Moon, MS Hongli Li, MSMichaella Latkovic-Taber, MPH Scientific Leadership Translational Medicine:William E. Carson, III, MD Radiation Oncology: Evan J. Wuthrick, MD Surgery: Robert H.I. Andtbacka, MD Imaging:.....Kenneth F. Grossmann, MD, PhD Martin Allen-Auerbach, MD Medical Oncology:Lawrence E. Flaherty, MD Pathology: TBD Non-Melanoma Skin Cancer:Nikhil Kushalani, MD Early Therapeutics:Jeffrey A. Sosman, MD SWOG's ECOG Liaisons: Sapna Pradyuman Patel, MD Kevin B. Kim, MDAndrew Poklepovic, MD Digital Engagement:......Zeynep Eroglu, MD **Designates** Cancer Control Liaison: Sancy Leachman, MD, PhD Data Coordinator:.....Joanna DurKrystle Pagarigan Oncology Research Professionals: CRA: Kacie L. Simpson, B.S., CCRP Nurse:Lisa S. Morgan, RN, OCN Pharmaceutical Science:Sun "Coco" Yang, PharmD, PhDMai T. Nguyen, PharmD

Time/Location

Saturday, April 14, 2018 9:30 a.m. - 11:30 a.m.

Room: Seacliff A-C (Bay Level)

Agenda

Welcome: Antoni Ribas MD/PhD 5 min

Introduction to digital engagement position (10 min, 9:35-9:45): Zeynep Eroglu MD



Melanoma Committee

- **Active Studies** (1 hr, 9:45-10:45, each talk capped to 10 min, presenters encouraged to be closer to 5 min)
- <u>\$1320,</u> "A Randomized Phase II Trial of Intermittent Versus Continuous Dosing of Dabrafenib (NSC-763760) and Trametinib (NSC-763093) in BRAFV600E/K Mutant Melanoma." Dr. Algazi. Activated: 7/22/14.
- <u>S1512</u>, "A Phase II Study of PD-1 Blockade with Pembrolizumab in Patients with Locally Advanced and Meta-static Desmoplastic Melanoma (DM)." Drs. K. Kendra and S. Hu-Lieskovan. Activated: 10/20/16.
- <u>S1616</u>, "A Phase II Randomized Study of Nivolumab (NSC-748726) with Ipilimumab (NSC-732442) OR Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD-1 or Anti-PD-IL1 Agent." Drs. A. VanderWalde and T. Ribas. Activated 7/17/17.
- <u>S1607</u>, "A Phase II Study of Combining T-VEC (NSC-785349) and Pembrolizumab (NSC-776864) in Pa-tients with Advanced Melanoma who have Progressed on Anti-PD1/L1 Based Therapy." Dr. Hu-Lieskovan.
- CTSU/EA6134, "A Randomized Phase III Trial of Dabrafenib + Trametinib Followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients with Advanced BRAFV600 Mutant Melanoma". Dr. Chmielowski. Activated: 7/13/15.
- CTSU/EA6141, "Randomized Phase II/III Study of Nivolumab Plus Ipilimumab Plus Sargramostim versus Nivolumab Plus Ipilimumab in Patients with Unresectable Stage III or Stage IV Melanoma." Dr. Kim. Activated: 9/10/15. Temporarily closed: 6/23/17.

Upcoming Studies

<u>\$1801</u> A Phase II Randomized Study of Adjuvant Versus Neo-Adjuvant MK-3475 for Clinically Detecta-ble Stage III-IV High Risk Melanoma

Follow Up on Recently Closed Studies (10 min 11:10-11:20)

- S1404, "A Phase III Randomized Trial Comparing Physician/Patient Choice of either High-Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High-Risk Resected Melanoma." Drs. Grossmann and Patel. Activated 10/15/15. Closed: 8/15/17.
- **S1221**, "Phase I/II Study of the Safety and Efficacy of the AKT Inhibitor GSK2141795 in Combination with Dabrafenib and Trametinib in Patients with BRAF Mutant Cancer." Drs. A. Algazi and T. Ribas. Activated: 7/1/13. Closed: 10/31/16.
- **ECOG/SWOG liason report** (10 min 11:20-11:30): David Lawson/Andrew Poklepovich

guidebook

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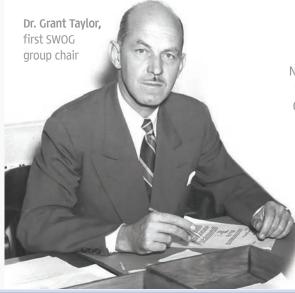


Melanoma Committee

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1221	S1320	S1404	S1512	S1616	E3612	EA6134	EA6141
Arizona MC, U of	_	2	11	_	_	_	_	_
Arkansas, U of	_	7	12	_	_	_	1	_
Baylor Univ Med Ctr	_	_	12	_	_	_	_	_
Boston Medical Ctr	_	1	_	_	_	_	_	_
CORA NCORP	_	1	9	_	_	_	_	_
CRC West MI NCORP	_	2	13	_	_	_	_	_
Cedars-Sinai Med Ctr	_	_	8	_	_	_	_	_
Cincinnati MC, U of	_	_	3	_	_	_	_	_
City of Hope Med Ctr	_	_	8	_	_	_	1	3
Cleveland Clinic OH	_	_	25	_	_	_	2	_
Colorado, U of	5	2	29	_	_	_	1	_
Columbia MU-NCORP	_	_	3	_	_	_	_	_
Columbus NCORP	_	3	4	_	_	_	_	_
Davis, U of CA	_	_	3	_	_	_	_	_
Dayton NCORP	_	1	7	_	_	_	_	_
Essentia Hlth NCORP	_	_	1	_	_	_	_	_
Georgia NCORP	_	_	20	1	_	_	_	_
Greenville NCORP	_	_	_	_	_	1	_	_
Gulf South MU-NCORP	_	_	4	_	_	_	_	_
H Lee Moffitt CC	_	_	52	_	_	_	_	_
Hawaii MU-NCORP	_	1	3	_	_	_	_	_
Heartland NCORP	_	5	27	_	_	_	_	_
Irvine, U of CA	_	_	1	_	_	_	_	_
Kaiser Perm NCORP	_	28	74	_	_	4	5	20
Kansas City NCORP	_	_	1	_	_	_	_	1
Kansas, U of	_	14	25	_	_	_	2	_
Lahey Hosp & Med Ctr	_	1	4	_	_	_	_	_
Los Angeles, U of CA	6	4	23	1	_	_	4	_
Loyola University	_	6	1	_	_	_	_	_
MD Anderson CC	_	_	43	_	_	_	_	_
Michigan CRC NCORP	_	_	8	_	_	_	_	_



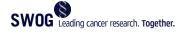
Our History

Founded in 1956 by the National Cancer Institute, we are part of the NCI's National Clinical Trials Network, the largest and oldest publicly funded cancer research network in the United States. We are also part of NCI's Community Oncology Research Program, which connects us to community hospitals and clinics across the nation — and the diverse populations they serve.





Our members include more than 12,000 research professionals working in 47 states and six other countries, and our biorepository holds more than 800,000 specimens accessible to fellow researchers around the world.



Melanoma Committee, cont.

Cumulative Accrual by Institution and Study

Includes accruals through 2/6/2018. Includes studies that are currently open, or that closed since 7/1/16.

	S1221	S1320	S1404	S1512	S1616	E3612	EA6134	EA6141
Michigan, U of	5	4	12	_	_	_	_	_
Mississippi, Univ of	_	_	1	_	_	_	_	_
Montana NCORP	_	_	4	_	_	_	_	_
Mt Sinai Med Ctr	_	_	10	_	_	_	_	_
Nevada CRF NCORP	_	3	_	_	_	_	_	_
New Mexico MU-NCORP	_	_	9	_	_	_	_	_
Northwest NCORP	_	_	11	_	_	_	_	_
Northwestern Univ	_	_	16	_	1	1	_	_
Ohio State Univ	6	14	33	2	_	_	2	_
Oregon Hlth Sci Univ	_	_	12	_	_	_	_	_
Ozarks NCORP	_	2	4	_	_	_	_	_
PCRC NCORP	2	2	17	_	_	_	_	_
Rochester, Univ of	_	3	6	_	_	_	2	_
San Antonio, U of TX	_	_	7	_	_	_	_	1
San Diego, U of CA	_	_	6	_	_	_	_	_
San Francisco, U-CA	1	8	_	_	_	_	_	_
So Calif, U of	_	_	_	1	_	_	_	_
Southeast COR NCORP	_	6	10	_	_	_	_	_
Sutter Cancer RC	2	_	5	_	_	_	2	5
Tennessee, U of	_	_	6	_	2	_	_	_
Utah, U of	_	7	31	_	_	_	_	_
VAMC Kansas City	_	_	1	_	_	_	_	_
Wayne State Univ	_	_	9	_	_	_	2	_
Wichita NCORP	_	4	13	_	_	_	_	_
Wisconsin NCORP	_	_	8	_	_	_	_	_
Yale University	_	_	6	_	_	_	_	6
Alliance	_	12	144	_	1	_	_	_
CCTG	_	_	122	_	_	_	_	_
ECOG-ACRIN	_	39	302	_	_	_	_	_
NRG	_	13	106	_	2	_	_	_
Total	27	195	1,345	5	6	6	24	36



Expert partners support SWOG in offices across the country. We're proud of our partners and staff in Oregon, Washington, Michigan and Texas. Together, we support more than 12,000 individuals and over 1,000 institutions. Our members reflect the full spectrum of professionals who design and conduct cancer trials — physicians, nurse oncologists, clinical research associates, statisticians, scientists, patient advocates, pharmacists, and more.

The publications listed below were received by the Group Chair's Office as published, accepted, submitted or reflect change in status since the SWOG Fall 2017 SWOG Group Meeting. Conference abstracts are not included.

ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

Published/Accepted Manuscripts

E2496/COG* Outcomes in adolescents and young adults (AYA) with hodgkin lymphoma (HL) treated on US cooperative group protocols: an adult intergroup (E2496) and Children's Oncology Group (COG AHOD 0031) comparative analysis. TO Henderson, SK Parsons, K Wroblewski, L Chen, F Hong, S Smith, J McNeer, R Advani, R Gascoyne, LS Constine, S Horning, NL Bartlett, B Shah, J Connors, J Leonard, BS Kahl, K Kelly, CL Schwartz, H Li, JW Friedberg, DL Friedman, LI Gordon, AM Evens.
Cancer Jan 1;124(1):136-144, 2018. [*COG AHOD 0031; see also Lymph Cmte https://www.ncbi.nlm.nih.gov/pubmed/29370458

Ten thousand attentive hours, rapid learning, dissemination of knowledge and the future of experience-based care in germ-cell tumors [Editorial]. CR Nichols, T Tandstad, W Lowrance, S Daneshmand. <u>Annals of Oncology</u>, accepted.

Submitted Manuscripts

No publication information for this cycle.

BARLOGIE-SALMON MYELOMA COMMITTEE

No publicaiton information for this cycle.

BREAST COMMITTEE

Published/Accepted Manuscripts

Supplement use and chemotherapy-induced peripheral neuropathy in patients treated in a SWOG cooperative group trial (S0221): the DELCaP Study. G Zirpoli, S McCann, L Sucheston-Campbell, D Hershman, G Ciupak, W Davis, J Unger, H Moore, JA Stewart, C Isaacs, T Hobday, M Salim, R Livingston, G Hortobagyi, J Gralow, D Hayes, G Budd, K Albain, C Ambrosone. <u>Journal of the National Cancer Institute</u>, in press. [see also SCQOLCmte]

<u>S0221</u> Genome-wide meta-analyses identifies novel taxane-induced peripheral neuropathy-associated loci. L Sucheston-Campbell, A Clay, W Barlow, GT Budd, D Stram, C Haiman, X Sheng, L Yan, G Zirpoli, S Yao, C Jiang, K Owzar, D Hershman, K Albain, D Hayes, H Moore, J Hobday, JA Stewart, C Isaacs, M Salim, J Gralow, G Hortobagyi, R Livingston, D Kroetz, C Ambrosone. Pharmacogenetics and Genomics Feb;28(2):49-55, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29278617

SO800 Tumor infiltrating lymphocytes and PD-L1 expression in pre- and post-treatment breast cancers in the SWOG S0800 Phase II neoadjuvant chemotherapy trial. V Pelekanou, WE Barlow, ZA Nahleh, B Wasserman, Y-C Lo, M-K von Wahlde, D Hayes, GN Hortobagyi, J Gralow, D Tripathy, P Porter, RB Livingston, B Szekely, C Hatzis, DL Rimm, L Pusztai. Molecular Cancer Therapeutics, in press.

S9313 Impact of homologous recombination deficiency biomarkers on outcomes in patients with triple-negative breast cancer treated with doxorubicin-based adjuvant chemotherapy (SWOG S9313). P Sharma, WE Barlow, AK Godwin, H Pathak, K Isakova, KM Timms, AR Hartman, RJ Wenstrup, HM Linden, D Tripathy, GN Hortobagyi, DF Hayes. Annals of Oncology, Dec 23 [Epub ahead of print], 2017. https://www.ncbi.nlm.nih.gov/pubmed/?term=sharma+p+s9313

Submitted Manuscripts

S0221 Associations between self-reported diet during treatment and chemotherapy-induced peripheral neuropathy in a cooperative group trial (S0221). J Mongiovi, G Zirpoli, R Cannioto, L Sucheston-Campbell, D Hershman, JM Unger, HCF Moore, JA Stewart, C Isaacs, TJ Hobday, M Salim, G Hortobagyi, JR Gralow, GT Budd, KS Albain, C Ambrosone, SE McCann. Breast Cancer Research, submitted. (see also SXCQOL Cmte)

SO230 Final analysis of the prevention of early menopause study (POEMS)/ SWOG Intergroup S0230. H Moore, J Unger, K-A Phillips, F Boyle, E Hitre, A Moseley, D Porter, P. Francis, L Goldstein, H Gomez, C Vallejos, A Partridge, S Dakhil, A Garcia, J Gralow, J Lombard, J Forbes, S Martino, W Barlow, C Fabian, L Minasian, F Meyskens, R Gelber, G Hortobagyi, KS Albain. Journal of the National Cancer Institute. [see also Ca Surv Cmte]

CANCER CARE DELIVERY COMMITTEE

Published/Accepted Manuscripts

S9217 Using Medicare claims to examine long-term prostate cancer risk of finasteride on the Prostate Cancer Prevention Trial. JM Unger, DL Hershman, C Till, CM Tangen, WE Barlow, SD Ramsey, PJ Goodman, IM Thompson. <u>Journal of the National Cancer Institute</u>, accepted. [see also Prev & Epid Cmte]

<u>Multiple Studies*</u> Survival by Hispanic ethnicity among SWOG cancer clinical trials patients. M Chavez-MacGregor, JM Unger, A Moseley, S Ramsey, DL Hershman [*studies: S8516, S8600, S8809, S8814, S8894, S8897, S8905, S9008, S9031, S9125, S9210, S9240, S9304, S9308, S9313,



S9321, S9333, S9346, S9349, S9415, S9420, S9509, S9623, S9704, S9800, S9911, S9916, S0003, S0012, S0016, S0033, S0106, S0221, S0226, S0232, S0307, S0421, S0500] . Cancer Jan 25 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29370458

Multiple Studies* History of diabetes and outcome among participants 65 or older in SWOG clinical trials. DL Hershman, C Till, JD Wright, S Ramsey, W Barlow, J Unger. [*studies: S0003, S0023, S0033, S0124, S0205, S0221, S0226, S0232, S0307, S0421, S0500, S0777, S9321, S9346, S9916]. JCO Clinical Cancer Informatics, accepted.

<u>Multiple Studies*</u> Association between cardiovascular risk factors, cardiac events and survival outcomes among breast cancer patients enrolled in SWOG clinical trials. D Hershman, C Till, S Shen, J Wright, S Ramsey, W Barlow, J Unger. [*S0012, S0221, S0226, S0307, S0500]. <u>Journal of Clinical Oncology</u>, accepted.

Responding to patient requests for hastened death: physician aid in dying and the clinical oncologist. RA Spence, CD Blanke, TJ Keating, LP Taylor. <u>Journal of Oncology Practice</u>, Oct;13(10):693-699, 2017. https://www.ncbi.nlm.nih.gov/pubmed/28915075

Submitted Manuscripts

S0000/S9217 The scientific impact and value of large, NCI-sponsored randomized phase III cancer prevention trials. JM Unger, WE Barlow, CM Tangen, SD Ramsey, IM Thompson, Jr., EA Klein, M LeBlanc, CD Blanke, PJ Goodman, LM Minasian, DL Hershman. Cancer Epidemiology, submitted.

<u>Multiple Studies</u> A new framework for patient engagement in cancer clinical trials cooperative group studies. P Deverka, R Bangs, K Kreizenbeck, D Delaney, D Hershman, CD Blanke, S Ramsey. <u>Journal of the National Cancer Institute</u>, revised and resubmitted.

<u>Multiple Studies</u> Integrating value of research into NCI clinical trials cooperative group research review and prioritization: a pilot study.

JJ Carlson, DD Kim, GF Guzauskas, CS Bennette, D Veenstra, A Basu, MS, N Hendrix, DL Hershman, L Baker, SD Ramsey. <u>Cancer Medicine</u>, under review.

CANCER SURVIVORSHIP COMMITTEE

Published/Accepted Manuscripts

50424 Smoking, sex and non-small cell lung cancer: examination of steroid hormone receptors in lung tumor tissue in SWOG S0424. T-Y D Cheng, AK Darke, MW Redman, GR Zirpoli, W Davis, R Payne Ondracek, W Bshara, A Omilian, R Kratzke, ME Reid, JR Molina, JM Kolesar, Y Chen, RM MacRae, J Moon, P Mack, DR Gandara, K Kelly, RM Santella, KS Albain, CB Ambrosone. <u>Journal of the National Cancer Institute</u>, Jan 13 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29346580 [see also Lung Cmte]

A011401 Randomized phase III trial evaluating the role of weight loss in adjuvant treatment of overweight and obese women with early breast cancer (A011401): study design and rationale. JA Ligibel, WT Barry, C Alfano, DL Hershman, M Irwin, ML Neuhouser, CA Thomson, LM Delahanty, E Frank, P Spears, ED Paskett, JO Hopkins, V Bernstein, V Stearns, J White, C Hudis, EP Winer, TA Wadden, PJ Goodwin. NPJ Breast Cancer Sep 21;3:37, 2017. https://www.ncbi.nlm.nih.gov/pubmed/28948213

C89803 Marine ω-3 polyunsaturated fatty acid and fish intake after colon cancer diagnosis and survival: CALGB 89803 (Alliance). E Van Blarigan, C Fuchs, D Niedzwiecki, X Ye, S Zhang, M Song, L Saltz, R Mayer, R Mowat, R Whittom, A Hantel, A Benson, D Atienza, M Messino, H Kindler, A Venook, S Ogino, E Giovannucci, J Meyerhardt. Cancer Epidemiology, Biomarkers & Prevention, Jan 22 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29358223 [see also GI Cmte]

C89803 Adherence to the American Cancer Society Nutrition and Physical Activity Guidelines for Cancer Survivors after colon cancer diagnosis and survival: CALGB 89803 (Alliance). Van Blarigan E, Fuchs C, Niedzwiecki D, Ye X, Zhang S, Saltz L, Mayer R, Mowat R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Ogino S, Giovannucci E, Ng K, Meyerhardt J. JAMA Oncology, accepted. [see also GI Cmte]

C89803 Nut consumption and survival in patients with stage III colon cancer: results from CALGB 89803 (Alliance). T Fadelu, S Zhang, D Niedzwiecki, X Ye, LB Saltz, RJ Mayer, RB Mowat, R Whittom, A Hantel, A Benson, D Atienza, M Messino, HL Kindler, A Venook, S Ogino, K Ng, K Wu, W Willett, E Giovannucci, J Meyerhardt , Y Bao, C Fuchs. Journal of Clinical Oncology Feb 28 [Epub ahead of print], 2018. [see also GI Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29489429

Submitted Manuscripts

<u>S0230</u> Final analysis of the prevention of early menopause study (POEMS)/
 SWOG Intergroup S0230. H Moore, J Unger, K-A Phillips, F Boyle,
 E Hitre, A Moseley, D Porter, P. Francis, L Goldstein, H Gomez, C Vallejos,
 A Partridge, S Dakhil, A Garcia, J Gralow, J Lombard, J Forbes, S Martino,
 W Barlow, C Fabian, L Minasian, F Meyskens, R Gelber, G Hortobagyi,
 KS Albain. <u>Journal of the National Cancer Institute</u>, submitted 2/23/18.
 [see also Breast Cmte]



- S1008 Phase II feasibility study of a physical activity and dietary change weight loss intervention in breast and colorectal cancer survivors (SWOG S1008). Greenlee H, Lew D, Hershman DL, Newman V, Hansen L, Hartman S, Korner J, Shi Z, Sardo Molmenti C, Sayegh A, Fehrenbacher L, Lo S, Klemp J, Rinn K, Robertson JM, Unger JM, Gralow JR, Albain K, Krouse RS, Fabian C. Obesity, submitted.
- C89803 Artificially sweetened beverage intake and outcome in stage iii colon cancer: results from CALGB 89803 (Alliance). C Fuchs, B Guercio, S Zhang, D Niedzwiecki, Z Yee, Y Li, A Babic, V Morales-Oyarvide, L Saltz, RJ Mayer, R Mowat, R Whittom, A Hantel, A Benson, DM Atienza, M Messino, H Kindler, A Venook, S Ogino, E Zoltick, M Stempfer, K Ng, K Wu, W Willett, E Giovannucci, J Meyerhardt. PLOS ONE, submitted [see also Gl Cmte]
- C89803 Grain intake and clinical outcome in stage III colon cancer: results from CALGB 89803 (Alliance). JC Brown, Sui Zhang, D Niedzwiecki, LB Saltz, RJ Mayer, RB Mowat, R Whittom, A Hantel, A Benson, D Atienza, M Messino, H Kindler, A Venook, S Ogino, Y Li; X Zhang, K Ng, WC Willett, E Giovannucci, CS Fuchs, Jeffrey A. Meyerhardt. JNCI Cancer Spectrum, submitted. [see also GI Cmte]
- C89803 The influence of dietary insulin load on cancer recurrence and survival in patients with stage III colon cancer: findings from CALGB 89803 (Alliance). V Morales-Oyarvide, C Yuan, A Babic, S Zhang, D Niedzwiecki, JC Brand-Miller, L Sampson-Kent, X Ye, Y Li, LB Saltz, RJ Mayer, RB Mowat, R Whittom, A Hantel, A Benson, D Atienza, M Messino, H Kindler, A Venook, S Ogino, K Wu, WC Willet, EL Giovannucci, BM Wolpin, JA Meyerhardt, CS Fuchs, K Ng. Journal of the National Cancer Institute, pending revision and re-submission. [see also GI Cmte]

PREVENTION AND EPIDEMIOLOGY COMMITTEE

Published/Accepted Manuscripts

Source Genome-wide meta-analysis identifies five new susceptibility loci for pancreatic cancer. AP Klein, B Wolpin, H Risch, R Stolzenberg-Solomon, E Mocci, M Zhang, O Obazee, E Childs, J Hoskins, A Jermusyk, J Zhong, F Chen, D Albanes, G Andreotti, A Arslan, A Babic, W Bamlet, L Beane-Freeman, B Berndt, A Blackford, M Borges, A Borgida, P Bracci, L Brais, P Brennan, H Brenner, B Bueno-de-Mesquita, J Buring, D Campa, G Capurso, G Cavestro, K Chaffee, C Chung, S Cleary, M Cotterchio, F Dijk, E Duell, L Foretova, C Fuchs, N Funel, S Gallinger, JM Gaziano, M Gazouli, G Giles, E Giovannucci, M Goggins, G Goodman, P Goodman, T Hackert, P Hartge. Nature Communications Feb 8;9(1):556, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29422604

- S0820 Updates on S0820/PACES: Preventing adenomas of the colon with eflornithine and sulindac. J Zell, R Krouse, N You. <u>Bulletin of the American</u> <u>College of Surgeons</u> October Volume 102, Issue 10, 2017. http://bulletin. facs.org/2017/10/preventing-colorectal-adenomas-in-cancer-survivorsan-update-on-the-pacess0820-trial/#.WpCpsa6nHIU
- <u>S9217</u> Circadian genes and risk of prostate cancer in the Prostate Cancer Prevention Trial. LW Chu, C Till, B Yang, C Tangen, P Goodman, K Yu, Y Zhu, S Han, A Hoque, C Ambrosone, I Thompson, R Leach, A Hsing.
 <u>Molecular Carcinogenesis</u> Mar;57(3):462-466, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29318656
- S9217 Associations between genetic polymorphisms in genes related to estrogen metabolism and function and prostate cancer risk: results from the Prostate Cancer Prevention Trial. L Tang, ME Platek, S Yao, C Till, P Goodman, C Tangen, Y Wu, EA Platz, ML Neuhouser, FZ Stanczyk, JKV Reichardt, RM Santella, A Hsing, WD Figg, SM Lippman, IM Thompson, CB Ambrosone. <u>Carcinogenesis</u> Feb 9;39(2):125-133, 2018. https://www. ncbi.nlm.nih.gov/pubmed/29228205
- S9217 Using Medicare claims to examine long-term prostate cancer risk of finasteride on the Prostate Cancer Prevention Trial. J Unger, D Hershman, C Till, C Tangen, W Barlow, SD Ramsey, P Goodman, IM Thompson. Journal of the National Cancer Institute, accepted. [see also CCD Cmte]

Submitted Manuscripts

<u>Multiple Studies*</u> Prostate cancer meta-analysis of more than 140,000 men identifies 63 novel prostate cancer susceptibility loci. F Schumacher, AA Al Olama, S Berndt, C Tangen, P Goodman, IM Thompson, D Albanes, C Haiman. [*S9217, other]. <u>Nature Genetics</u>, submitted.

SYMPTOM CONTROL AND QUALITY OF LIFE COMMITTEE

Published/Accepted Manuscripts

- Supplement use and chemotherapy-induced peripheral neuropathy in patients treated in a SWOG cooperative group trial (S0221): the DELCaP Study. G Zirpoli, S McCann, L Sucheston-Campbell, D Hershman, G Ciupak, W Davis, J Unger, H Moore, JA Stewart, C Isaacs, T Hobday, M Salim, R Livingston, G Hortobagyi, J Gralow, D Hayes, G Budd, K Albain, C Ambrosone. Journal of the National Cancer Institute, in press. [see also Breast Cmte]
- S0715 Two-year trends of taxane-induced neuropathy in women enrolled in a randomized trial of acetyl-l-carnitine (SWOG S0715). DL Hershman, JM Unger, K Crew, C Till, H Greenlee, L Minasian, C Moinpour, DL Lew,



- L Fehrenbacher, JL Wade, SF Wong, M Fisch, K Albain. <u>Journal of the National Cancer Institute</u> Jan 18 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/?term=hershman+d+s0715
- S1202 Randomized multicenter placebo-controlled clinical trial of duloxetine versus placebo for aromatase inhibitor-associated arthralgias in early stage breast cancer: SWOG S1202. NL Henry, JM Unger, AF Schott, L Fehrenbacher, PJ Flynn, DM Prow, CW Sharer, G Von Burton, CS Kuzma, A Moseley, DL Lew, M Fisch, C Moinpour, DL Hershman, JL Wade, Ill. <u>Journal of Clinical Oncology</u> Feb 1;36(4):326-332, 2018. https://www. ncbi.nlm.nih.gov/pubmed/29136387
- E3805 Quality of life (QOL) during treatment with chemohormonal therapy: analysis of ECOG 3805 chemohormonal androgen ablation randomized trial in prostate cancer (CHAARTED). A Morgans, Y Chen, C Sweeney, D Jarrard, E Plimack, B Gartrell, M Carducci, M Hussain J. Garcia, D Cella, R DiPaola, L Patrick-Miller. Journal of Clinical Oncology, accepted. [see also GU Cmte]
- <u>Multiple Studies*</u> Key design and analysis principles for quality of life and patient reported outcomes in clinical trials. JM Unger, R Vaidya, JL Gore. <u>Urologic Oncology</u>, accepted. [*S9916, S1804, other] [see also GU Cmte]

Submitted Manuscripts

- <u>S0221</u> Associations between self-reported diet during treatment and chemotherapy-induced peripheral neuropathy in a cooperative group trial (S0221). J Mongiovi, G Zirpoli, R Cannioto, L Sucheston-Campbell, D Hershman, J Unger, H Moore, J Stewart, C Isaacs, T Hobday, M Salim, G Hortobagyi, J Gralow, G Budd, K Albain, C Ambrosone, S McCann. <u>Breast Cancer Research</u>, submitted. [see also Breast Cmte]
- S0421 Inclusion of patient-reported outcomes in metastatic castration-resistant prostate cancer clinical trials: SWOG S0421 PRO results and methodological issues. J Unger, K Griffin, G Donaldson, K Baranowski, M Good, P Twardowski, P Van Veldhuizen, M Hussain, C Higano, P Lara, C Tangen, D Quinn, J Wade, N Vogelzang, I Thompson, C Moinpour. Journal of Patient- Reported Outcomes, submitted. [see also GU Cmte]
- S1200 Randomized blinded sham- and waitlist-controlled trial of acupuncture for joint symptoms related to aromatase inhibitors in women with early stage breast cancer (S1200). D Hershman, J Unger, H Greenlee, J Capodice, D Lew, A Darke, A Kengla, M Melnik, C Jorgensen, W Kreisle, L Minasian, M Fisch, NL Henry, K Crew. <u>JAMA</u>, revised and resubmitted.
- NO147 Cetuximab reduces patient quality of life when administered with mFOLFOX6 as adjuvant treatment following complete resection of KRAS

wild-type tumors for stage III colorectal cancer (N0147 Alliance). MR Mahoney, JA Sloan, JM Hubbard, AD Tan, H Liu, RM Goldberg, SG Nair, AF Shields, S Gill, B Jahagirdar, AB Benson, DJ Sargent, SR Alberts. <u>Journal of Patient-Reported Outcomes</u>, pending revision and resubmission. [see also GI Cmte]

DIGITAL ENGAGEMENT COMMITTEE

Published/Accepted Manuscripts

Multiple Studies Incorporating digital tools to improve cancer clinical trials: A white paper from the digital engagement committee of SWOG. D Dizon, M Sedrak, MA Lewis, ED Cook, MJ Fisch, J Klemp, J Sommers, A Ciccarella, JR Gralow, W Lawton, C Nichols. JCO Clinical Cancer Informatics, accepted.

EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE

No publication information for this cycle

GASTROINTESTINAL COMMITTEE

Published/Accepted Manuscripts

- S0713 A phase II study of cetuximab added to induction chemotherapy of oxaliplatin and capecitabine, followed by neoadjuvant chemoradiation for locally advanced rectal cancer. C Leichman, S McDonough, S Smalley, K Billingsley, H Lenz, M Beldner, A Hezel, M Velasco, K Guthrie, C Blanke, H Hochster. SWOG S0713: Clinical Colorectal Cancer Mar;17(1):e121-e125, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29233486
- C80702 Duration of adjuvant chemotherapy for stage III colon cancer. A Grothey, AF Sobrero, A Shields, T Yoshino, J Paul, J Taieb, I Souglakos, Q Shi, R Kerr, R Labianca, J Meyerhardt, D Vernerey,T Yamanaka, I Boukovinas, JP Meyers, LA Renfro, D Niedzwiecki, V Torri, DJ Sargent, T Andre, T Iveson. NEJM, in press.
- C89803 Marine ω-3 polyunsaturated fatty acid and fish intake after colon cancer diagnosis and survival: CALGB 89803 (Alliance). E Van Blarigan, C Fuchs, D Niedzwiecki, X Ye, S Zhang, M Song, L Saltz, R Mayer, R Mowat, R Whittom, A Hantel, A Benson, D Atienza, Messino, H Kindler, A Venook, S Ogino, E Giovannucci, J Meyerhardt. Cancer Epidemiology, Biomarkers & Prevention, Jan 22 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29358223 [see also Ca Surv Cmte]
- C89803 Adherence to the American Cancer Society Nutrition and Physical Activity Guidelines for Cancer Survivors after colon cancer diagnosis and survival: CALGB 89803 (Alliance). Van Blarigan E, Fuchs C, Niedzwiecki D, Ye X, Zhang S, Saltz L, Mayer R, Mowat R, Whittom R, Hantel A, Benson A, Atienza D, Messino M, Kindler H, Venook A, Ogino S, Giovannucci E, Ng



K, Meyerhardt J. JAMA Oncology, accepted. [see also Ca Surv Cmte]

C89803 Nut consumption and survival in patients with stage III colon cancer: results from CALGB 89803 (Alliance). T Fadelu, S Zhang, D Niedzwiecki, X Ye, LB Saltz, RJ Mayer, RB Mowat, R Whittom, A Hantel, A Benson, D Atienza, M Messino, HL Kindler, A Venook, S Ogino, K Ng, K Wu, W Willett, E Giovannucci, J Meyerhardt, Y Bao, C Fuchs. <u>Journal of Clinical Oncology</u> Feb 28 [Epub ahead of print], 2018. [see also Ca Surv Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29489429

Submitted Manuscripts

- C89803 Artificially sweetened beverage intake and outcome in stage iii colon cancer: results from CALGB 89803 (Alliance). C Fuchs, B Guercio, S Zhang, D Niedzwiecki, Z Yee, Y Li, A Babic, V Morales-Oyarvide, L Saltz, RJ Mayer, R Mowat, R Whittom, A Hantel, A Benson, DM Atienza, M Messino, H Kindler, A Venook, S Ogino, E Zoltick, M Stempfer, K Ng, K Wu, W Willett, E Giovannucci, J Meyerhardt . PLOS ONE, submitted. [see also Ca Surv Cmte]
- C89803 Grain intake and clinical outcome in stage III colon cancer: results from CALGB 89803 (Alliance). JC Brown, Sui Zhang, D Niedzwiecki, LB Saltz, RJ Mayer, RB Mowat, R Whittom, A Hantel, A Benson, D Atienza, M Messino, H Kindler, A Venook, S Ogino, Y Li; X Zhang, K Ng, WC Willett, E Giovannucci, CS Fuchs, Jeffrey A. Meyerhardt. JNCI Cancer Spectrum, submitted. [see also Ca Surv Cmte]
- NO147 Cetuximab reduces patient quality of life when administered with mFOLFOX6 as adjuvant treatment following complete resection of KRAS wild-type tumors for stage III colorectal cancer (N0147 Alliance). MR Mahoney, JA Sloan, JM Hubbard, AD Tan, H Liu, RM Goldberg, SG Nair, AF Shields, S Gill, B Jahagirdar, AB Benson, DJ Sargent, SR Alberts. Journal of Patient-Reported Outcomes, pending revision and resubmission. [see also SXCQOL Cmte]

GENITOURINARY COMMITTEE

Note: All PCPT and SELECT publications are listed under Cancer Control & Prevention Committees

Published/Accepted Manuscripts

S0925 Circulating microRNAs and treatment response in SWOG S0925, a randomized phase II study of androgen deprivation combined with cixutumumab versus androgen deprivation alone for patients with new metastatic hormone-sensitive prostate cancer. HH Cheng, M Plets, H Li, CS Higano, CM Tangen, N Agarwal, NJ Vogelzang, M Hussain, IM Thompson, Jr., M Tewari, EY Yu. Prostate, Feb;78(2):121-127, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29105802

- S1107 Parallel (randomized) phase ii evaluation of tivantinib (arq197) and tivantinib in combination with erlotinib in papillary renal cell carcinoma: SWOG S1107. PW Twardowski, CM Tangen, X Wu, MR Plets, ER Plimack, N Agarwal, NJ Vogelzang, J Wang, S Tao, IM Thompson, Jr, P Lara Jr. <u>Kidney Cancer</u>, accepted.
- S9921 A phase III intergroup trial of adjuvant androgen deprivation +/mitoxantrone + prednisone in patients with high-risk prostate cancer post-radical prostatectomy: SWOG S9921. M Hussain, C Tangen, I Thompson Jr., G Swanson, DP Wood, W Sakr, N Dawson, N. Haas, T Flaig, T Dorff, DW Lin, ED Crawford, D Quinn, N Vogelzang, LM Glode. <u>Journal</u> of Clinical Oncology, accepted.
- E3805 Quality of life (QOL) during treatment with chemohormonal therapy: analysis of ECOG 3805 chemohormonal androgen ablation randomized trial in prostate cancer (CHAARTED). A Morgans, Y Chen, C Sweeney, D Jarrard, E Plimack, B Gartrell, M Carducci, M Hussain J. Garcia, D Cella, R DiPaola, L Patrick-Miller. Journal of Clinical Oncology, accepted. [see also SXCQOL Cmte]
- E3805 Chemohormonal therapy in metastatic hormone-sensitive prostate cancer: long-term survival analysis of the randomized phase III E3805 Trial. CE Kyriakopoulos, Y-H Chen, M Carducci, G Liu, DF Jarrard, M Eisenberger, Y Wong, N Hahn, M Kohli, MM Cooney, R Dreicer, NJ Vogelzang, J Picus, D Shevrin, M Hussain, JA Garcia, RS DiPaola, CJ Sweeney. Journal of Clinical Oncology, Jan 31 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29384722
- <u>Multiple Studies*</u> Key design and analysis principles for quality of life and patient reported outcomes in clinical trials. JM Unger, R Vaidya, JL Gore. <u>Urologic Oncology</u>, accepted. [*S9916, S1804, other] [see also SXCQOL Cmte]

Submitted Manuscripts

- SO337 Immediate post TURBT instillation of gemcitabine vs saline for suspected low grade bladder cancer: SWOG S0337. EM Messing, CM Tangen, SP Lerner, DM Sahasrabudhe, TM Koppie, DP Wood, Jr, PC Mack, RS Svatek, CP Evans, KS Hafez, DJ Culkin, TC Brand, LI Karsh, JM Holzbeierlein, SS Wilson, G Wu, M Plets, NJ Vogelzang, IM Thompson, Jr. JAMA, revised and resubmitted.
- S0421 Bone turnover biomarkers identify unique prognostic risk groups in men with castration resistant prostate cancer and skeletal metastases: results from SWOG S0421. PN Lara, Jr., M Plets, C Tangen, E Gertz, NJ Vogelzang, M Hussain, PW Twardowski, MG Garzotto, JP Monk, M Carducci, A Goldkorn, PC Mack, DI Quinn, IM Thompson, M Van Loan. <u>Prostate Cancer and Prostate Diseases</u>, submitted.



S0421 Inclusion of patient-reported outcomes in metastatic castration-resistant prostate cancer clinical trials: SWOG S0421 PRO results and methodological issues. J Unger, K Griffin, G Donaldson, K Baranowski, M Good, P Twardowski, P Van Veldhuizen, M Hussain, C Higano, P Lara, C Tangen, D Quinn, JL Wade, N Vogelzang, I Thompson, C Moinpour. <u>Journal of Patient-Reported Outcomes</u>, submitted. [see also SXCQOL Cmte]

LEUKEMIA COMMITTEE

Published/Accepted Manuscripts

- S0919 Report of the relapsed/ refractory cohort of SWOG S0919: a phase 2 study of idarubicin and cytarabine in combination with pravastatin for acute myelogenous leukemia. AS Advani, Hongli Li, LC Michaelis, BC Medeiros, M Liedtke, AF List, K O'Dwyer, M Othus, HP Erba, FR Appelbaum. Leukemia Research Jan 31;67:17-20, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29407182
- S1612 Intergroup LEAP trial (S1612): a randomized rolling-arms platform to test therapeutics in less-fit older adults with AML. RB Walter, LC Michaelis, M Othus, GL Uy, JP Radich, RF Little, S Hita, L Saini, JM Foran, AT Gerds, HD Klepin, AE Hay, JE Lancet, S Couban, MR Litzow, RM Stone, HP Erba. <u>American Journal of Hematology</u> Feb;93(2):E49-E52, 2018. <u>https://www.ncbi.nlm.nih.gov/pubmed/?term=walter+rb+LEAP</u>
- Multiple Studies* Impact of specimen heterogeneity on biomarkers in repository samples from patients with AML: a SWOG report. E Pogosova-Agadjanyan, A Moseley, M Othus, FR Appelbaum, T Chauncey, I-M L Chen, HP Erba, JE Godwin, M Fang, K Kopecky, AF List, GL Pogosov, JP Radich, CL Willman, BL Wood, S Meshinchi, DL Stirewalt. Biopreservation and Biobanking, Feb;16(1):42-52, 2018. [*studies: S9031, S9333, S0106, S0112] https://www.ncbi.nlm.nih.gov/pubmed/29172682

Submitted Manuscripts

- S0106_E1900 Higher clinical trial accrual volume improves outcomes in acute myeloid leukemia: A SWOG/ECOG-ACRIN Study. BC Medeiros, M Othus, MS Tallman, Z Sun, HF Fernandez, JM Rowe, HM Lazarus, FR Appelbaum, SM Luger, MR Litzow, HP Erba. <u>Leukemia Research</u>, submitted.
- <u>Multiple Studies*</u> Comparable outcomes of patients eligible versus ineligible for SWOG leukemia studies. A Statler, M Othus, H Erba, T Chauncey, J Radich, S Coutre, A Advani, S Nand, F Ravandi, S Mukherjee, M Sekeres. [*S0106, S0301, S0325, S0333, S0432, S0520, S0521, S0605, S0703, S0805, S0910, S0919, S1117]. <u>Blood</u>, submitted.

LUNG COMMITTEE

Published/Accepted Manuscripts

- <u>S0424</u> Smoking, sex and non-small cell lung cancer: examination of steroid hormone receptors in lung tumor tissue in SWOG S0424. T-Y D Cheng, AK Darke, MW Redman, GR Zirpoli, W Davis,
 - R Payne Ondracek, W Bshara, A Omilian, R Kratzke, ME Reid, JR Molina, JM Kolesar, Y Chen, RM MacRae, J Moon, P Mack, DR Gandara, K Kelly, RM Santella, KS Albain, CB Ambrosone. <u>Journal of the National Cancer Institute</u>, Jan13 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29346580 [see also Ca Surv Cmte]
- Solatin A randomized, phase iii study of carboplatin/paclitaxel or carboplatin/paclitaxel/ bevacizumab with or without concurrent cetuximab investigating EGFR FISH in patients with advanced non-small cell lung cancer: SWOG Solatin R Herbst, M Redman, E Kim, T Semrad, L Bazhenova, G Masters, K Oettel, P Guaglianone, C Reynolds, A Karnad, S Arnold, M Varella-Garcia, J Moon, P Mack, C Blanke, F Hirsch, K Kelly, DR Gandara. Lancet Oncology Jan;19(1):101-114, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29169877
- E1505 Randomized phase III trial of adjuvant chemotherapy with or without bevacizumab in resected non-small cell lung cancer (NSCLC): results of E1505. H Wakelee, S Dahlberg, S Keller, W Tester, D Gandara, S Graziano, A Adjei, N Leighl, S Aisner, J Rothman, J Patel, MD Sborov, S McDermott, R Perez-Soler, A Traynor, C Butts, T Evans, L Horn, SS Ramalingam, J Schiller on behalf of ECOG-ACRIN. Lancet Oncology Dec;18(12):1610-1623, 2017. https://www.ncbi.nlm.nih.gov/pubmed/29129443

Submitted Manuscripts

No publication information for this cycle.

LYMPHOMA COMMITTEE

Published/Accepted Manuscripts

Soo16 Continued excellent outcomes in previously untreated follicular lymphoma patients after treatment with CHOP plus Rituximab or CHOP plus 131lodine-Tositumomab - long term follow-up of phase III randomized study SWOG-S0016. M Shadman, H Li, L Rimsza, JP Leonard, MS Kaminski, RM Braziel, CM Spier, AK Gopal, DG Maloney, B Cheson, S Dakhil, M LeBlanc, SM Smith, RI Fisher, JW Friedberg, OW Press. Journal of Clinical Oncology, Mar 1;36(7):697-703, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29356608



S0016 Impact of histologic grading on survival in the SWOG S0016 follicular lymphoma cohort. L Rimsza, H Li, R Braziel, C Spier, D Persky, J Dunlap, M LeBlanc, N Barlett, JP Leonard, SM Smith, OW Press, JW Friedberg. Haematologica Feb 22 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29472351

<u>S0410</u> Tandem autologous hematopoietic cell transplantation for patients with primary progressive or recurrent hodgkin lymphoma: a SWOG and Blood & Marrow Transplant Clinical Trials Network phase II Trial (SWOG S0410/BMT CTN 0703). EP Smith, H Li, JW Friedberg, LS Constine, LM Rimsza, JR Cook, GG Laport, LL Popplewell, L A Holmberg, SM Smith, M LeBlanc, SJ Forman, RI Fisher, PJ Stiff. <u>Biology of Blood and Marrow Transplantation</u>, Dec 28.[Epub ahead of print], 2017. https://www.ncbi.nlm.nih.gov/pubmed/29289757

SO801 Phase 2 study of RCHOP, radioimmunotherapy and maintenance rituximab in untreated follicular lymphoma: SWOG S0801. PM Barr, H Li, WR Burack, M LeBlanc, SM Smith, AK Gopal, JD Floyd, DO Persky, OW Press, RI Fisher, JW Friedberg. Lancet Haematology Mar;5(3):e102-e108, 2018. https://www.ncbi.nlm.nih.gov/pubmed/?term=barr+pm+s0801

SO806 A phase I/II trial of vorinostat (SAHA) in combination with rituximab-chop in patients with newly diagnosed advanced stage diffuse large B-cell lymphoma (DLBCL): SWOG S0806. DO Persky, H Li, LM Rimsza, PM Barr, LL Popplewell, CL Bane, A Von Gehr, M LeBlanc, RI Fisher, SM Smith, JW Friedberg. American Journal of Hematology Dec 20 [Epub ahead of print], 2017. https://www.ncbi.nlm.nih.gov/pubmed/29266344

E2496/COG* Outcomes in adolescents and young adults (AYA) with hodgkin lymphoma (HL) treated on US cooperative group protocols: an adult intergroup (E2496) and Children's Oncology Group (COG AHOD 0031) comparative analysis. TO Henderson, SK Parsons, K Wroblewski, L Chen, F Hong, S Smith, J McNeer, R Advani, R Gascoyne, LS Constine, S Horning, NL Bartlett, B Shah, JM Connors, J Leonard, BS Kahl, K Kelly, CL Schwartz, H Li, JW Friedberg, DL Friedman, LI Gordon, AM Evens. Cancer Jan 1;124(1):136-144, 2018. [*COG AHOD 0031; see also AYA Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29370458

Submitted Manuscripts

C50604 Results of US intergroup trial of response-adapted chemotherapy or chemotherapy/radiation therapy based on interim FDG-PET for nonbulky stage I and II hodgkin lymphoma. DJ Straus, S-H Jung, B Pitcher, L Kostakoglu, JC Grecula, ED Hsi, H Schöder, LL Popplewell, JE Chang, CH Moskowitz, N Wagner-Johnson, JP Leonard, JW Friedberg, BS Kahl, BD Cheson, NL Bartlett. <u>Blood</u>, pending revision and resubmission.

CTSU 9177 Multicenter phase II study of DA-EPOCH-R in MYC-rearranged aggressive B-cell lymphoma. K Dunleavy, MA Fanale, JS Abramson, A Noy, P Fabrizio Caimi, S Pittaluga, S Parekh, A Lacasce, JW Hayslip, D Jagadeesh, S Nagpal, MJ Lechowicz, R Gaur, JW Leach, A Lucas, C Melani, M Roschewski, SM Steinberg, ES Jaffe, B Kahl, JW Friedberg, RF Little, NL Bartlett, WH Wilson. Blood, under review.

MELANOMA COMMITTEE

Published/Accepted Manuscripts

S0008 High frequency of brain metastases after adjuvant therapy for highrisk melanoma. WE Samlowski, J Moon, M Witter, M Atkins, J Kirkwood, M Othus, A Ribas, V Sondak, L Flaherty. <u>Cancer Medicine</u> Nov;6(11):2576-2585, 2017. https://www.ncbi.nlm.nih.gov/pubmed/28994212

Submitted Manuscripts

No publication information for this cycle.

PHARMACEUTICAL SCIENCES COMMITTEE

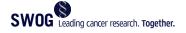
Published/Accepted Manuscripts

<u>Multiple Studies</u> Frequency and description of drug interaction screening within SWOG Clinical Trials. DL Hertz, R Siden, J Modlin, L Au, LL Gabel, S-F Wong. American Journal of Health-System Pharmacy, accepted.

RADIATION ONCOLOGY COMMITTEE

Submitted Manuscripts

Multiple Studies Report from the SWOG Radiation Oncology Committee: Research Objectives Workshop 2017. P Okunieff, K Casey-Sawicki, N Lockney, B Hoppe, H Enderling, C Pinnix, J Welsh, S Krishnan, M Brown, G Yothers, S Knox, R Bristow, P Spellman, C Thomas, N Nabavizadeh, J Jaboin, H Manning, F Feng, S Galbraith, A Solanki, M Harkenrider, R Tuli, L Kachnic, R Decker, S Finkelstein, C Hsu, C Ha, R Jagsi, M Daily, T Wang, T Fitzgerald, F Laurie, D Marshall, D Raben. Clinical Cancer Research, submitted.



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