

### **Building on Our Efforts**

Fall always marks a real turning point in the year for me. Cooler weather, the changes in the leaves, and recovery from a languid summer always feels both familiar and fresh. The meeting here in Chicago feels like a turning point, too – a time to begin a new chapter for SWOG,

one that builds on years of effort and planning.

At the general plenary, I will unveil new logos for SWOG and The Hope Foundation and celebrate our wonderful score on our NCTN operations grant application. When that grant funding kicks in next spring, it will bring with it new staff, programs, committees, and, yes, dreams.

Also at plenary, we will hear about NAVIGATE, a new NCI and U.S. Department



of Veterans Affairs program aimed at enrolling more military veterans onto NCI trials. And we will hear the latest on the recommended changes to trial eligibility requirements laid out by ASCO and Friends of Cancer Research last year.

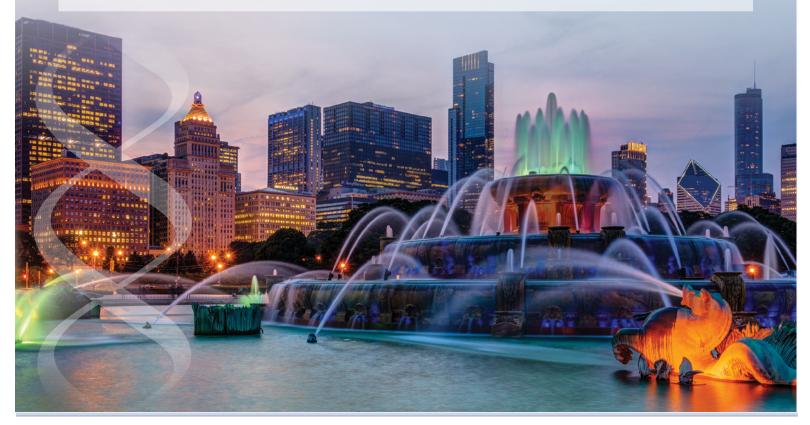
Finally, here in Chicago, the Board of Governors will vote on whether to grant the palliative and end of life care committee full, permanent status as a research committee, a move that will

open up an exciting new line of inquiry for our group for decades to come. At our next meeting, by the way, I also expect to see the immunotherapy and CNS tumors committees firmly advanced.

I wish you a productive and positive group meeting, one full of new possibilities.

Chalo Ble My

Charles D. Blanke, MD
SWOG Chair



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### WELCOME TO HYATT REGENCY CHICAGO.

Meeting rooms, ballrooms, restaurants and guest amenities are listed in alphabetical order and color coded by floor. For help, dial Guest Services at Extension **4460**.

ESCALATORS,
ELEVATORS AND
RESTROOMS are indicated on each floor. Elevators are conveniently located throughout the hotel for guests with disabilities or where no escalator is

#### **CROSSING BETWEEN**

present.

**TOWERS:** Cross between towers via the Skybridge or the Concourse.
You may also cross from the lobby level via the

crosswalk on Stetson Drive.

- ACAPULCO (International and City Suites)
  West Tower, Ballroom Level
- ADDAMS (Founders Suites)
  West Tower, Third Floor
- AMERICAN CRAFT KITCHEN & BAR East Tower, Lobby Level
- ATLANTA (International and City Suites)
  West Tower, Ballroom Level
- BELL DESK
  East Tower, Skyway Level
- BIG BAR
  East Tower, Skyway Level
- BURNHAM (Founders Suites)
  West Tower, Third Floor
- BUSINESS CENTER, PACKAGE ROOM East Tower, Exhibit Level
- COLUMBIAN (Landmark Suites)
  West Tower, Concourse Level
- COLUMBUS HALL (ROOMS A-L)
  East Tower, Ballroom Level
- COMISKEY (Landmark Suites)
  West Tower, Concourse Level
- CONCIERGE
  East Tower, Lobby Level
- CRYSTAL BALLROOM West Tower, Lobby Level
- DUSABLE (Founders Suites)
  West Tower, Third Floor
- EAST TOWER MAIN ENTRANCE
  East Tower, Lobby Level
- EAST TOWER VALET East Tower, Ballroom Level
- FIELD (Founders Suites)
  West Tower, Third Floor
- FITNESS CENTER
  West Tower, Skyway Level
- FRONT DESK
  East Tower, Skyway Level
- THE GALLERY COLLECTION
  West Tower, Skyway Level
- GIFT SHOP East Tower, Concourse Level
- GOLD COAST (Landmark Suites)
  West Tower, Concourse Level
- GRAND BALLROOM
  East Tower, Ballroom Level
- GRAND SUITES
  East Tower, Ballroom Level
- HAYMARKET (Landmark Suites)
  West Tower, Concourse Level
- HERTZ
  East Tower, Lobby Level

- HONG KONG (International and City Suites)
  West Tower, Ballroom Level
- HORNER (Founders Suites)
  West Tower, Third Floor
- THE LIVING ROOM
  West Tower, Skyway Level
- MARKET CHICAGO
  East Tower, Lobby Level
- McCORMICK (Founders Suites)
  West Tower, Third Floor
- MICHIGAN (Lakeshore Meeting Rooms)

  East Tower, Concourse Level
- MONROE (Lakeshore Meeting Rooms)

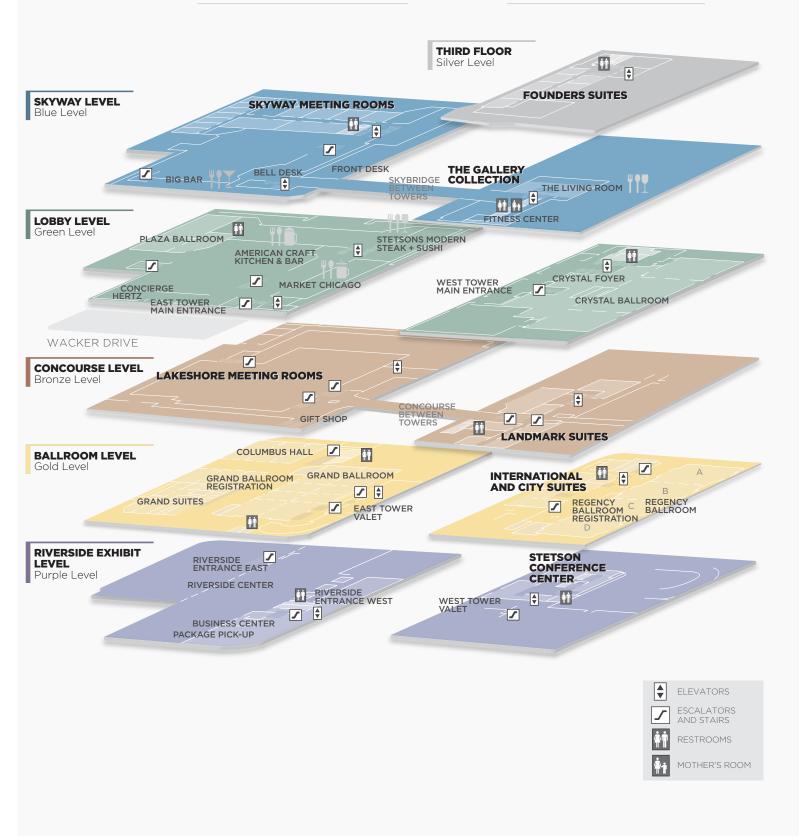
  East Tower, Concourse Level
- NEW ORLEANS (International and City Suites)
  West Tower, Ballroom Level
- OGDEN (Founders Suites)
  West Tower, Third Floor
- PICASSO (Landmark Suites) West Tower, Concourse Level
- PLAZA BALLROOM East Tower, Lobby Level
- RANDOLPH (Lakeshore Meeting Rooms)
  East Tower, Concourse Level
- REGENCY BALLROOM West Tower, Ballroom Level
- RIVERSIDE CENTER
  East Tower, Exhibit Level
- ROOSEVELT (Lakeshore Meeting Rooms)
  East Tower, Concourse Level
- SAN FRANCISCO (International and City Suites)
  West Tower, Ballroom Level
- SANDBURG (Founders Suites)
  West Tower, Third Floor
- SKYWAY MEETING ROOMS
  East Tower, Skyway Level
- SOLDIER FIELD (Landmark Suites)
  West Tower, Concourse Level
- STETSON CONFERENCE CENTER
- West Tower, Exhibit LevelSTETSONS MODERN STEAK + SUSHI
- East Tower, Lobby Level

  TORONTO (International and City Suites)
  West Tower, Ballroom Level
- WATER TOWER (Landmark Suites)
  West Tower, Concourse Level
- WEST TOWER VALET West Tower, Exhibit Level
- WRIGHT (Founders Suites)
  West Tower, Third Floor
- WRIGLEY (Landmark Suites)
  West Tower, Concourse Level



#### **EAST TOWER**

#### WEST TOWER



### **Chicago Travel & Hotel Information**

Hyatt Regency Chicago 151 East Wacker Drive Chicago, Illinois 60601 • Phone: 312-565-1234 • Fax: 312 239 4541



#### **Arrival/Departure:**

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

#### **Hotel Safety Deposit Boxes:**

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

#### **Recreational Facilities:**

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

**Hotel Restaurants and Lounges:** Stetsons Modern Steak & Sushi: Non-traditional steakhouse experience in a comfortable urban setting, specializing in steaks and seafood. *Restaurant is open daily from 5:00 pm— 11:00 pm* 

American Craft Kitchen & Bar: Regionally inspired by all corners of the country, they offer an approachable dining experience with handcrafted food and drink. This atrium restaurant is the perfect stop for breakfast or lunch. *Open daily from 6:00 am— 3:00 pm* 

**Market Chicago:** Offers breakfast, lunch or dinner for a quick meal or coffee to go. *Open 24 hours a day.* 

**DaddyO's Pub & Game Room:** Corner pub featuring juicy burgers, local brews and wall-to-wall entertainment. *Open 5:00 pm— 1:00 am* 

**The BIG Bar** features the longest free-standing bar in North America and specializes in a wide variety of cocktails, wines, champagnes and cognacs and snacks.

Open daily at 5:00 pm

*In-room dining is available from 6:00 am— 12:00 am daily.* 

#### **Business Center:**

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



### Chicago Travel & Hotel Information, cont.

#### **Ground Transportation:**

A taxi ride from O'Hare International Airport to the hotel is approximately \$35.00 one-way.

A taxi ride from Midway International Airport to the hotel is approximately \$30.00 one-way.

Valet parking at the hotel is a maximum of \$65.00 per day for hotel guests.

#### Temperature:

The average high for September is 75 degrees and the average low is 54 degrees.

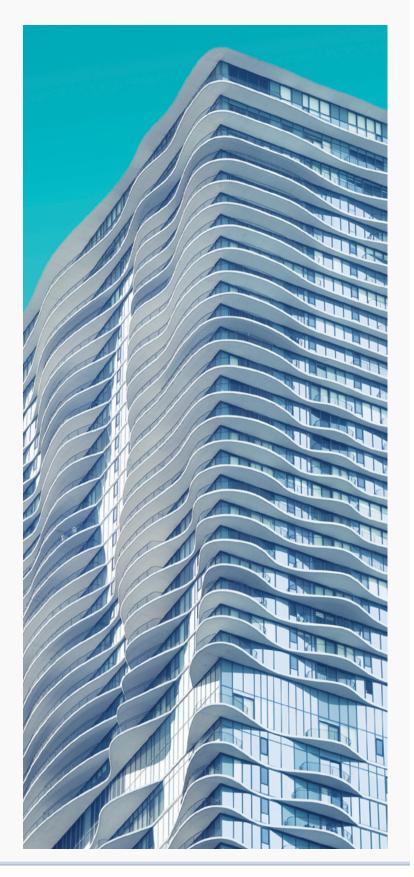
#### **AREA ATTRACTIONS:**

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

#### **Local Restaurants:**

(The hotel concierge can assist with reservations and suggestions)

- •Alinea— Eclectic
- Atwood Cafe— American
- •Mia Francesca— Italian
- •Mon Ami Gabi— French
- •Shaw's Crab House and Blue Crab Lounge— Seafood
- •Spiaggia— Italian





#### Plenary Part I

Regency A-C (Ballroom Level, West Tower)
The fall meeting's translational medicine plenary will take place
Thursday, October 4, 3:00 - 4:30 pm. Speakers and topics will include:

#### Plenary Part II

Regency A-C (Ballroom Level, West Tower)
The fall meeting's general plenary will take place
Friday, Oct. 5 from 12:00-2:00 pm. Speakers and topics will include:

#### Welcome and Introduction Lee M. Ellis, MD, FASCO

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



Chair's Welcome and Update
Charles D. Blanke, MD
SWOG Chair
Oregon Health & Science University

#### Targeting the DNA Damage Response: Lessons Learned and the Path Forward

Timothy A. Yap, MD, PhD

Associate Professor, Departments of Investigational Cancer Therapeutics (Phase I Program) and Thoracic/ Head and Neck Medical Oncology Medical Director, Institute for Applied Cancer Science Associate Director of Translational Research, Khalifa Institute for Personalized Cancer Therapy University of Texas MD Anderson Cancer Center



NAVIGATE: NCI and VA Interagency Group to Accelerate Trials Enrollment Sheila Prindiville, MD, MPH

Director, Coordinating Center for Clinical Trials National Cancer Institute Medical Center



Chief, Division of Solid Tumor Oncology Memorial Sloan Kettering Cancer Center



# Broadening Eligibility Criteria for Oncology Clinical Trials

Paul Hesketh, MD

Chair and Director
Lahey Health Cancer Institute
Lung Committee and Board of Governors
SWOG



Edison T. Liu, MD

President and CEO
The Jackson Laboratory







Harry E. Hynes Memorial Lecture: Cancer Control in the 21st Century Otis Brawley, MD, MACP, FASCO, FACE

Chief Medical and Scientific Officer American Cancer Society





Jack Aiello, MS, EE *Myeloma* 



Rick Bangs, MBA, PMP Genitourinary



Tony Crispino Genitourinary



Hildy Dillon, MPH *Lymphoma* 



Amy Geschwender, PhD Symptom Control + Quality of Life



Valerie Guild, MBA, CPA *Melanoma* 



Sandra Hamilton, RN, BSN, MEd Recruitment + Retention



Marcia K. Horn, JD

Early Therapeutics and Rare Cancers



# **Our Advocates**

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



Cheryl Jernigan, CPA, FACHE Prevention and Epidemiology



Judy Johnson, MBA *Lung* 



Lee Jones, MBA
Survivorship



Florence Kurttila, MS

Gastrointestinal



Ginny Mason, RN

Breast



Elda Railey Breast



Barbara Segarra-Vazquez, DHSc Cancer Care Delivery



Carole Seigel, MBA

Gastrointestinal



Gail Sperling, MPH Leukemia



Peggy Zuckerman, M.Ed. *Genitourinary* 

# Chicago Special Sessions

S1806 Kick-Off meeting | S1501 Kick-Off meeting
Translational Medicine Mini-Retreat on Liquid Biopsies
SWOG NCORP Research Base Clinical Trials Workshop
Federal Site Payment Transition — Office Hours | SWOG Surgical Based Trials
Jeri and Noboru Oishi Symposium | S1400 Lung-Map



### S1806 Kick-Off meeting

Friday, October 5th | 10:30 am - 12:00 pm | Crystal C, Lobby Level

Open to All SWOG Members; Suggested for Site Staff

Phase III Randomized Trial of Concurrent Chemoradiotherapy
With or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer

This session provides an overview of a novel new trial at SWOG from the genitourinary committee. The trial aims to answer a critical question bladder cancer patients ask their doctors: What is a good option to save my life — and my bladder? The randomized trial will test the standard chemoradiation regimen given to muscle invasive bladder cancer patients against that same regimen with the addition of atezolizumab, a monoclonal antibody approved by the FDA in 2016 for bladder cancer treatment.

**S1806 will test** an entirely new endpoint — bladder intact event-free survival. Does the addition of this immunotherapy help patients live longer without their cancer returning — and with their bladders intact? S1806 also has extensive and unique quality of life endpoints gauging pain, fatigue, and diarrhea, as well as several secondary and translational medicine objectives.

SWOG study chairs include Parminder Singh, MD from Mayo Clinic Arizona, Seth Lerner, MD, from Baylor College of Medicine, Sameer Jhavar, MD, from Baylor Scott & White Health, along with NRG study chair Jason Efstathiou, MD, from Massachusetts General Hospital. They will explain the trial design and goals, as well as eligibility and other logistics. Trial leaders will also discuss patient need. A recent 2017 guideline from the American Urological Association, American Society of Clinical Oncology, American Society of Radiation Oncology, and Society of Urologic Oncology recommended that bladder preservation therapy is the preferred treatment for patients who desire bladder preservation and who understand the unique risks associated with this approach.

### S1501 Kick-Off meeting

Friday, October 5th | 2:00 – 3:30 pm | Gold Coast (Concourse Level, West Tower)

Open to All SWOG Members; Suggested for Site Staff

Prospective Evaluation of Carvedilol vs No treatment in Prevention of Cardiac Dysfunction in Women with Metastatic HER-2+ Breast Cancer

Come hear about S1501, a unique trial backed by the SWOG breast cancer and survivorship committees. This study aims to determine whether treatment with carvedilol, a beta-blocker used to treat high blood pressure and heart failure, can prevent cardiac dysfunction in women with metastatic HER-2+ breast cancer. Therapies for this type of aggressive breast cancer have caused cardiac adverse events, such as heart failure.

S1501 principal investigator Justin Floyd, DO, of Heartland NCORP/Cancer Care Specialists of Illinois, and members of the study team will discuss the trial design, endpoints, and eligibility, as well as the medical importance of the trial. Attendance is encouraged for sites activating S1501, and site staff will receive credit for participating.



### Translational Medicine Mini-Retreat on Liquid Biopsies

"Liquid Biopsies: Using Cell-Free DNA Methodologies to Assess Clinical Trial Outcomes"

Thursday, October 4th | 6:00 – 9:00 pm | Crystal BC (Lobby Level, West Tower)

#### Open to All Members | Registration Required | Sponsored by The Hope Foundation

6:00PM - 6:05PM

Welcome and Introductions

James M. Rae, PhD

Rogel Cancer Center University of Michigan

6:05PM-7:05PM

Session 1

### How to Choose the Right Platform for Your Clinical Trial

Chair: Honey V. Reddi, PhD, FACMG
The Jackson Laboratory for Genomic Medicine

#### Speakers:

1) Honey V. Reddi, PhD, FACMG
The Jackson Laboratory for Genomic Medicine

Title: Technical Considerations for Taking Liquid Biopsy to the Clinic

2) Philip C. Mack, PhD

UC Davis Comprehensive Cancer Center

Title: Clinical Utility of ctDNA Analysis

3) Funda Meric-Bernstam, MD

University of Texas MD Anderson Cancer Center

Title: Opportunities and Challenges of Incorporating cfDNA into

**Clinical Trials** 

7:05PM - 8:05PM

Session 2

#### Novel trail designs with ctDNA

Chair: Dan Levy, PhD

Cold Spring Harbor Laboratory

Speakers:

1) Alex Herrera, MD

Beckman Research Institute at the City of Hope

Title: Incorporating ctDNA into Lymphoma Clinical Trials

2) Van K. Morris, MD

University of Texas MD Anderson Cancer Center

Title: ctDNA as a Predictive Biomarker for Adjuvant Chemotherapy in Patients with Stage II Colon Cancer

3) Filip Janku, MD, PhD, MDACC

University of Texas MD Anderson Cancer Center

Title: Liquid Biopsies in Personalized Medicine Strategies in Early Phase Clinical Trials

8:00-8:15PM

Break

8:15PM - 9:00PM

Session 3

#### Commercial ctDNA Platforms

Chair: Lee Ellis, MD

University of Texas MD Anderson Cancer Center

Speakers:

1) Guardant Health, Inc.

Becky Nagy, MS LGC

Director, Medical Affairs at Guardant Health

Title: Cell-free DNA Analysis to Assess Tumor Genomics

2) PGDx, Personal Genome Diagnostics, Inc.

Luis A. Diaz, MD

Chief, Division of Solid Tumor Oncology Memorial Sloan Kettering Cancer Center

Title: New Insights in Clinical Application of ctDNA

3) Foundation Medicine, Inc.

Jon Chung, PhD

Senior Manager, Clinical Development at Foundation Medicine

Title: Hybrid Capture-based Genomic Profiling of ctDNA to Assess Genomic Alterations and Tumor Mutational Burden

4) DiaCarta, Inc.

Paul Okunieff, MD

Professor and Chair, Department of Radiation Oncology University of Florida College of Medicine

Title: Using XNA Clamps as Liquid Biopsies for Screening, Follow up Evaluation and for Personalized Quantitative Measurement of Drug Response



### SWOG NCORP Research Base Clinical Trials Workshop

An in-depth session on clinical trials in these areas — cancer care delivery, cancer survivorship, prevention and epidemiology, symptom control and quality of life, and palliative and end of life care.

Wednesday, October 3 | 12:30 pm Check in | 1:00-5:00 pm | Regency B (Ballroom Level, West Tower)

All SWOG members welcome and encouraged to attend

Attendees receive up to four hours of credits from the

Society of Clinical Research Associates (SoCRA)



Participants will gain new perspectives on conducting studies in the NCI's Community Oncology Research Program (NCORP) areas. At this session, leaders will present from SWOG's NCORP and disease research committees, with talks on topics such as current SWOG NCORP clinical trials, cardiotoxicology research, trial recruitment and retention, cancer disparities, and more.

Participants will also take part in breakout discussion sessions on a variety of topics.



### **SWOG Surgical Based Trials**

#### A special education session hosted by the surgery committee

Friday, Oct. 5, 2018 | 9:00 to 11:00 am Plaza Ballroom (Lobby Level, East Tower)

Update: S1505 — Neoadjuvant Therapy for Resectable Pancreas Cancer & GI SWOG Surgical Trials

#### Syed A. Ahmad, MD, FACS

Professor of Surgery Chief Division Surgical Oncology, The University of Cincinnati Medical Center

#### Breast Cancer Surgical Trials in SWOG

#### Christine A. Lee, MD, FACS

Medical Director, SCI Cancer Program & Breast Program — Swedish Cancer Institute
Thoracic surgical trials in SWOG

#### Wayne Hofstetter, MD

Thoracic Surgeon, MDAAC University of Texas MD Anderson Cancer Center

Update on S1011: Comparing Extended vs. Standard Lymphadenectomy with Radical Cystectomy for Invasive Bladder Cancer & Update-GU SWOG Surgical Trials

#### Rob Svatek, MD, MSCI

Chief, Division of Urologic Oncology UT Health San Antonio

S1316: Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction

#### Robert S. Krouse, MD, FACS

Professor of Surgery at U of Pennsylvania. Chief of Surgery at the Michael J. Crescenz VAMC in Philadelphia S1820: A Randomized Phase II Trial of the Altering Intake, Managing Symptoms (AIMS) Intervention for Bowel Dysfunction in Rectal Cancer Survivors.

#### Virginia Sun, PhD, RN

Associate Professor, Department of Population Sciences City of Hope

E S1600 SIMmune: A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes

#### Jill Hamilton-Reeves, PhD, RD, CSO

Associate Professor Department of Urology and Dietetics/Nutrition, University of Kansas Medical Center

Update 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- Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES)

#### Jason A. Zell, DO, MPH

Associate Professor, Division of Hematology/Oncology, Departments of Medicine & Epidemiology, University of California, Irvine



### Jeri and Noboru Oishi Symposium

A special session organized by the Oncology Research Professionals Committee

Thursday, Oct. 4 | 1:00-5:00 pm | Regency AB (Ballroom Level, West Tower)

#### Open to all members

7:30 – 8:00 Registration | 8:00 – 8:15 Welcome and Introductions

#### Keisha Humphries RN, BSN, MHCL, OCN

Chair, Oncology Research Professionals Committee

8:15 - 9:15

Social Media and the Research Enterprise: On Applications and Practical Utilization

#### Don S. Dizon, MD, FACP, FASCO

Director, Women's Cancers, Lifespan Cancer Institute Director of Medical Oncology, Rhode Island Hospital

9:15 - 9:45

Clinical Trials Support Unit Updates

9:45 - 10:00

Break

10:00-11:00

SWOG Data Operations & Statistical Center Updates

11:00 - 11:30

S1609 DART Protocol Update

#### Sandip Patel, MD

Medical Oncologist
Assistant Professor of Medicine
UC San Diego Health
Moores Cancer Center

### Federal Site Payment Transition — Office Hours

Thursday, Oct. 4 | 4:30-6:00 pm | Picasso (Concourse Level, West Tower)

Due to changes mandated by the National Cancer Institute, SWOG in 2019 will be changing the way it sends federal funds to its member sites, moving from purchase service agreements to a fixed-price sub-award system.

What will this mean for you? Site staff are encouraged to drop by and talk with the SWOG grants team, Pat Mize and Kyle Theige, to learn more about the new process.

No registration necessary. Just stop in!

Can't make the session and want to learn more? Email theige@ohsu.edu



### TeamScience@SWOG Kick Off in Chicago



Rick Bangs, Patient advocate chair

**TeamScience@SWOG** is a new, five-module training program which aims to ensure that patient advocates are consistently and seamlessly engaged in SWOG trials.

**A cross-disciplinary SWOG team,** led by patient advocate chair Rick Bangs, created the self-study training including videos, slides, and exercises with funding from a Patient-Centered Outcomes Research Institute (PCORI) grant.

**At the meeting,** SWOG leadership will be introduced to TeamScience@ SWOG, and the program will roll out to other stakeholders in 2019. Look for training materials and details coming soon on SWOG.org.

# Lung-MAP is Bigger and Better

### Our major precision medicine trial is expanding!

Lung-MAP is opening to patients with all types of non-small cell lung cancers — which make up 80-85 percent of all lung cancers.

Learn about this and other exciting trial changes by attending this session here in Chicago:

Lung-MAP Update Meeting | Friday, Oct. 5 | 2:30 pm - 4:00 pm S1400 Lung-Map: Regency D (Ballroom Level, West Tower)







#### Administrative **Committees**

**Board of Governors** 

Charles D. Blanke, MD

**Conflict Management** 

Paul Okunieff, MD

**Publications** 

Hagen F. Kennecke, MD

**Professional Review** 

Paul Hesketh, MD

### **Research Support Committees**

Adolescents and **Young Adults** 

Mark A. Lewis, MD

**Bone Marrow** and Stem Cell **Transplantation** 

Patrick J. Stiff, MD

**Digital Engagement** 

Don S. Dizon, MD

**Imaging** 

Lawrence H. Schwartz, MD

**Oncology Research Professionals** 

Keisha Humphries, RN, BSN

**Patient Advocates** 

Rick Bangs, MBA

**Pharmaceutical Sciences** 

Co-Chair: Siu-Fun Wong, PharmD Co-Chair: Susan Kadlubar, PhD

**Radiation Oncology** 

Paul Okunieff, MD

Recruitment and Retention

Elise D. Cook, MD

Surgery

George H. Yoo, MD

**Future** Meeting **Dates** 

Spring 2019

April 24-27, 2019 Hyatt Regency

San Francisco

San Francisco, CA

Fall 2019

October 2-5, 2019 **Hyatt Regency** 

Chicago Chicago, IL Spring 2020

April 22-25, 2020 **Hyatt Regency** San Francisco

San Francisco, CA

Fall 2020

September 23-26, 2020 **Hyatt Regency** 

Chicago Chicago, IL



#### WEDNESDAY, OCTOBER 3, 2018

Group Meeting Registration & Information Desk 1:00 pm— 5:00 pm— Regency Foyer, Ballroom Level, West Tower

\* Unless otherwise indicated, all meetings are in the West Tower of the hotel

10:00 AM - 12:00 PM

Soldier Field, Concourse Level Oncology Research Professional

Executive Meeting (Committee

Members Only

12:00 PM - 1:45 PM

Haymarket, Concourse Level Nursing Research Subcommittee

12:00 PM - 2:00 PM

Acapulco, Ballroom Level Core Office Staff Meeting

(Invitation Only)

12:30 PM - 1:00 PM

Regency B Foyer, Ballroom Level SWOG NCORP Research Base

Clinical Trials Workshop Check-In

1:00 PM - 5:00 PM

**Regency B, Ballroom Level** SWOG NCORP Research Base

Clinical Trials Workshop

2:00 PM - 3:30 PM

**Soldier Field, Concourse Level** SWOG Tissue Banking Meeting

(Invitation Only)

3:00 PM - 5:00 PM

Gallery 5, Skyway Level Hope Foundation Board Meeting

(Board Members Only)

4:30 PM - 5:30 PM

Acapulco, Ballroom Level ORP Liaison Subcommittee

5:30 PM - 7:30 PM

**Regency D, Ballroom Level** Site Operations (Open Session)

5:30 PM - 7:30 PM

**Haymarket, Concourse Level**ITSC Steering Committee (Committee Members Only)

5:30 PM - 8:00 PM

Regency C, Ballroom Level

NCORP Research Base Executive Committee Meeting (Committee

Members Only)

THURSDAY, OCTOBER 4, 2018

Group Meeting Registration & Information Desk 7:00 am— 5:00 pm— Regency Foyer, Ballroom Level, West Tower

Hope Foundation Information Desk

8:00 am— 5:00 pm— Regency Foyer, Ballroom Level,

West Tower

**Exhibits & Complimentary Coffee Service** 

7:00 am— 4:00 pm— Toronto/Hong Kong, Ballroom

Level, West Tower

\* Unless otherwise indicated, all meetings are in the West Tower of the hotel

7:00 AM - 8:00 AM

Water Tower, Concourse Level Advocates Committee Meeting

(Committee Members Only)

7:30 AM - 8:00 AM

Regency B Foyer, Ballroom Level Jeri & Noboru Oishi Symposium

Check-In

8:00 AM - 11:30 AM

**Regency AB, Ballroom Level** Jeri & Noboru Oishi Symposium

(Open Session)

8:00 AM - 10:00 AM

Regency C, Ballroom Level CANCER CARE DELIVERY

COMMITTEE

10:00 AM - 12:00 PM

**Haymarket, Concourse Level** Quality Initiative Meeting

(Committee Members Only)

10:00 AM - 12:15 PM

Regency D, Ballroom Level EARLY THERAPEUTICS AND RARE

CANCERS COMMITTEE



10:15 AM - 12:15 PM

Regency C, Ballroom Level PREVENTION AND EPIDEMIOLOGY

**COMMITTEE** 

12:00 PM - 1:00 PM

Water Tower, Concourse Level Leadership Academy Retreat

(Invitation Only)

12:00 PM - 2:00 PM

Adolescent and Young Adult (AYA) Comiskey, Concourse Level

Committee

12:00 PM - 2:00 PM

San Francisco, Ballroom Level Lung-MAP Site Coordinators Committee Meeting (Committee

Members Only)

12:30 PM - 2:00 PM

Acapulco, Ballroom Level **ORP Open Forum** 

12:30 PM - 2:30 PM

SYMPTOM CONTROL AND Regency D, Ballroom Level

**QUALITY OF LIFE COMMITTEE** 

1:00 PM - 2:00 PM

New Orleans, Ballroom Level Lung Executive Subcommittee

(Invitation Only)

2:00 PM - 3:00 PM

Regency Foyer, Ballroom Level Plenary Reception

(Light Hors D'oeuvres)

2:00 PM - 3:00 PM

Gold Coast, Concourse Level **ORP Education Subcommittee** 

3:00 PM - 5:00 PM

Wrigley, Concourse Level Advocates Committee Meeting

(Committee Members Only)

3:00 PM - 4:30 PM

Regency A-C, Ballroom Level PLENARY I (TRANSLATIONAL

**MEDICINE**)

4:30 PM - 6:00 PM

Picasso, Concourse Level Federal Site Payment Transition

Office Hours (Open for Drop-Ins)

4:30 PM - 6:30 PM

Water Tower, Concourse Level Lymphoma Working Group

(Working Group Members Only)

4:30 PM - 6:30 PM

San Francisco, Ballroom Level

Drug Information Subcommittee and Pharmacy Working Group

(Working Group Members Only)

4:30 PM - 7:30 PM

Acapulco, Ballroom Level

Myeloma Working Group

(Working Group Members Only)

4:45 PM - 6:45 PM

Regency D, Ballroom Level

Palliative and End of Life Care

Committee In Development

5:00 PM - 7:00 PM

Comiskey, Concourse Level

Lung Working Group (Working

Group Members Only)

5:00 PM - 7:00 PM

Haymarket, Concourse Level

**Conflict Management Committee** 

(Committee Members Only)

6:00 PM - 9:00 PM

Crystal BC, Lobby Level

Translational Medicine Retreat on

Liquid Biopsies

7:00 PM - 9:00 PM

Gold Coast, Concourse Level

Latin American Symposium

(Invitation Only)



FRIDAY, OCTOBER 5, 2018

Group Meeting Registration & Information Desk 7:00 am— 5:00 pm— Regency Foyer, Ballroom Level, West Tower

Hope Foundation Information Desk 8:00 am— 5:00 pm— Regency Foyer, Ballroom Level, West Tower

Exhibits & Complimentary Coffee Service 7:00 am— 4:00 pm— Toronto/Hong Kong, Ballroom Level, West Tower

\* Unless otherwise indicated, all meetings are in the West Tower of the hotel

7:30 AM - 9:30 AM

Regency D, Ballroom Level CANCER SURVIVORSHIP COMMITTEE

7:30 AM – 9:30 AM

Gold Coast, Concourse Level Melanoma Working Group (Working Group Members Only)

7:30 AM - 9:30 AM

Crystal A, Lobby Level BARLOGIE-SALMON MYELOMA

COMMITTEE

7:30 AM - 9:30 AM

Comiskey, Concourse Level Imaging Committee (Committee

Members Only)

7:30 AM - 9:30 AM

Acapulco, Ballroom Level S1400 Administrative Meeting

(Invitation Only)

7:30 AM - 9:30 AM

Haymarket, Concourse Level SWOG Data and Safety Monitoring

Committee (Committee Members

Only)

8:00 AM - 9:00 AM

San Francisco, Ballroom Level Professional Review Committee (Committee Members Only)

8:00 AM - 10:00 AM

New Orleans, Ballroom Level Digital Engagement Committee

(Committee Members Only)

8:30 AM - 9:30 AM

Water Tower, Concourse Level Lung Surgery Subcommittee

(Committee Members Only)

9:00 AM - 10:00 AM

Crystal C, Lobby Level S1602 and S1605 Joint Protocol

Meeting

9:00 AM - 11:00 AM

Plaza Ballroom, Lobby Level,

East Tower SURGERY COMMITTEE

9:30 AM - 10:30 AM

Water Tower, Concourse Level Lung Radiation Subcommittee

(Committee Members Only)

9:30 AM - 11:30 AM

Crystal B, Lobby Level MELANOMA COMMITTEE

10:00 AM - 11:30 AM

Gold Coast, Concourse Level S1714 Certification Meeting

10:00 AM - 11:30 AM

Haymarket, Concourse LevelQuality Assurance Committee

Meeting (Committee Members

Only)

10:00 AM - 12:00 PM

**Crystal A, Lobby Level** Breast Working Group Meeting

(Working Group Members Only)

10:30 AM - 11:30 AM

Water Tower, Concourse Level Lung Translational Medicine

Subcommittee (Committee

Members Only)

10:30 AM - 12:00 PM

Regency D, Ballroom Level Bone Marrow & Stem Cell

Transplantation Committee



10:30 AM - 12:00 PM

Crystal C, Lobby Level S1806 Kick-Off Meeting

11:00 AM - 12:00 PM

Comiskey, Concourse Level S1316 Protocol Update Meeting

(Invitation Only)

11:00 AM - 12:00 PM

New Orleans, Ballroom Level GI Translational Medicine Working

Group (Working Group Members

Only)

11:00 AM - 12:00 PM

**Regency Foyer, Ballroom Level** Plenary Reception (Light Hors

D'oeuvres)

12:00 PM - 2:00 PM

**Regency A-C, Ballroom Level** PLENARY II (GENERAL)

2:00 PM - 3:30 PM

Gold Coast, Concourse Level S1501 Kick-Off Meeting

2:15 PM - 3:15 PM

Crystal C, Lobby Level NCORP/MU-NCORP Site PI Meeting

2:15 PM - 4:15 PM

**Acapulco, Ballroom Level** GI Working Group (Working Group)

Members Only)

2:15 PM - 4:15 PM

Plaza Ballroom, Lobby Level,

**East Tower** Breast Translational Medicine

Working Group (Working Group

Members Only)

2:30 PM - 4:00 PM

**Regency D, Ballroom Level** S1400 Lung-MAP Update Meeting

2:30 PM - 4:00 PM

New Orleans, Ballroom Level VA Working Group

(Invitation Only)

2:30 PM - 4:00 PM:

**Columbian, Concourse Level** Immunotherapeutics Meeting

(Invitation Only)

2:30 PM - 4:30 PM

Comiskey, Concourse Level Leukemia Working Group

(Working Group Members Only)

2:30 PM - 6:15 PM

Crystal A, Lobby Level GU COMMITTEE PART I: Prostate

Cancer (2:30-4:15); TM (4:15-5:30); Cancer Control (5:30-6:15)

3:00 PM - 5:00 PM

Wrigley, Concourse Level ORP Planning Meeting (Committee

Members Only)

4:00 PM - 6:00 PM

Water Tower, Concourse Level Recruitment and Retention

Committee Meeting (Committee

Members Only)

4:00 PM - 7:00 PM

Crystal B, Lobby Level LYMPHOMA COMMITTEE

4:30 PM - 6:30 PM

San Francisco, Ballroom Level Pharmaceutical Sciences

Committee

4:30 PM - 6:30 PM

Regency B, Ballroom Level GI COMMITTEE

4:30 PM - 7:30 PM

Regency A, Ballroom Level LUNG COMMITTEE

6:00 PM - 7:00 PM

Executive Reception (Invitation Only)

6:45 PM - 8:00 PM

**Regency CD, Ballroom Level** Reception

8:00 PM - 10:00 PM

**Comiskey, Concourse Level** Early Therapeutics Working Group

(Invitation Only)





#### SATURDAY, OCTOBER 6, 2018

Group Meeting Registration & Information Desk 7:00 am— 11:00 am— Regency Foyer, Ballroom Level, West Tower

Hope Foundation Information Desk 8:00 am— 11:00 am— Regency Foyer, Ballroom Level, West Tower

#### \* Unless otherwise indicated, all meetings are in the West Tower of the hotel

7:15 AM - 8:00 AM

**Regency B, Ballroom Level** Board of Governors (Board

Members Only)

8:15 AM - 9:15 AM

**Regency B, Ballroom Level** Committee Chairs (Committee

Chairs Only)

9:30 AM - 11:30 AM

Crystal C, Lobby Level RADIATION ONCOLOGY

COMMITTEE

9:30 AM - 11:30 AM

Regency A, Ballroom Level LEUKEMIA COMMITTEE

9:30 AM - 12:30 PM

Crystal B, Lobby Level BREAST COMMITTEE

9:30 AM - 12:30 PM

Crystal A, Ballroom Level GU COMMITTEE PART II:

Renal Cancer (9:30-11:00 am); Bladder Cancer (11:00 am -12:30 pm)

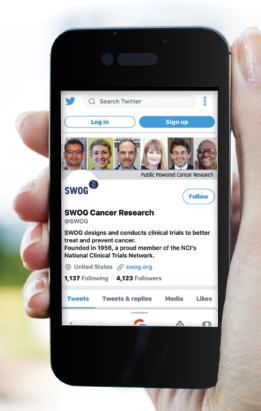
# Tweet the meeting

Our Twitterverse is expanding fast!

We've got more than 5,000 followers of @SWOG.

Be one of them. Follow us! And post your meeting tweets with the hashtag





### 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.

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!



### Barlogie-Salmon Myeloma Committee

#### Leadership Vice-Chair: ..... Brian G.M. Durie, M.D. Executive Officer.....Susan M. O'Brien, M.D. Statisticians: ...... Antje Hoering, Ph.D. ...... Rachael Sexton, M.S. ...... Kari Chansky, M.S. Scientific Leadership Translational Medicine: ..... Brian A. Walker, B.Sc., Ph.D. Radiation: TBD Surgery: ...... J. Sybil Biermann, M.D. Imaging:.....Saad Z. Usmani, M.D. ..... Eric M. Rohren, M.D., Ph.D. Pathology: ...... Robert B. Lorsbach, M.D., Ph.D. Early Therapeutics:..... Frits van Rhee, M.D., Ph.D. Designates Data Coordinators: Jeri Jardine .....Laura Kingsbury, M.R.T. ......Sean O'Bryan .....Joanna Dur **Oncology Research Professionals:** CRA: ...... TBD Nurses: ..... Deborah A. Shaw, R.N. Patient Advocate:......Jack Aiello, M.S. Pharmaceutical Science: ...... Lara M. Au, Pharm.D.

...... Craig Elg, Pharm.D.

#### Time/Location

Friday, October 5, 2018 7:30 am— 9:30 am

Room: Crystal A (Lobby Level)

#### **Active Studies**

<u>S1702</u>, "A Phase II Study of Isatuximab (SAR650984) for Patients with Previously Treated AL Amyloido-sis." Drs. Scott, Sanchorawala, and Walker. Activated: 3/8/18.

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. Zonder. Activated: 11/13/13.

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. Manasanch. Activated: 12/23/15.

#### **Closed Studies**

<u>S0777</u> "A Randomized Phase III Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexame-thasone (LLD) Versus Bortezomib (PS-341, NSC-681239), Lenalidomide And Low Dose Dexamethasone (BLLD) for Induction, in Patients with Previously Untreated Multiple Myeloma Without an Intent for Imme-diate Autologous Stem Cell Transplant." Drs. Durie and Barlogie. Activated: 2/28/08; Closed: 2/1/12.

<u>S1211</u>, "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. Usmani, Ailawadhi, and Lipe. Activated: 10/12/12; Closed: 5/15/18.

<u>S1304</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. Ailawadhi, Abidi, S. Lentzsch, et al. Activated: 10/18/13; Closed: 5/15/16.



CTSU/E3A06, "Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma." Dr. Dhodapkar. Activated: 10/5/10; Closed: 7/27/17.

#### **Proposed Studies**

- <u>S1611</u>, "A Phase II Non-Randomized Study of 11-1F4 Chimeric Monoclonal Ab Added to Standard Induc-tion Therapy in Untreated Subjects with Light Chain (AL) Amyloidosis." Dr. Lentzsch.
- <u>S1803</u>, "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. Krishnan, Hari, Wallace, et al.
- <u>\$1825:</u> "Randomized Phase II Trial of Weekly Carfilzomib ± Selinexor in Relapsed Multiple Myeloma (MM)." Dr. Zonder.
- "Randomized Phase III Study of Optimal Therapy for Newly Diagnosed High Risk Multiple Myeloma." Drs. Lipe and Usmani.
- "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 Immunomodulato-ry-Based Regimen for Multiple Myeloma." Drs. Calverley, Meyers, and Scott.

#### **Open Forum Discussion**

#### **Working Groups**

Amyloidosis Working Group update

Waldenström's Working Group update

Myeloma Translational Medicine Subcommittee update

### Barlogie-Salmon Myeloma Committee

#### Cumulative Accrual by Institution and Study

"Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51211	51702	EIATT	E3A06
Arkansas, U of	_	_	3	_
Baylor College	_	_	8	_
Beaumont NCORP	_	_	4	_
CORA NCORP	_	_	1	_
CRC West MI NCORP	1	_	_	_
City of Hope Med Ctr	7	_	_	_
Cleveland Clinic OH	10	_	_	_
Columbus NCORP	4	_	_	_
Davis, U of CA	_	_	20	_
Dayton NCORP	1	_	2	_
Essentia HIth NCORP	1	_	_	_
Greenville NCORP	_	_	_	6
Hawaii MU-NCORP	_	_	1	_
Heartland NCORP	3	1	_	_
Henry Ford Hospital	_	_	13	1
Irvine, U of CA	_	_	6	1
Kaiser Perm NCORP	_	_	31	
Kansas City NCORP	1	_	_	_
Kansas, U of	13	_	2	 15
Loyola University	3	1	8	
MD Anderson CC	10		8	_
Michigan CRC NCORP	5		_	_
Michigan, U of	,	_	<u> </u>	<del>-</del>
Montana NCORP	_	_	3	2
Nevada CRF NCORP	_	_	1	_
Oklahoma, Univ of	1	_	1	_
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Oregon HIth Sci Univ Ozarks NCORP	2	,		_ 1
	2	_	6	-
PCRC NCORP	4	_	10	1
Providence Hosp	-	_	10	2
Rochester, Univ of	7	_	_	_
San Antonio, U of TX	15	_	8	_
So Calif, U of	2	_	_	_
Southeast COR NCORP	4	_	10	_
Sutter Cancer RC	_	_	6	_
Tennessee, U of	_	_	_	1
Tulane University	1	_	_	2
VAMC Kansas City	_	_	4	_
Wayne State Univ	3	_	12	_
Yale University	_	_	40	3
Alliance	10	_	_	_
ECOG-ACRIN	31		_	_
NRG	3	_	_	_
Total	142	3	208	35

#### Leadership

Chair:	Lajos Pusztai, M.D., Ph.D.
Vice-Chair:	Priyanka Sharma, M.D.
Executive Officer:	Julie R. Gralow, M.D.
Statisticians:	William E. Barlow, Ph.D.
	Danika Lew, M.A.
	Jieling Miao, M.S.
Scientific Leadership	-
Translational Medicine:	Alastair M. Thompson, M.D.
	Andrew K. Godwin, Ph.D.
Radiation Oncology:	Reshma Jagsi, M.D.
	Christine Lee, M.D.
	Joanne E. Mortimer, M.D.
	Wei Tse Yang, M.B.B.S.
	David L. Rimm, M.D.
= 1	George Somlo, M.D.
Designates	J ,
•	Melinda L. Irwin, Ph.D., M.P.H. (Survivorship)
D	awn L. Hershman, M.D. (Cancer Care Delivery)
	Banu Arun, M.D. (Prevention)
	lelen K. Chew, M.D. (Symptom Control & QOL)
	Philip Lammers, M.D.
•	Iris Syquia
	Larry Kaye
	Jacqueline Scurlock
	Sewan Gurung
Oncology Research Professi	
• •	Karyn N. Hart, C.C.R.P.
	Dorothy Coleman, R.N., M.S.
r rotocor coordinator	

#### Time/Location

Saturday, October 6, 2018 9:30 am— 12:30 pm

Room: Crystal B (Lobby Level)

#### Agenda

<u>9:30 – 9:35 am</u> Welcome and Introductions – Lajos Pusztai, M.D. D.Phil and Priyanka Sharma, M.D.

<u>9:35 – 10:40 am</u> Breast Committee Mini-Symposium: "Improving Precision of Next Generation Clinical Trials using Liquid Biopsy Tools"

9:35 – 9:50am "Selection and Molecular Profiling of Circulating Tumor Cell (CTC) Subpopulations: Interrogating CTCs undergoing Epithelial-to-Mesenchymal Transitions (EMT)" Steven Soper, PhD

<u>9:50 – 10:05am</u> "The Time-Space-Continuum of Breast Cancer: Scientific Discovery with Single Cell Proteogenomics in Solid and Liquid Biopsies" Peter Kuhn PhD

10:05- 10:20am "Potential Clinical Utility of Plasma-based Comprehensive Genomic Profiling in Advanced Breast Cancer" Rick Lanman

10:20 – 10:40 am Panel discussion and audience Q & A

10:40 – 10:50 am Publications update - Bill Barlow, Ph.D.

<u>10:50 – 11:45 am</u> Update of open SWOG and SWOG-Championed CTSU trials - All

11:45 - 11:55 am Studies in Development - All

<u>11:55 – 12:10 pm</u> Reports from Committee Liaisons

Patient Advocate - Ginny Mason and Elda Railey

Radiotherapy - Reshma Jagsi, M.D.

Surgery - Christine Lee, M.D.

Cancer Survivorship - Melinda L. Irwin, Ph.D., M.P.H.

Cancer Care Delivery - Dawn Hershman, M.D.

Prevention – Banu Arun, M.D.

Symptom Control & QOL- Helen K. Chew, M.D.

NCORP (NCI Community Oncology Research Program)

<u>12:10 – 12:25 pm</u> Translational Medicine Sub-Committee Update – Alastair Thompson, M.D. and Andrew K. Godwin, Ph.D

12:25 - 12:30 pm New Business - All

12:30 pm Closing Comments and Adjourn



#### **Active Studies**

- <u>S1207</u>, "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.
- S1416, "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.
- S1418, "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.
- <u>S1706</u>, "A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer." Dr. Jagsi. Activated: TBD.
- 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.
- <u>CTSU/A221405</u>, "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 EA1151, "Tomosynthesis Mammographic Imaging Screening Trial (TMIST)." Dr. Pisano. SWOG Champion: TBD. Activated by ECOG-ACRIN 7/6/17. SWOG champion letter forthcoming.
- 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/NRG-BR005, "A Phase II Trial Assessing the Accuracy of Tumor Bed Biopsies in Predicting Pathologic Response in Patients with Clinical/Radiologic Complete Response after Neoadjuvant Chemotherapy in Order to Explore the Feasibility of Breast Conserving Treatment without Surgery." Dr. Basik. SWOG Champion: Dr. Thompson. Activated: 4/13/17.
- 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. SWOG champion Dr Jagsi. Activated: 08/22/13.
- 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.



# Helping SWOG Do More Since 1993

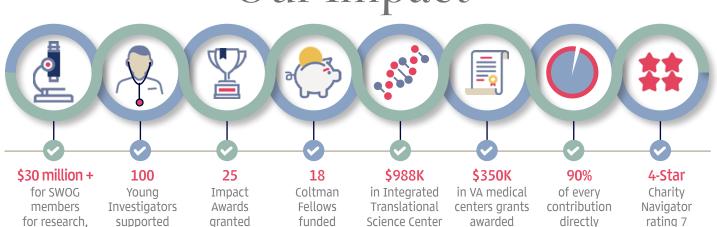
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# Our Impact



grants funded

invested in

**SWOG** 

consecutive

years

education,

and travel

#### **Active and Developing Cancer Control Studies**

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, 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. Activated: 9/15/17.

<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. Accordino.

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.

#### **Closed Studies**

<u>S1007</u>, "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**

S1200, "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**

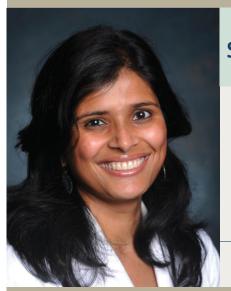
<u>\$1609</u>, "DART: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors." Drs. Patel and Chae. Activated 1/13/17.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)". Dr. Villalobos. Activated 07/15/2015.

#### **Studies in Development**

<u>S1807</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.

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.



### SWOG Early Exploration and Development (SEED) Fund

Apply by: **December 1, 2018**tinyurl.com/SWOG-SEED

Uma Borate, MD, MS, 2017 SEED Fund Grantee



#### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51007	51207	51416	51418	A011706	A011202	A011203	A017407	A017502	A227405	B51	855	EIZI	E2112	EA1131	EA1151	NRGBROS	NRGBRO	NRGBROOS
Arizona MC, U of	_	14	_	_	25	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Arkansas, U of	22	16	_	7	_	_	_	2	_	_	_	_	_	_	_	_	_	_	_
Atlanta Reg CCOP	11	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baptist MU-NCORP	1	5	1	_	10	1	1	6	_	_	_	_	1	1	_	_	_	1	_
Bay Area NCORP	3	1	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Baylor Univ Med Ctr	_	2	_	_	_	1	_	_	_	_	2	_	_	_	_	_	_	_	_
Beaumont NCORP	30	7	2	_	_	4	_	3	2	_	1	_	3	_	_	_	1	_	_
Boston Medical Ctr	_	2	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Brooke Army Med Ctr	2	_	_	2	_	_	_	_	1	_	_	1	_	_	2	_	_	1	_
CORA NCORP	16	18	1	6	1	_	_	_	_	_	2	_	1	3	_	_	_	_	_
CRC West MI NCORP	7	9	3	9	_	_	_	1	_	_	_	_	2	_	_	_	_	_	_
Carle CC NCORP	_	5	2	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Cedars-Sinai Med Ctr	8	9	_	_	_	_	_	_	_	_	_	6	_	_	_	_	_	_	_
Cincinnati MC, U of	3	9	_	_	_	_	_	_	_	_	1	_	4	_	_	_	_	_	_
City of Hope Med Ctr	45	21	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Cleveland Clinic OH	27	12	7	2	_	_	_	_	_	_	1	2	_	16	_	_	_	6	_
Colorado, U of	29	15	4	5	12	30	_	12	3	7	1	2	2	_	_	_	_	_	_
Columbia MU-NCORP	16	6	_	2	_	_	_	_	_	_	_	_	17	2	_	_	_	_	_
Columbia University	2	_	_	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_
Columbus NCORP	18	15	7	4		_	_	_	_	_	_	_	2	_	_	_	_	_	_
Davis, U of CA	8	7	8	3		2	_	_	7	_	_	_	1	_	_	_	_	_	_
Dayton NCORP	6	6	4	_	2	_	_	1	_	_	_	_	2	_	_	_	_	_	_
Desert Hospital	2	1	_	_	_	3	_	_	_	_	4	_	_	_	_	_	_	_	_
Essentia HIth NCORP	_	3	_	1		_	_	_	_	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	6	21	8	3	_	_	_	3	2	2	_	2	_	2	_	_	_	_	_
Georgia NCORP	_	2	_	5	_	_	_	2	_	_	_	_	8	_	_	_	_	_	_
Greenville NCORP	4	_	2	1		_	_	_	_	_	_	_	12	_	_	_	_	_	_
Gulf Coast MBCCOP	2	_	_			_	_	_	_	_	_	_		_	_	_	_	_	_
Gulf South MU-NCORP	6	19	_	2	_	_	_	_	_	_	_	_	5	_	_	_	_	3	_
H Lee Moffitt CC	2	5	_			1	_	3	2	_	_	_	_	_	_	_	_	_	_
Harrington CC	2	1	_	_		4	_	2		_	_	_	_	_	_	_	_	_	_
Harrison Medical Ctr	9	<u> </u>	_	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	12	12	_	_		_	_	_	_	_	_	_	20	_	_	_	_	_	_
Heartland NCORP	12	24	4	7		_	_	_	1	_	_	_	_	_	_	_	_	_	_
Henry Ford Hospital	11	6		_		_	_	_		_	_	_	_	1	1	_	_	_	_
INC, Bogota	11	_	_	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_
INC, Bogota INCan	96	_	_	_		_	_	_	_	_	_	_	_		_	_	_	_	_
Intermountain MC	5	_	_	_		_	_	_	_	_	_	_	_	_	_	_	_	_	_
	21	10		1	3	3	_	2	_	_	_		_	_	_	_	_	_	_
Irvine, U of CA Kaiser Perm NCORP	89	41	7	11	_	1	2	25	3		_	5	32			_	_	13	_
	11	8	_	1	_	_	_	_	_	_	_	_			_	_	_	_	_
Kansas City NCORP	33	44	_	7		4		10	_		_	1	_	9		_	_	1	1
Kansas, U of	21			_	_	_	_	_	_	_					_	_	_	-	· —
Kentucky, U of	3		_		_		_	_	_		_			_	_		_		_
King Faisal Spec Hos	19	4			_			1	_	_							_		_
Lahey Hosp & Med Ctr	19 5	10	_			2		_	_		3		_						
Loma Linda Univ			_	2		_		4			1		_						_
Loyola University	30	14	2	2	_	_	_	7	_	_	,	_		_	_	_	_	_	



#### **Cumulative Accrual by Institution and Study**

*Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.* 

	51007	51207	57476	57478	A011706	4011505	A011203	A017407	A071502	A227405	B51	855	EIZII	E2112	EA1131	EA1151	NRGBRO	NRGBRO	03 NRGBROOS
MD Anderson CC	147	79	_	3	_	· 	,. 	<i>''</i> -	·	·		_	_	_	_	_	·	· 	_
MUSC MU-NCORP	21	10	7	3	1	_	_	_					5	_	_				_
	3	_	_	_		_					_		,						
Madigan Army Med Ctr		2		_		_					_								_
Memorial Hermann	7	_		_		_			_		_								_
Methodist Hospital	44	22	11	4		_			_		_		_		_				
Michigan CRC NCORP		18	5	3			_	5	<u> </u>	_	_	1	11	_	_			_	
Michigan, U of	29	_	,	_				,	3		_	,	11	_	_			3	_
Mississippi, Univ of	4	8	2	_			_	_	_	_	_	_	4	_	_	_	_	_	
Montana NCORP	9		2				_	_	_	_	_		4	_	_			_	_
National Cancer Ctr	143	_	_				_	_	_	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	1	1	10	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	27	25	10	3	'	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	28	9	_	1	_		_	_	_	_	_	1	_	_	_	_	_	_	_
Northwestern Univ	3	14	_	_	_	_	4	_	_	1	_	_	_	2	_	_	_	1	_
Oklahoma, Univ of	8	9	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Oregon Hlth Sci Univ	4	23	3	2	_	1	_	_	_	_	1	_	_	_	_	_	_	1	_
Ozarks NCORP	9	14	4	1	_	_	_	_	_	_	_	_	9	_	_	_	_	3	_
PCRC NCORP	31	17	3	2	_	_	_	1	_	_	_	_	6	_	_	_	_	1	_
Providence Hosp	8	8	1	2	1	3	_	5	1	_	5	1	2	_	_	_	_	3	_
Rochester, Univ of	7	5	_	_	_	_	_	_	_	_	_	_	_	3	1	77	_	3	_
San Antonio, U of TX	25	21	_	3	1	_	_	_	_	_	2	1	_	4	_	_	_	4	_
San Diego, U of CA	9	_	_	_	_	_	_	2	_	_	_	_	_	_	_	_	_	1	_
Scott & White Mem	_	_	_	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
So Calif, U of	15	14	_	_	_	2	_	_	_	_	_	1	_	_	_	_	_	_	_
Southeast COR NCORP	38	30	4	13	_	_	_	1	6	_	_	_	_	_	_	76	_	_	_
St Louis CCOP	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
St Louis University	1	1	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC		10	1	_	4	_	_	4	1	_	1	_	_	_	_	_	_	2	_
Tennessee, U of	5	8	_	_	_	5	_	_	_	_	4	_	_	_	_	_	_	_	_
Tulane Univ MBCCOP	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Tulane University	6	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Univ of Louisville	8	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Upstate Carolina	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	18	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Wayne State Univ	23	15	_	_	_	8	_	7	2	_	_	3	_	3	3	_	_	6	_
Wichita NCORP	57	30	3	4	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Wisconsin NCORP	_	1	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Yale University	24	46	_	2	2	_	_	58	14	1	_	1	2	6	4	_	_	6	_
Alliance	526	243	46	19	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
CCTG	328	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	713	222	31	26	_	_	_	_	_	_		_	_	_	_	_	_	_	_
GEICAM	792	_	_	_		_	_	_	_				_	_	_	_	_		_
NRG	265	353	48	56	_	_	_	_	_	_			_	_	_	_	_		_
UNICANCER	1,022	_	_	_	_	_	_		_					_	_				_
	5,083	1.664	245	236	64	77	7	162	50	11	29	28	151	52	11	153	1	59	1
Total	3,003	.,004	213		04	,,	,	102	50	, ,	27	20	131	JZ		. 33	•	33	•



### **Cancer Control & Prevention Committee**

Leadership
Vice-Chair NCORP:Dawn L. Hershman, M.D., M.S.
Cancer Care Delivery Cmte Co-Chairs: Dawn L. Hershman, M.D., M.S.
Scott D. Ramsey, M.D., Ph.D.
Cancer Survivorship Cmte Co-Chairs: Halle C.F. Moore, M.D.
Melinda L. Irwin, Ph.D., M.P.H.
Palliative & End of Life Cmte Co-Chairs:Robert S. Krouse, M.D., F.A.C.S.
Prevention & Epidemiology Cmte Co-Chairs: Banu Arun, M.D.
Symptom Control & QOL Cmte Co-Chairs: Michael Fisch, M.D., M.P.H.
Norah Lynn Henry, M.D., Ph.D.
Executive Officers:Katherine D. Crew, M.D. (Palliative, Prevention,
Survivorship)
Gary Lyman, M.D. (CCD, Symptom Control & QOL)
Senior Advisor: Frank L. Meyskens, Jr., M.D.
Statisticians:
William E. Barlow, Ph.D.
Joseph M. Unger, Ph.D.
Kathryn B. Arnold, M.S.
Phyllis J. Goodman, M.S.
Danika Lew, M.A.
Anna Moseley, M.S.
Eddie Mayerson, M.S.
$Administrative \ Lead\ Statistics\ \&\ Data\ Management \ .\ Monica\ Yee, C.C.R.P.$
Scientific Leadership
NCORP Representative: Mark A. O'Rourke, M.D.
$\label{lem:constraint} {\sf Radiation\ Oncology\ Committee:} Louis\ {\it ``Sandy''\ Constine,\ M.D.}$
Surgery Committee:Robert S. Krouse, M.D.FACS
Translational Medicine: James (Jimmy) Rae, Ph.D.
Liaisons:
Breast Committee: Melinda L. Irwin, Ph.D., M.P.H. (Survivorship)
Helen K. Chew, M.D. (Symptom Control & QOL)
Dawn Hershman, M.D, M.S. (CCD)

...... Banu Arun, M.D. (Prevention)

CCDR Committee:
Designates
Oncology Research Professionals
Clinical Research Associates: Amanda R. Dinsdale, M.H.A., C.C.R.C.
Mindy Whisnant, C.C.R.P.
Nurses: Joan Long, R.N., O.C.N.
Joyce N. Tull, R.N.
Pharmaceutical Sciences Committee: Kimberly McConnell, Pharm.D.
Siu-Fun Wong, Pharm.D.
Sun "Coco" Yang, Pharm.D., Ph.D.
SDMC Data Coordinators and Staff:
Kimberly Carvalho
Diane Liggett
Roxanne Topacio
Monica Yee
Recruitment and Retention Specialist: Jennifer Maeser, M.S.
Patient Advocates: Barbara Segarra-Vazquez, D.H.Sc. (CCD)
Hartley "Lee" M. Jones, M.B.A. (Survivorship)
Sandra Jean Hamilton, R.N., 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):
Protocol Coordinator (Symptom Control and
Quality of Life Committee):



# Cancer Control and Prevention Committees

#### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	50820	A277702	A217201	EATTAT
Baptist MU-NCORP	3	_	_	_
Brooke Army Med Ctr	2	_	_	_
CORA NCORP	3	_	_	_
CRC West MI NCORP	1	_	_	_
City of Hope Med Ctr	1	2	_	_
Colorado, U of	4	_	_	_
Columbia MU-NCORP	1	1	2	_
Columbus NCORP	4	_	_	_
Dayton NCORP	1	_	_	_
Essentia HIth NCORP	4	_	_	_
Georgia NCORP	2	_	_	_
Hawaii MU-NCORP	7	_	_	_
Heartland NCORP	2	_	_	_
Irvine, U of CA	20	_	_	_
Kaiser Perm NCORP	24	_	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	_	_	_
New Mexico MU-NCORP	1	_	_	_
Northwest NCORP	6	_	_	_
Oklahoma, Univ of	1	_	_	_
PCRC NCORP	1	_	_	_
Providence Hosp	1	_	_	_
San Antonio, U of TX	8	_	_	_
So Calif, U of	5	_	_	_
Southeast COR NCORP	1	_	_	_
Wayne State Univ	2	_	_	_
Wichita NCORP	11	_	_	_
Yale University	11	_	_	_
Alliance	21	_	_	_
ECOG-ACRIN	15	_	_	_
NRG	22	_	_	_
Total	208	3	14	44

# Save the date for the spring 2019 meeting

April 24-27 | San Francisco, CA



### guidebook

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- Open Guidebook and look for the guide:

SWOG Fall 2018 Group Meeting





### Cancer Care Delivery (CCD) Committee

#### Leadership

Co-Chairs: ...... Dawn L. Hershman, M.D., M.S. ..... Scott D. Ramsey, M.D., Ph.D.

#### Time/Location

Thursday, October 4, 2018 8:00 am— 10:00 am Room: Regency C (Ballroom Level)

#### Agenda

**CCDR Updates -** Drs. Dawn Hershman and Scott Ramsey

#### **Presentations/Concepts**

The Maine Cancer Genomics Initiative – A Unique Precision Medicine Collaboration between JAX and Rural Oncology Practices in Maine, Jens Rueter, M.D., Medical Director, Q/A with Dr. Ed Liu, CEO and President, Maine Cancer Genomics Initiative, The Jackson Laboratory.

The Role of Informal Support Persons in Receipt of High Quality Cancer Care Across the Continuum, Christine Veenstra, M.D, Q/A with Sarah Hawley, PhD, MPH, University of Michigan.

Improving Health Insurance Experiences for Adolescent and Young Adult Cancer Patients, Anne Kirchhoff, PhD, MPH, Huntsman Cancer Institute.

Newly Activated Study - S1703, "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. Activated: 7/16/18.

Results from S1204, "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.

#### **Active Studies**

S1400 (Genomics), "Ancillary Study to Evaluate Patient & Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in SWOG 1400 (Lung-MAP)." Dr. Roth. Activated: 2/5/18.

<u>S1415CD</u>, "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, Hershman, 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. Shankaran. Activated: 4/15/16.

#### **Concepts Submitted to DCP**

<u>S1908</u>, "A Prospective, Patient-Level Survey Evaluating Health Insurance Coverage as a Barrier to Enrollment in Adult Cancer Treatment Clinical Trials." Dr. Roth, Fred Hutchinson Cancer Research Center.

Sta21, "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. Mougalian, Yale University (Primary committee is Symptom Control/QOL)

#### **Concepts in Development**

Feasibility of a Digital Health Offering in Optimizing Opioid Pain Control in Cancer Patients. Drs. Hershman and Shen, Columbia University Medical Center. (Pilot study sponsored by Proteus).

Randomized Trial of a Proactive Financial Navigation Intervention for Cancer Patients and Caregivers. Dr. Shankaran, University of Washington

A Pilot Project to Identify Techniques to Raise Awareness about SWOG Clinical Trials on an Online Oncologist Q&A Network. Dr. Housri, Yale Cancer Center (SEED Funded Pilot Trial).

Optimizing Clinical Work Intensity Among Medical Oncologists. Dr. Hudson, Greenville Health System (Abstract accepted for poster presentation to ASCO Quality Care Symposium, 2018)

### Substudies (Economic Analyses / Cost Effectiveness from NCTN trials)

<u>S1007</u>, Update on Quality of Life and Economic Analysis Sub-study of Breast protocol S1007. Dr. Barlow.



### **Cancer Care Delivery Committee**

<u>S1207</u>, 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.

<u>S1806</u>, Healthcare Cost Comparison of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle-invasive Bladder Cancer, Dr. R. Vaidya, Dr. Unger.

S1826, Health Economic Substudy of "Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) Plus AVD in Patients with Newly Diagnosed Advanced Stage Classical Hodgkin Lymphoma". Drs. Prica, Cheung, Parsons, and Vaidya.

#### **Updates on Closed Studies and Projects**

<u>PCORI Project:</u> A Structured Approach to Prioritizing Cancer Research Using Stakeholders and Value of Information (VOI). Drs. Ramsey and Carlson.

#### **Database/Grant Funded Projects**

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

#### **Database Studies**

Development of Prognostic Risk Models for Response to Treatment and Placebo for Aromatase Inhibitor-Associated Musculoskeletal Symptoms. Dr. Henry.

Analysis of Accrual Patterns of Adolescent & Young Adult (AYA) Patients to A National Cooperative Research Group Over 25 years: The SWOG Experience. Dr. Lewis.

#### **Database Pilot Studies**

Ethnic disparities among participants in SWOG randomized clinical trials. Dr. Chavez. (Cancer, 2018)

Osteoporosis in Patients with Colorectal Cancer Enrolled on SWOG Trials. Dr. Barzi. (Manuscript submitted)

Evaluating the role of geographic location on outcomes among patients enrolled in SWOG trials. Dr. Symington. (JAMA Network Open)

### **Cancer Care Delivery Committee**

#### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	s120 <sup>4</sup>	514 <sup>15</sup> CD	5147700	A071704	A197402C
Baptist MU-NCORP	_	65	_	1	_
Bay Area NCORP	92	19	2	_	_
Beaumont NCORP	_	3	_	_	4
Boston MC MBCCOP	33	_	_	_	_
Boston Medical Ctr	69	_	_	_	_
Brooke Army Med Cr	_	_	_	2	_
CORA NCORP	_	38	15	_	_
CRC West MI NCORP	_	16	16	_	_
Carle CC NCORP	_	60	1	_	_
Columbia MU-NCORP	266	65	9	_	_
Columbus NCORP	_	16	22	_	_
Dayton NCORP	_	22	4	_	_
Desert Hospital	77	_	_	_	_
Essentia HIth NCORP	_	61	_	_	_
GRU MU-NCORP	_	9	_	_	_
Georgia NCORP	_	32	9	_	_
Greenville NCORP	542	61	15	_	_
Gulf South MU-NCORP	426	49	9	_	_
Harrington CC	147	_	_	_	_
Hawaii MU-NCORP	86	39	3	_	_
Heartland NCORP	_	197	26	_	_
Kaiser Perm NCORP	624	_	34	_	6
Kansas City NCORP	_	1	_	_	_
Loyola University	74	_	_	_	_
MD Anderson CC	354	_	_	_	_
Michigan CRC NCORP	_	147	7	_	_
Montana NCORP	33	52	1	_	_
Nevada CRF NCORP	_	_	1	_	_
New Mexico MU-NCORP	_	94	4	_	_
Northwest NCORP	_	46	3	_	_
Ozarks NCORP	_	100	3	_	_
PCRC NCORP	6	136	8	_	_
Providence Hosp	_	_	_	8	_
Southeast COR NCORP	146	_	_	_	_
Sutter Cancer RC	_	107	9	2	_
VAMC Kansas City	10	_	_	_	_
Wayne State Univ	107	_	_	_	_
Wichita NCORP	_	_	_	1	_
Wisconsin NCO	_	60	6	_	_
RP	_	68	1	_	_
Alliance	_	184	19	_	_
ECOG-ACRIN	_	173	44	_	_
NRG	_	77	15	_	_
Total	3,092	1,997	286	14	10



### **Cancer Survivorship Committee**

#### Leadership

Co-Chairs: Halle C.F. Moore, M.D.
.....Melinda L. Irwin, Ph.D., M.P.H.

#### Time/Location

Friday, October 5, 2018 7:30 a.m.— 9:30 a.m. Room: Regency D (Ballroom Level)

#### **Agenda**

Survivorship Presentation: Wendy Demark-Wahnefried, PhD, RD, Professor and Webb Endowed Chair of Nutrition Sciences Associate Director, UAB Comprehensive Cancer Center, American Cancer Society Clinical Research Professor, University of Alabama at Birmingham

#### **Active Study**

<u>\$1501,</u> "Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer." Justin Floyd, D.O. and Monika Leja, M.D.

#### **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>\$1903,</u> "Breast Cancer Cardiovascular Risk Reduction Text Trial." Dawn Hershman, M.D.

#### **Update of Concepts Previously Proposed**

"A Phase II Trial of Flibanserin to Improve Desire in Women with Cancer." Don Dizon, M.D.

"Physical Function in Sarcoma Survivors." Lara Davis, M.D., Kerri Winters-Stone, Ph.D., F.A.C.S.M., Kim Templeton, M.D.

#### **New Ideas**

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

"Cardiac Evaluation and Monitoring in Oncology Patients Receiving Immunotherapy." Krishna Gunturu, M.D.

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

### **Cancer Survivorship Committee**

#### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51316	51501	E1011	EA9737
Arizona MC, U of	10	_	_	_
Arkansas, U of	6	_	_	_
Baylor College	1	_	_	_
City of Hope Med Ctr	4	_	_	_
Columbia MU-NCORP	1	_	_	_
Essentia Hlth NCORP	1	_	_	_
Georgia NCORP	_	1	_	_
Greenville NCORP	_	1	_	_
H Lee Moffitt CC	2	_	_	_
Hawaii MU-NCORP	_	_	12	_
Heartland NCORP	_	8	_	_
Kaiser Perm NCORP	_	_	_	9
Kansas, U of	16	2	_	_
Lahey Hosp & Med Ctr	_	2	_	_
Loyola University	_	3	_	_
MD Anderson CC	1	_	_	_
MUSC MU-NCORP	5	_	_	_
Michigan, U of	7	_	_	_
New Mexico MU-NCORF	1	_	_	_
Oklahoma, Univ of	2	_	_	_
Providence Hosp	_	1	_	_
San Antonio, U of TX	3	_	_	_
Tennessee, U of	31	_	_	_
Alliance	17	2	_	_
NRG	49	_	_	_
Total	157	20	12	9

"A Randomized study of Usual Care with or without Fracture Prevention Education and Postural and Spine Strengthening Exercise to improve quality of life and kyphosis angle in Cancer Patients." Cherie Hayostek, M.D.

"Immune Checkpoint Inhibitors and Female Fertility." Katy Tsai, M.D.

"Examining psychosocial and emotional issues commonly affecting patients undergoing therapy for metastatic kidney cancer." Cristiane Bergerot, M.D.

Patient Advocate Update: Lee Jones

**Other Business** 



# Palliative & End of Life Care Committee

### Leadership

Co-Chairs:	Robert S. Krouse, M.D
	Mark O'Rourke, M.D
	Marie Bakitas, D.N.Sc, C.R.N.P

### Time/Location

Thursday, October 4, 2018 4:45 pm— 6:45 pm Room: Regency D (Ballroom Level)

### **Agenda**

### Introduction

Description and status of "full committee": Frank Meyskens, M.D.

Introduction and welcome of Dr. Bakitas: Drs. Krouse and O'Rourke

### Plenary

Marie A. Bakitas, DNSc, NP-C, FAAN | Professor, Marie O'Koren Endowed Chair Associate Director | Center for Palliative and Supportive Care School of Nursing/Department of Medicine UAB | The University of Alabama at Birmingham

Advocate Update: Rick Bangs, M.B.A.

Introduction of new Advocate - TBD

### **Active Studies**

<u>S1316</u>, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15.

### **Proposed Studies (Approved)**

<u>S1820</u>, "A Personalized Dietary Intervention to Manage Bowel Dysfunction in Rectal Cancer Survivors." Dr. Sun.

# Proposed Concepts: 3 minute overview and 7 minute discussion each

- "A Cluster Randomized Phase II Trial of a Palliative Care Planning Intervention in Pancreatic Cancer." Dr. Sun.
- "Symptom Management of Treatment-Related Toxicities from Oral Targeted Agents in Metastatic Renal Cell Carcinoma Patients." Drs. Reding and Fung.
- "Hyperthermic Intraperitoneal Chemotherapy for High Volume Peritoneal Carcinomatosis of Colorectal and Appendiceal Adenocarcinoma Origin." Dr. Deneve.

"Tocilizumab for Cancer Patients with Cachexia: A Phase Ib/II Trial." Dr. Jafri.

"Exploring Intimacy for Patients in Palliative Care." Drs. Yung and Dizon.

"Intervention to Enhance Hopefulness for Providers and Patients." Dr. Corn.

"Clinical Trial using Ariadne Labs Serious Illness Care Program (SICP)
Implementation and PREPARE Advance Care Planning." Dr. O'Rourke

### **Other Business**

Clinical Advisory Panel to Palliative and End of Life Care Committee: Mark A. O'Rourke, M.D.



Dr. Charles A. Coltman, Jr. Fellowship Program

Apply by:

March 1, 2019

tinyurl.com/SWOG-Coltman

Mina Sedrak, MD, MS, 2017 Coltman Fellow



# **Prevention & Epidemiology Committee**

### Leadership

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

### Time/Location

Thursday, October 4, 2018 10:15 a.m.— 12:15 p.m.

Room: Regency C (Ballroom Level)

### **Agenda**

### Introduction

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

### **Presentation**

Aspirin for the Precision Prevention of Colorectal Cancer – Andrew Chan, M.D., Harvard Medical School, Clinical and Translational Epidemiology Unit, Massachusetts General Hospital

### **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. Zell, Brown, Lance, et al. Activated: 3/1/13.

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

### **Closed Studies**

**S0812**, "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. Crew. Activated: 11/1/11; Closed: 8/15/14.

### **New Business**

### **Concepts approved by Triage**

**S1823**, "miR-371-3a-p (miRNA371) for Biomarker-Based Care in Testicular Cancer". Drs. Nappi and Nichols.

**S1824**, "Exploratory Study to Evaluate Mammographic Density Changes in Patients Receiving Pembrolizumab in S1418." Dr. Arun.

<u>S1904</u>, "Cluster Randomized Controlled Trial of Patient and Provider Decision Support to Increase Chemoprevention Informed Choice Among Women With Atypical Hyperplasia Or Lobular Carcinoma In Situ." Dr. Crew.

<u>S1906</u>, "A Randomized Double-Blind Placebo-Controlled Biomarker Study of Aspirin in Addition to Non-Steroidal Aromatase Inhibitors in Women of High BMI (≥ 30 kg/m2) with Breast Cancer." Dr. Brenner.

### **Concepts Approved By NCORP Executive Committee**

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

### **Concepts in Development**

Project STOP (SWOG Tobacco Program for Oncology Practice). Dr. Tami-

Bazedoxefine + Conjugated Estrogen for Cancer Prevention in Women with Hot Flashes. Drs. Fabian and Nye.

Melanoma Chemoprevention. Dr. S. Leachman.

### Other Concepts to discuss

1. Open discussion



# Prevention & Epidemiology Committee

### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	50820	A211102	A271201	EATTAT
Baptist MU-NCORP	3	_	_	_
Brooke Army Med Ctr	2	_	_	_
CORA NCORP	3	_	_	_
CRC West MI NCORP	1	_	_	_
City of Hope Med Ctr	1	2	_	_
Colorado, U of	4	_	_	_
Columbia MU-NCORP	1	1	2	_
Columbus NCORP	4	_	_	_
Dayton NCORP	1	_	_	_
Essentia HIth NCORP	4	_	_	_
Georgia NCORP	2	_	_	_
Hawaii MU-NCORP	7	_	_	_
Heartland NCORP	2	_	_	_
Irvine, U of CA	20	_	_	_
Kaiser Perm NCORP	24	_	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	_	_	_
New Mexico MU-NCORP	1	_	_	_
Northwest NCORP	6	_	_	_
Oklahoma, Univ of	1	_	_	_
PCRC NCORP	1	_	_	_
Providence Hosp	1	_	_	_
San Antonio, U of TX	8	_	_	_
So Calif, U of	5	_	_	_
Southeast COR NCORP	1	_	_	_
Wayne State Univ	2	_	_	_
Wichita NCORP	11	_	_	_
Yale University	11	_	_	_
Alliance	21	_	_	_
ECOG-ACRIN	15	_	_	_
NRG	22	_	_	_
Total	208	3	14	44

# **Your SWOG Support Teams**

SWOG investigators can tap several research support committees for advice and resources as they develop and launch their clinical trials.

To find contact information for each committee, visit the "Member Resources" section of SWOG.org

# Recruitment and Retention Committee

For help enrolling minority, underserved, or special population patients



Elise Cook, MD, Recruitment and Retention Chair

# Digital Engagement Committee

For help incorporating digital tools, such as text messaging or apps, into trials



**Don Dizon, MD,** Digital Engagement Chair

# Adolescent and Young Adult Committee

For help enrolling patients aged 15-39 onto trials



Mark Lewis, MD, AYA Chair

# Pharmaceutical Sciences Committee

For help with investigational drug handling, interactions, and quality control



**Siu-Fun Wong,** PharmD, Pharmaceutical Sciences Co-Chair

# Symptom Control & Quality of Life Committee

### Leadership

Co-Chairs:	Norah Lynn Henry, M.D., Ph.D.
	Michael J. Fisch, M.D., M.P.H.

### Time/Location

Thursday, October 4, 2018 12:30 pm— 2:30 pm Room: Regency D (Ballroom Level)

### **Agenda**

### Feature Presentations (90 minutes):

Linda E. Carlson, Ph.D.: "Mindfulness Based Cancer Recovery"

Joe Unger, Ph.D., M.S.: "Key Design and Analysis Strategies for Patient-Reported Outcomes"

### Discussion

### **Updates on Trials under development (20 minutes)**

### Other Discussion Topics (10 minutes)

### Approved Trials (not yet active)

- <u>\$1600,</u> "Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes." Drs. Hamilton-Reeves and 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. Hwang, Lok, Ghering, et al.
- **<u>\$1714</u>**, "A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients." Drs. Trivedi, Hershman, Brannagan, et al.
- **S1821**<sub>r</sub> "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. Mougalian.

### **Other Concepts in Development**

- "mHealth Mindfulness Intervention to Improve Adjuvant Endocrine Therapy Symptoms and Adherence." Drs. Kubo and Greyz.
- "Integrative Mindfulness treatment for post-operative breast pain", Dr. Fukui.
- "A Randomized Phase II Trial of the Altering Intake, Managing Symptoms (AIMS) Intervention for Bowel Dysfunction in Rectal Cancer Survivorsz", Dr. Sun.

- "Emerging from the Haze™ (Haze) A randomized, wait-list controlled trial to measure the impact of a multi-dimensional psycho-educational program on perceived cognitive function after breast cancer treatment." Drs. Asher and Myers.
- "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. Wong, Ryan, Moinpour, et al.

### **Closed Studies**

- **S1200**, "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.
- **51202**, "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. Henry and Schott. Activated: 5/15/13; Closed: 10/1/15.

# 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. Chavez-MacGregor. Activated: 9/3/13.
- S1418, "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 Mammen, Henry, et al. Activated: 11/15/16.
- <u>S1706</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, Controlled Study of Tucatinib (ONT-380) Following Stereotactic Radiosurgery (SRS) HER2-Positive Breast Cancer Brain Metastases." Dr. Tsien.

### GU

<u>\$1802</u>, "Phase III Randomized Trial of Standard Systemic Therapy (SST)

Versus Standard Systemic Therapy plus Definitive Treatment (Surgery



# Symptom Control & Quality of Life Committee

or Radiation) of the Primary Tumor in Metastatic Prostate Cancer." Dr. Chapin.

<u>S-N1806</u>, "Phase III Randomized Trial of Concurrent Chemoradiotherapy with or Without Atezolizumab in Localized Muscle Invasive Bladder Cancer." Dr. 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. Michaelis, Walter, Assouline, et al. Activated: 12/22/17.

### Lung

- **S1400I**, "A Phase III Randomized Study of Nivolumab plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (LUNG-MAP Sub-Study)." Drs. Gettinger and Bazhenova. Activated: 12/18/15.
- <u>S1400GEN</u>, "Ancillary Study to Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results in S1400." Drs. Ramsey and Hershman. Activated: 2/5/18.
- **<u>\$1827</u>**, "PCI vs Active MRI Surveillance in Small-Cell Lung Cancer." Dr. Rusthoven.
- "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. 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. Brem and Smith.

### Melanoma

**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, Patel, Knopp, et al. Activated: 10/15/15; Closed: 11/2/17.

### Myeloma

<u>\$1803</u>, "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. Krishnan, Hari, Wallace, et al.

### Survivorship

"A Randomized study of Usual Care with or without Fracture Prevention Education and Postural and Spine Strengthening Exercise to improve quality of life and kyphosis angle in Cancer Patients." Dr. Hayostek.

### **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. Overman. Activated 11/7/17.
- CTSU/A021202, "Prospective Randomized Phase II Trial of Pazopanib (NSC #737754, IND 75648) Versus Placebo in Patients with Progressive Carcinoid Tumors." Dr. Phan. Activated: 6/21/13; Closed: 10/7/16.
- CTSU/A041202, "A Randomized Phase III Study of Bendamustine plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)". Dr. Coutre. Activated: 12/9/13; Closed: 5/16/16.
- 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. Gadgeel and Gaspar. Activated: 3/15/08; Closed: 8/30/17.
- CTSU/C51101, "A Randomized Phase II Trial of Myeloablative Versus Non-Myeloablative Consolidation Chemotherapy for Newly Diagnosed Primary CNS B-Cell Lymphoma." Dr. Mohile. Activated: 6/15/12; Closed: 5/2/17.
- 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. Kim. Activated: 12/15/06; Closed:10/2/15.
- CTSU/E1411, "Intergroup Randomized Phase II Four Arm Study in Patients with Previously Untreated Mantle Cell Lymphoma of Therapy with: Arm A = Rituximab + Bendamustine Followed by Rituximab Consolidation (RB -->R); Arm B = Rituximab + Bendamustine + Bortezomib Followed by Rituximab Consolidation (RBV--> R), Arm C = Rituximab+Bendamustine



# Patient Voice



Followed by Lenalidomide + Rituximab Consolidation (RB --> LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed by Lenalidomide + Rituximab Consolidation (RBV --> LR)." Dr. Till. Activated 5/22/12; Closed: 9/9/16.

- 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: 5/25/11; Closed: 7/26/16.
- 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. O'Brien. Activated: 2/20/14; Closed: 6/9/16.
- CTSU/E1A11, "Randomized Phase III Trial of Bortezomib, LENalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide, Dexamethasone (CRd) Followed by Limited or Indefinite DURation Lenalidomide MaintenANCE in Patients with Newly Diagnosed Symptomatic Multiple Myeloma (ENDURANCE)." Dr. Zonder. Activated: 12/2/13.
- 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. Pal. Activated: 8/8/12; Closed: 7/25/17.
- CTSU/E2906, "Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age ≥ 60 Years)." Dr. Godwin. Activated: 12/28/10; Temporarily Closed: 2/23/15.
- CTSU/E3A06, "Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma." Drs. Dhodapkar and Epstein. Activated: 10/5/10; Closed: 7/14/17.
- 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/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

# Symptom Control & Quality of Life Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51200	A221101	A227702	NRGGU003
Arkansas, U of	_	1	_	_
CORA NCORP	_	_	7	_
CRC West MI NCORP	68	_	_	_
Cleveland Clinic OH	_	_	_	3
Columbia MU-NCORP	29	_	_	_
Fred Hutchinson CRC	11	_	_	_
Greenville NCORP	15	_	_	_
Irvine, U of CA	_	8	_	_
Kaiser Perm NCORP	56	_	_	_
Kansas, U of	_	1	_	_
Kentucky, U of	_	1	_	_
Lahey Hosp & Med Ctr	10	_	_	_
Loma Linda Univ	_	2	_	_
Northwest NCORP	_	1	_	_
Oregon HIth Sci Univ	9	_	_	_
PCRC NCORP	20	_	1	_
Providence Hosp	_	3	_	_
San Antonio, U of TX	_	1	_	_
So Calif, U of	5	_	_	_
Sutter Cancer RC	_	1	2	_
Upstate Carolina	_	1	_	_
Utah, U of	3	_	_	_
VAMC Kansas City	_	_	_	3
Total	226	20	10	6

Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision." Dr. Eng. Activated: 1/13/12.

- CTSU/N107C, "A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease." Dr. Gaspar. Activated: 7/8/11; Closed: 12/18/15.
- CTSU/R0848, "A Phase II-R and a Phase III Trial Evaluating Both Erlotinib (Ph II-R) and Chemoradiation (Ph III) as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma." Dr. Philip. Activated: 11/17/09.
- CTSU/R1010, "A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma." Dr. Leichman. Activated: 12/30/10; Closed: 11/10/15.
- **Committee Process:** Sign and/or correct the meeting attendance/ contact list



# **Early Therapeutics & Rare Cancers Committee**

### Leadership

Chair:	Razelle Kurzrock, M.D.
Vice-Chair:	Young Kwang Chae, M.D., M.P.H.
Executive Officer:	Christopher W. Ryan, M.D.
Statisticians:	Megan Othus, Ph.D.
	Melissa Plets, M.S.
	Edward Mayerson, M.S.
Designates	
Data Coordinators:	Christine McLeod
	Jourdain Hayward
Oncology Research Professionals:	
CRA:	
Nurse:	
Pharmaceutical Science:	Craig Elg, Pharm.D.
	Sun "Coco" Yang, Pharm.D., Ph.D.
Patient Advocate:	Marcia K. Horn, J.D.
Protocol Coordinator:	Dion Holmes
Early Therapeutics Liaisons	
Breast Committee Liaison:	George Somlo, M.D.
Genitourinary Committee Liaison:	Neeraj Agarwal, M.D.
lmaging:	TBD
Lung Committee Liaison:	Shirish M. Gadgeel, M.D.
Lymphoma Committee Liaison:	Daruka Mahadevan, M.D., Ph.D.
Melanoma Committee Liaison :	Jeffrey A. Sosman, M.D.
Myeloma Committee Liaison:	Frits van Rhee, M.D., Ph.D.

### Time/Location

Thursday, October 4, 2018 10:00 am— 12:15 pm Room: Regency D (Ballroom Level)

### Agenda

### Introduction

10:00 am -10:05 am: Razelle Kurzrock, M.D., 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 am 10:25 am: Hypermutations in gliomas: Target for immunotherapy?" Manmeet Ahluwalia, M.D., F.A.C.P., Professor of Medicine, Miller Family Endowed Chair in Neuro-Oncology, Head of Opera-tions, Burkhardt Brain Tumor Center, Cleveland Clinic
- <u>10:25 am 10:45 am:</u> "Dual Anti-CTLA-4 and Anti-PD-1 blockage in Rare Tumors (DART)." Sandip Pa-tel M.D., Assistant Professor, UC San Diego Moores Comprehensive Cancer Center, San Diego, CA
- 10:45 am 11:05 am: "Translational Medicine Initiatives in the DART trial" Young Kwang Chae, M.D., Assis-tant Professor Co-Director, Early Therapeutics, Northwestern University, Robert H. Lurie Comprehensive Cancer Center
- 11:05 am 11:35 am: "Innovative Developments in Early Therapeutics: What is New?" Monica Mita, M.D., Associate Professor, Department of Medicine; Co-Director, Experimental Therapeutics Program, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center
- 11:35 am 11:55 am: "A phase II trial of carboplatin, ATR inhibitor (M-6620), and pembolizumab in metastatic head and neck cancer-CAP Trial" Paul Swiecicki, M.D., Assistant Professor, Divison of Hema-tology/ Oncology Head and Neck Program, University of Michigan
- 11:55 pm 12:15 pm: Wrap Up and Open Discussion. Razelle Kurzrock, M.D., Chief, Division of He-matology 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. Patel, Chae, Giles, and 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. Piccioni. Activated by Alliance 12/15/14. Activated by SWOG: 4/1/15. Temporarily closed: 10/21/16.



# **Early Therapeutics & Rare Cancers Committee**

### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51609	A077102	A077407	ARST1321	EN131
Arizona MC, U of	3	_	_	_	2
Arkansas, U of	3	_	_	_	3
Baptist MU-NCORP	2	_	_	_	_
Baylor College	_	2	_	_	_
Brooke Army Med Ctr	_	2	_	_	_
CORA NCORP	5	1	1	_	1
Carle CC NCORP	2	_	_	_	_
Cedars-Sinai Med Ctr	5	_	_	_	3
City of Hope Med Ctr	_	_	_	_	5
Cleveland Clinic OH	_	_	_	_	5
Colorado, U of	6	2	1	_	9
Columbus NCORP	2	_	_	_	_
Davis, U of CA	8	_	_	_	7
Dayton NCORP	1	_	_	_	1
Essentia HIth NCORP	3	_	_	_	_
Fred Hutchinson CRC	6	_	_	_	2
Georgia NCORP	3	_	_	_	_
Gulf South MU-NCORP	2	_	_	_	_
H Lee Moffitt CC	16	_	_	_	_
Hawaii MU-NCORP	3	_	_	_	1
Heartland NCORP	12	_	_	_	1
Henry Ford Hospital	11	_	_	_	10
Irvine, U of CA	7	2	1	_	7
Kaiser Perm NCORP	22	5	_	_	5
Kansas City NCORP	_	_	_	_	1
Kansas, U of	24	_	_	1	5
Kentucky, U of	_	_	_	_	9
Lahey Hosp & Med Ctr	_	3	_	_	_
Loma Linda Univ	1	_	_	_	1
Loyola University	1	_	_	_	_

	51609	4077702	A077407	ARST1321	EAY131
MAVERIC	3	_	_	_	_
MD Anderson CC	17	_	_	_	_
MUSC MU-NCORP	4	_	_	_	_
Methodist Hospital	_	_	_	_	1
Michigan CRC NCORP	14	_	_	_	_
Michigan, U of	24	_	_	_	7
Mississippi, Univ of	3	1	_	_	_
Montana NCORP	10	_	_	_	_
Nevada CRF NCORP	15	_	_	_	_
New Mexico MU-NCORP	12	_	_	_	_
Northwest NCORP	2	_	_	_	_
Northwestern Univ	8	1	_	1	_
Oregon Hlth Sci Univ	_	_	_	4	_
Ozarks NCORP	1	2	_	_	_
PCRC NCORP	9	3	_	_	_
Providence Hosp	1	1	_	_	2
Rochester, Univ of	_	11	_	_	_
Antonio, U of TX	5	_	_	3	4
San Diego, U of CA	16	7	2	_	_
Southeast COR NCORP	4	_	_	_	6
Sutter Cancer RC	2	_	_	_	4
Tulane University	_	_	_	_	1
Utah, U of	1	_	_	_	_
Wayne State Univ	_	_	_	_	1
Wisconsin NCORP	7	_	_	_	_
Yale University	4	3	_	_	8
Alliance	67	_	_	_	_
ECOG-ACRIN	<i>57</i>	_	_	_	_
NRG	86	_	_	_	_
Total	520	46	5	9	112

CTSU/A071401, "Phase II Trial of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas with SMO/AKT/ NF2 Mutations." Dr. Piccioni. Activated by Alliance 8/28/15. Activated by SWOG: 1/1/16.

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. Villalobos. Activated by COG 1/27/14. Activated by SWOG: 3/15/2016.

CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.

### **Proposed Studies**

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



# **Gastrointestinal Committee**

### Leadership

Leadership
Chair:Howard S. Hochster, M.D.
Vice-Chair: Heinz-Josef Lenz, M.D.
Executive Officer: Christopher W. Ryan, M.D.
Statisticians: Katherine A. Guthrie, Ph.D.
Shannon McDonough, M.S.
Scientific Leadership
Gastroesophageal:
Lawrence P. Leichman, M.D.
Scott A. Hundahl, M.D. (Surgical representative)
Pancreatic: Philip A. Philip, M.D., Ph.D.
Andrew M. Lowy, M.D. (Surgical representative)
Hepatobiliary: Anthony B. El-Khoueiry, M.D.
Syed Ahmad, M.D. (Surgical representative)
Colon:Philip J. Gold, M.D.
Kevin G. Billingsley, M.D. (Surgical representative)
Rectal: Lisa A. Kachnic, M.D.
Translational Medicine:
Drug Development:
Sunil Sharma, M.D.
Imaging: Anthony F. Shields, M.D., Ph.D.
Hiram Shaish, M.D.
Radiation Oncology: Lisa A. Kachnic, M.D.
Designates
Cancer Control Liaison:Jason A. Zell, D.O.
Data Coordinators:
Jacqueline Scurlock
Brian Zeller
Sewan Gurung
Oncology Research Professionals:
CRA: Sandy Annis, C.C.R.P.
Nurses:
Patient Advocate (Pancreatic):
Patient Advocate (Colon): Florence Kurttila, M.S.
Pharmaceutical Science: Linda Lee-Gabel, Pharm.D.
Jason M. Reed, Pharm.D., R.Ph.
Protocol Coordinator: Danae Campos

### Time/Location

Friday, October 5, 2018 4:30 pm— 6:30 pm Room: Regency B (Ballroom Level)

**Introduction**: Howard Hochster, M.D., Rutgers University.

**Presentation:** "Molecular profiling of gastric cancer and therapeutic implications." Dr. Daniel Catenacci, Associate Professor, University of Chicago

### **Featured Trials:**

COMMIT and ATOMIC: Michael Overman

S1613: Kanwal Raghav

### Gastroesophageal

### No studies

### **Pancreatic**

### **Active Studies**

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: 11/6/15.

### **Closed Studies**

<u>S1313,</u> "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.

<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: 12/13/17.

<u>S1505</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; Closed: 4/20/18.

CTSU/RTOG 0848, "A Phase II-R and a Phase III Trial Evaluating Both



# **Gastrointestinal Committee**

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; Closed: 6/1/18.

### **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>S1815, "</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**

- <u>S0820</u>, "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.
- S1613, "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**

<u>S1907</u>, "Phase III Study of Maintenance TAS-102 and Bevacizumab compared with Capecitabine and Bevacizumab following induction therapy as first line therapy for metastatic Colorectal Cancer". Dr. Hochster

### 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: 10/12/16.

### **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: 9/2717

### Other

### **Active Studies**

- <u>S1316</u>, "Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction." Dr. Krouse. Activated: 3/9/15.
- <u>S1609</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 Studies**

<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**

- <u>S9008A</u>, "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 accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51313	51505	51513	51613	A027507	A021502	E1208	EA2133	EA2142	N1048	NRGG1002	NRGGI004	R0848
Arizona MC, U of	4	1	_	_	_	_	_	_	_	4	_	_	_
Baptist MU-NCORP	_	1	_	_	_	_	_	_	_	_	_	_	_
Baylor College	_	_	_	_	_	_	_	_	_	23	_	_	_
Beaumont NCORP	_	_	2	_	_	1	_	_	_	_	_	_	_
Boston Medical Ctr	_	_	_	_	_	_	_	_	_	3	_	_	_
CORA NCORP	_	_	2	_	_	_	1	_	_	2	_	_	_
CRC West MI NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_
Carle CC NCORP	_	2	1	_	_	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	2	_	_	2	_	_	_	_	_	_	_	_
City of Hope Med Ctr	3	_	2	_	_	_	_	_	_	_	_	_	_
Cleveland Clinic OH	_	6	_	_	_	_	_	_	_	_	_	_	_
Colorado, U of	_	_	2	_	_	_	_	_	_	1	_	_	_
Columbia MU-NCORP	_	_	2	_	_	_	_	_	_	_	_	_	2
Columbia University	_	_	_	_	_	_	_	_	_	_	_	_	1
Columbus NCORP	_	1	_	_	_	_	_	_	_	_	_	_	_
Davis, U of CA	1	_	_	_	_	1	_	_	_	2	_	_	_
Dayton NCORP	_	3	2	_	_	_	_	_	_	2	2	_	_
Fred Hutchinson CRC	14	_	2	_	_	_	_	_	_	17	3	_	_
Greenville NCORP	_	4	_	_	_	_	_	_	_	_	_	_	1
Gulf South MU-NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	_	_	_	_	_	_	_	_	_	_	_	_	1
Heartland NCORP	8	7	5	_	_	_	_	_	_	_	_	_	_
Irvine, U of CA	7	_	_	_	3	_	_	_	_	15	_	_	6
Kaiser Perm NCORP	_	5	8	_	1	2	_	_	1	22	_	_	_
Kansas City NCORP	7	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	_	3	2	_	_	_	_	1	_	_	_	_	1
Kentucky, U of	_	3	_	_	_	_	_	_	_	_	_	_	_
Lahey Hosp & Med Ctr	_	_	_	_	_	_	_	_	_	12	_	_	_
Loyola University	_	_	_	_	_	_	_	_	_	_	_	_	4
MD Anderson CC	_	_	_	5	_	_	_	_	_	_	_	2	_

# Dr. Grant Taylor, first SWOG group chair Founded in Trials Netter States. We to community to community to community the state of the s

# **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 bio-repository holds more than 800,000 specimens accessible to fellow researchers around the world.



# **Gastrointestinal Committee, cont.**

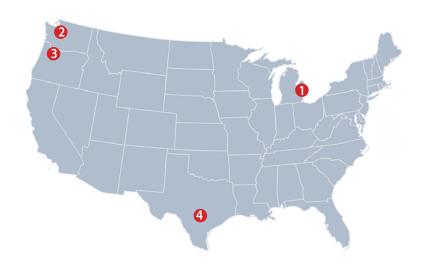
### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51313	51505	51513	51613	A021501	A021502	E1208	EA2133	EA2142	N1048	NRGGI002	NRGG1004	R0848
MUSC MU-NCORP	5	3	1	_	_	_	_	_	_	_	_	_	_
Methodist Hospital	_	_	_	_	_	_	_	_	_	11	_	_	_
Michigan CRC NCORP	_	2	2	_	_	_	_	_	_	_	_	_	_
Michigan, U of	_	6	2	_	6	_	1	_	3	4	_	_	_
Montana NCORP	_	_	1	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	1	5	_	_	_	_	_	_	2	_	_	_
Northwest NCORP	_	_	_	_	_	_	_	_	_	_	_	_	3
Northwestern Univ	_	_	_	_	_	_	1	_	_	1	_	_	_
Oklahoma, Univ of	_	1	_	_	_	_	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	_	_	_	_	_	_	_	_	_	1	_	_
Oregon HIth Sci Univ	_	1	_	_	_	_	_	_	_	_	_	_	_
Ozarks NCORP	_	2	_	_	_	_	_	_	_	1	_	_	_
PCRC NCORP	6	5	_	_	_	_	_	_	_	1	_	_	_
Providence Hosp	_	_	_	_	_	_	1	_	_	_	_	_	_
Rochester, Univ of	_	4	11	_	1	1	_	_	_	22	_	_	_
San Antonio, U of TX	_	1	_	_	_	_	_	_	_	_	_	_	_
San Diego, U of CA	_	6	_	_	_	_	_	_	_	4	_	_	_
Scott & White Mem	_	_	_	_	_	_	1	_	_	1	_	_	_
So Calif, U of	6	_	_	_	_	_	6	_	_	3	_	_	_
Southeast COR NCORP	5	3	4	_	_	_	_	_	_	_	_	_	_
Sutter Cancer RC	9	_	_	_	1	_	_	_	_	_	_	_	_
Utah, U of	_	_	7	_	_	_	_	_	_	3	_	_	_
Wayne State Univ	11	_	2	_	1	_	1	_	_	_	_	_	_
Wichita NCORP	_	_	_	_	_	_	_	_	_	_	_	_	1
Wisconsin NCORP	_	3	1	_	_	_	_	_	_	_	_	_	_
Yale University	40	_	3	_	_	_	11	_	_	_	_	_	_
Alliance	_	18	17	2	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	_	32	18	1	_	_	_	_	_	_	_	_	_
NRG	_	21	17	_	_	_	_	_	_	_	_	_	_
Total	126	147	123	8	15	5	23	1	4	156	6	2	20

### **SWOG Offices**

- 1. The Hope Foundation, Ann Arbor, MI
- 2. SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Research Center, Seattle, WA
- 3. SWOG Group Chair's Office, Knight Cancer Institute at Oregon Health & Science University, Portland, OR
- 4. SWOG Operations, San Antonio, TX





# **Genitourinary Committee**

### Leadership

Vice-Chair:	Nicholas J. Vogelzang, M.D.
	Christopher W. Ryan, M.D.
	Cathy M. Tangen, Dr.P.H.
	Melissa Plets, M.S.
	Eddie Mayerson, M.S.
Scientific Leadership	Zadie mayerson, mis.
•	David J. McConkey, Ph.D. (GU Chair)
	Joshua J. Meeks, M.D., Ph.D. (Bladder)
	Amir Goldkorn, M.D. (Prostate)
	Brian Shuch, M.D. (Renal)
	David Raben, M.D.
<del>-</del>	Daniel W. Lin, M.D.
	Hiram Shaish, M.D.
	John D. Hazle, Ph.D.
	M. Scott Lucia, M.D.
3,	Colin P.N. Dinney, M.D.
	Neeraj Agarwal, M.D.
	Seth P. Lerner, M.D. (Localized)
	Daniel P. Petrylak, M.D. (Advanced)
	Daniel W. Lin, M.D. (Localized)
	David I. Quinn, M.D., Ph.D. (Advanced)
	. Edward M. Messing, M.D. (Localized)
•	lka N. Vaishampayan, M.D. (Advanced)
Designates	ita iv. vaishampayan, wib. (vavaneea)
•	Peter J. Van Veldhuizen, Jr., M.D.
	Sean O'Bryan
	Joseph Sanchez
	Vicky Kim
Oncology Research Professionals:	
	TBD
	Deborah A. Shaw, R.N.
	Cheryl Kefauver, R.N.
Patient Advocates	Rick Bangs, M.B.A. (Bladder)
	Tony Crispino (Prostate)
	aret "Peggy" Zuckerman, M.Ed. (Renal)
	Joyce Lee, Pharm.D.
	Jason M. Reed, Pharm.D., R.Ph.
	TBD
i iotocoi coordinator	

Chair: ......lan M. Thompson, Jr., M.D.

### Time/Location

GU Committee Part I: Friday, October 5, 2018 2:30 pm— 6:15 pm

Room: Crystal A (Lobby Level)

GU Committee Part II: Saturday, October 6, 2018 9:30 am— 12:30 pm

Room: Crystal A (Lobby Level)

### **Agenda**

### GU Committee, Part I: Friday October 5, 2018, 2:30 pm – 6:15 pm

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

### **Prostate**

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

### **Priority Study**

<u>S1802</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." Drs. and Aparicio.

### **Active Studies**

CTSU/NRG-GU006, "A Phase II, Double-Blinded, Placebo-Controlled Randomized Trial of Sal-vage Radiotherapy with or Without Enhanced Anti-Androgen Therapy with Apalutamide in Recur-rent Prostate Cancer." Dr.Zeng. Activated: 4/27/18.

CTSU/NRG-GU002, "Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Follow-ing Radical Prostatectomy with or without Adjuvant Docetaxel." Dr. Raben. Activated: 12/30/16.

CTSU/EA8153, "Cabazitaxel with Abiraterone Versus Abiraterone Alone Randomized Trial for Ex-tensive Disease Following Docetaxel: The CHAARTED2 Trial." Dr. 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. 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. Marshall. Activated: 7/7/11.

### **Closed Study**

<u>S1216</u>, "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: 7/15/17.



# **Genitourinary Committee**

### **Translational Medicine**

Chair: Dr. David McConkey

Bladder Chair: Dr. Joshua Meeks

Prostate Chair: Dr. Amir Goldkorn

Renal Chair: Dr. Brian Shuch

### **Cancer Control**

Liaison: Dr. Peter J. Van Veldhuizen

### **Active Study**

<u>S1316</u>, "Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction." Drs. Krouse, Badgwell, and Sun. Activated: 3/9/15.

### **Developing Study**

<u>S1600</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.

### **Diverse Studies of Interest**

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

CTSU/EAY 131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.

### GU Committee, Part II: Saturday, October 6, 2018 9:30 – 12:30 Renal

Organ Site Chairs: Drs. Ulka Vaishampayan (Advanced) and Edward M. Messing (Local). Dr. Brian Shuch (Local-elect).

### **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**

50931, "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.

### **Bladder**

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

### **Priority Studies**

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

S1909, "A Phase III Randomized Trial of Eribulin with or without Gemcitabine Versus Stand-ard of Care (Physician's Choice) for Treatment of Metastatic Urothelial Carcinoma Refractory to, or Ineligible for, Anti PD1/PDL1 Therapy." Dr. Sadeghi.

### **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>S1605</u>, "Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer." 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: 2/15/17.

<u>S1314</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. Godoy and Alva. Activated 4/10/15; Closed 1/5/18.



# **Genitourinary Committee**

### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51011	51216	51314	51500	51602	51605	A031702	A037507	E2810	EA8747	EA8143	NRGGU002	R0924
Arizona MC, U of	_	10	3	_	_	_	_	_	_	_	3	_	_
Arkansas, U of	_	6	_	1	_	_	_	_	_	_	_	_	_
BC Cancer Agency	22	_	_	_	_	_	_	_	_	_	_	_	_
Baptist MU-NCORP	_	1	_	_	_	_	_	_	_	_	_	_	_
Baylor College	51	16	3	_	5	_	_	_	_	_	_	_	_
Beaumont NCORP	_	3	_	_	_	_	_	_	_	_	_	_	2
Birmingham, U of AL	_	_	1	_	_	_	_	_	_	1	_	_	_
Boston MC MBCCOP	_	3	_	_	_	_	_	_	_	_	_	_	_
CORA NCORP	_	2	_	_	_	_	_	_	_	_	_	_	1
CRC West MI NCORP	_	4	_	1	_	_	_	_	_	_	_	_	_
Carle CC NCORP	_	2	_	_	_	_	_	_	_	_	_	_	_
Cedars-Sinai Med Ctr	_	_	_	1	_	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	1	_	_	_	_	_	_	_	_	_	_	_
City of Hope Med Ctr	_	49	8	17	1	_	_	_	16	_	_	_	_
Cleveland Clinic OH	7	_	12	_	_	_	_	_	_	_	_	_	4
Colorado, U of	3	4	11	_	2	2	_	2	_	5	1	1	_
Columbia MU-NCORP	_	2	_	_	_	_	_	_	1	_	_	_	_
Columbus NCORP	_	6	_	1	_	_	_	_	_	_	_	_	_
Davis, U of CA	12	37	4	2	_	1	_	_	_	_	1	_	_
Dayton NCORP	_	9	_	_	1	_	_	_	_	_	_	_	_
Desert Hospital	_	_	_	_	_	_	_	_	_	_	_	_	7
Essentia HIth NCORP	_	_	_	_	_	1	_	_	_	_	_	_	_
Fred Hutchinson CRC	_	28	_	_	_	_	_	_	_	_	_	_	_
Georgia NCORP	_	2	_	_	_	_	_	_	1	_	_	_	_
Greenville NCORP	_	_	3	_	_	1	_	_	_	_	_	_	_
Gulf South MU-NCORP	4	2	3	_	23	1	_	_	_	_	_	_	_
H Lee Moffitt CC	2	32	_	_	_	_	_	_	_	_	1	_	_
Heartland NCORP	_	38	18	4	1	2	_	_	_	_	_	_	_
Henry Ford Hospital	_	_	_	_	_	_	_	_	1	_	_	_	_
Irvine, U of CA	_	6	_	_	_	_	_	_	_	_	_	_	_
Kaiser Perm NCORP	_	83	_	_	1	_	_	3	_	_	1	_	_
Kansas City NCORP	_	6	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	_	29	10	_	1	_	_	1	6	1	_	_	5
Kentucky, U of	_	16	_	_	_	_	_	_	_	_	2	_	_
Lahey Hosp & Med Ctr	_	3	_	_	_	_	_	_	_	_	1	_	_
Loma Linda Univ	_	11	6	_	_	_	_	_	_	_	_	_	_
Loyola University	15	6	2	_	_	2	_	_	1	_	_	_	_

# **Genitourinary Committee, cont.**

### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51011	57216	51314	51500	51602	51605	A031702	A037507	E2810	EA8747	EA8143	NRGGU002	R0924
MAVERIC	_	1	_	_	_	_	_	_	_	_	_	_	_
MD Anderson CC	49	4	2	_	2	_	_	_	_	1	_	_	_
MUSC MU-NCORP	_	12	1	1	_	_	_	_	_	_	_	_	2
Madigan Army Med Ctr	_	2	_	_	_	_	_	_	_	_	_	_	_
Michigan CRC NCORP	_	17	6	1	_	_	_	_	_	_	_	_	_
Michigan, U of	_	17	_	4	7	_	_	_	1	_	_	_	_
Mississippi, Univ of	_	1	_	_	_	_	_	_	_	_	_	_	_
Montana NCORP	_	3	2	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	_	45	10	3	_	1	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	26	_	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	_	4	_	_	_	_	_	_	_	_	_	_	_
Northwestern Univ	_	3	_	_	8	_	_	_	_	_	_	_	_
Oklahoma, Univ of	_	16	5	1	5	3	_	_	_	_	_	_	_
Orange Reg Med Ctr	_	1	_	_	_	_	_	_	_	_	_	_	_
Oregon HIth Sci Univ	19	21	4	3	_	2	_	_	6	_	_	_	_
Ozarks NCORP	_	5	3	2	_	_	_	_	_	_	_	_	_
PCRC NCORP	_	7	_	2	11	_	_	_	_	_	_	_	_
Rochester, Univ of	1	7	5	_	_	_	_	_	_	_	_	_	24
San Antonio, U of TX	50	3	8	_	10	_	_	_	_	_	2	_	_
San Diego, U of CA	_	6	1	_	_	3	_	_	_	_	1	_	_
So Calif, U of	153	34	11	1	2	_	3	_	1	_	_	_	_
Southeast COR NCORP	_	6	2	_	_	_	_	_	1	_	_	_	_
Sutter Cancer RC	_	5	_	_	_	_	_	_	_	_	_	_	2
Tennessee, U of	_	_	_	_	_	_	_	_	1	_	_	_	_
Upstate Carolina	_	1	_	_	_	_	_	_	_	_	_	_	_
Utah, U of	_	106	5	2	18	5	_	_	12	_	1	_	_
VAMC Kansas City	_	2	_	_	_	_	_	_	_	_	_	_	39
Wayne State Univ	_	_	1	2	_	_	_	_	_	_	_	_	_
Wichita NCORP	_	12	1	1	_	_	_	_	_	_	_	_	_
Wisconsin NCORP	_	2	2	1	_	_	_	_	_	_	_	_	_
Yale University	_	7	1	_	_	2	_	1	_	_	1	_	_
Alliance	105	239	45	14	13	16	_	_	_	_	_	_	_
CCTG	38	_	_	12	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	87	241	20	14	2	10	_	_	_	_	_	_	_
NRG	_	40	18	9	15	8	_	_	_	_	_	_	_
Total	618	1,313	237	100	128	60	3	7	48	8	15	1	86



# Leukemia Committee

### Agenda

### Introduction

Leukemia Committee Updates – Dr. Harry Erba

### **AML/MDS Studies**

### **Active Studies**

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. Schiffer. Activated by ECOG: 1/29/09; Activated by SWOG: 2/15/09.

<u>S1612</u>, "A Randomized Phase II/III Trial of "Novel Therapeutics" versus Azacitidine in Newly Diagnosed Patients with Acute Myeloid Leukemia or High-Risk Myelodyslplastic Syndrome (MDS), Age 60 or Older." Drs. Michaelis and Walter. Activated by SWOG 12/22/17.

### **Closed Studies**

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

### **ALL Studies**

### **Active Studies**

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

<u>\$1312</u>, "A Phase I Study of Inotuzumab Ozogamicin (NSC-772518) in Combination with CVP (Cyclophosphamide, Vincristine, Prednisone) for Patients with Relapsed/Refractory CD22-Positive Acute Leukemia (Including B-ALL, Mixed Phenotypic Leukemia and Burkitt's Leukemia)." Drs. Advani and Liedtke. Activated: 4/1/14. CTSU/E1910, "A Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-Negative B Lineage Acute Lymphoblastic Leukemia in Adults." Dr. Liedtke. Activated by ECOG: 12/17/13. Activated by SWOG: 1/15/14.

### **Proposed Studies**

<u>\$1902</u>, "Randomized Phase III Study Comparing a Combination of MiniHCVD with and without Inotuzumab Ozogamicin (InO) in Patients ≥60 Years with Newly Diagnosed Philadelphia (Ph)-Negative B-cell Acute Lymphoblastic Leukemia (ALL)." Dr. Jabbour.

**S1905**, "A Phase I/II Study of OBI-3424 in Patients with Relapsed/ Refractory T-Cell Acute Lymphoblastic Leukemia." Drs. Advani and 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. 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. Phelan, Ofran, and Jamieson.

### **CLL Studies**

### **Active 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. O'Brien. Activated by ECOG: 1/31/14; Activated by SWOG: 2/15/14.

### **Closed Studies**

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

### **CML Studies**

### **Active Studies**

**51712**, "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. Sweet and Radich. (Formerly S1615) Activated by SWOG: 7/20/18.



# Leukemia Committee

### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

merades decraal in oagn	50919	51312	51318	51672	E1910	E2906	NHLBINDS
Arizona MC, U of	_	, 	, 	_	4	7	MI.
Arkansas, U of		_	1	_			_
Baylor College	5	6	<u>.</u>	_	3	_	_
Beaumont NCORP	_	_	_	_	_	_	1
	3	_	1	_	_	_	<u>'</u>
Birmingham, U of AL	3	_	,	_	8	_	_
CRC West MI NCORP	_	_	_	1	_	4	_
Carle CC NCORP	_	_	_	1	_	_	_
Cincinnati MC, U of	_	 15	_	_	_	3	_
City of Hope Med Ctr	_		4	_	_	_	_
Cleveland Clinic OH	23	10	4	_	7	_	3
Colorado, U of	6	_	_	_	_	_	_
Columbia MU-NCORP	_	_	_	_	_	3	_
Dayton NCORP	_	_	_	_	1	5	_
Greenville NCORP	_	_	1	1	1	_	1
Gulf South MU-NCORP	1	_	_	_	_	_	_
H Lee Moffitt CC	11	_	_	_	_	_	_
Hawaii MU-NCORP	_	_	_	_	_	_	3
Heartland NCORP	_	_	1	5	_	_	_
Henry Ford Hospital	_	_	_	_	3	_	_
Irvine, U of CA	_	_	3	_	9	_	_
Kaiser Perm NCORP	_	_	_	4	_	_	3
Kansas City NCORP	_	_	_	_	_	_	2
Kansas, U of	_	_	_	_	10	_	_
Kentucky, U of	_	_	_	_	_	7	_
Loma Linda Univ	_	_	1	_	_	_	_
Loyola University	4	_	_	_	1	9	_
Michigan CRC NCORP	_	_	_	1	_	_	_
Michigan, U of	_	_	2	_	_	_	_
Mississippi, Univ of	1	_	_	_		1	_
Montana NCORP	_	_	_	2	_	_	_
New Mexico MU-NCORP	5	_	1	2	_	1	_
Northwest NCORP	_	_	_	_	7	_	_
Northwestern Univ	_	_	_	_	1	_	_
Oregon Hlth Sci Univ	6	_	_	_	1	_	3
PCRC NCORP	2	_	_	1	_	_	_
Rochester, Univ of	15	8	1	2	5	27	_
San Diego, U of CA	_	_	1	_	3	2/	_
So Calif, U of	_	_	3	_	3	_	_
Southeast COR NCORP	_	_	_	1	_	_	_
Stanford University	24	2	_	_	10	_	_
Tulane Univ MBCCOP	1	_	_	_	10	_	_
	2		_	_	_	_	_
Tulane University	_	_		_	_	_	_
Upstate Carolina	_	_		2	_	3	_
Wayne State Univ	6		1		3	_	
Wichita NCORP	U	_	1	_	_	_	_
Yale University	_	_	1 15	<u> </u>	15	5	_
Alliance	_	_		14	_	_	_
ECOG-ACRIN	_	_	6		_	_	_
NRG		<u> </u>	47	9 <b>46</b>	_	_	16
Total	115	41	47	40	91	75	16



LASMARC	nı	м
Leaders		U
		r

Chair:	Time/Lo	
Vice-Chair:Roy S. Herbst, M.D., Ph.D.	Friday, Oct	cober 5, 2018 4:30 pm— 7:30 pm
Executive Officer:	Room: Re	gency A (Ballroom Level)
Statisticians:Mary Redman, Ph.D.	Agenda	
Yingqi Zhao, Ph.D.	71801144	
Katherine Minichiello, M.S.	4:30 pm	Opening Remarks and General Update – Dr. Kelly
Jieling Miao, M.S.		Highlights from World Conference on Lung Cancer (WCLC)
		2018
Scientific Leadership		
Translational Medicine:	4:50 pm	Thoracic Surgery Session – Dr. Hofstetter
Biology/PathologyPhilip C. Mack, Ph.D.		Trial updates
Fred R. Hirsch, M.D., Ph.D.		·
lgnacio I. Wistuba M.D.	5:10 pm	Thoracic Radiation Session – Dr. Decker
Imaging:		Highlights from World Conference on Lung Cancer (WCLC)
Myrna C. Godoy, M.D., Ph.D.		2018
Radiation Oncology: Roy H. Decker, M.D., Ph.D.		2010
Surgery:Wayne L. Hofstetter, M.D.		Trial updates
Subcommittee Chairs:	5:30 pm	Translational Medicine Session – Biology/Pathology – Dr. Mack
Early Stage Disease:Wayne L. Hofstetter, M.D.	3.30 p	•
Raymond Osarogiagbon, M.D.	5:45 pm	Translational Medicine Session – Imaging – Dr. Wright
Locally Advanced Disease: Roy H. Decker, M.D., Ph.D.		Scientific Presentation: "NCTN IROC and SWOG Imaging
Shirish Gadgeel, M.D. (Early Therapeutics)		CoreLab Update on Lung Cancer Trials." Michael Knopp, M.D.,
Metastatic Disease: Ross Camidge, M.D.		Ph.D., The Ohio State University College of Medi-cine
Karen Reckamp, M.D.		, ,
Community Engagement:	6:10 pm	Community Engagement Core – Dr. Hesketh
Suzanne Cole, M.D.	6:30 pm	Thoracic Oncology Session – Lung Cancer
	0.00 p	•
Designates		Scientific Presentation: "Personalized Immunotherapy for Lung
Cancer Control Liaison:		Cancer: Sensitivity, Resistance and Combination Regimens."
Data Coordinators:Louise Highleyman		Roy Herbst, M.D., Ph.D., Yale School of Medi-cine
Larry Kaye		Trial updates
Sarah Basse		·
Oncology Research Professionals:	7:00 pm	Thoracic Oncology – Mesothelioma/Thymic Malignancies
CRAs:Courtney L. Williamson		Scientific Presentation: "Update in the management of
Ginny M. Keeling, M.S.		mesothelioma." Anne Tsao, M.D., The University of Texas MD
Nurses: Kimberly M. Belzer, M.S., P.A.C		Anderson Cancer Center
Rosalie Zablocki, R.N.		
Patient Advocate:Judy Johnson, M.B.A.		Trial updates
Pharmaceutical Science: Joyce Lee, Pharm.D.		
Linda Lee-Gabel, Pharm.D.		
Protocol Coordinator: Gretchen Goetz		
Crystal Miwa (Lung-MAP Protocol)		
Mariah Norman (Lung-MAP Protocol)		



### **Active Studies**

- <u>S1400</u>, "A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer." Drs. Papadimitrakopoulou, Hirsch, Herbst, et al. Activated: 6/16/14.
- S1400F, "A Phase II Study of MEDI4736 plus Tremelimumab as Therapy for Patients with Previously Treated Anti-PD-1/PD-L1 Resistant Stage IV Squamous Patients (Lung-MAP Sub-study)." Drs. Leighl and Rizvi. Activated: 10/2/17.
- S1400K, "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. Wagar and 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. Ramsey and Roth. Activated: 2/5/18.
- S1619, "A Feasibility Trial of Neoadjuvant Cisplatin-Pemetrexed with Atezolizumab in Combination and in Maintenance for Resectable Malignant Pleural Mesothelioma." Drs. Tsao, Cetnar, Sepesi, et al. Activat-ed: 11/3/17.
- S1701, "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." Drs. Tsao and Koczywas. Activated: 8/9/18.
- 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/A151216, "Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHE-MIST)." Dr. Gandara. Activated: 8/18/14.
- CTSU/CALGB 30610, "Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer Also Receiving Cisplatin or Carboplatin and Etoposide." Drs. Gadgeel and Gaspar. Activated: 3/15/08.

- CTSU/E4512, "A Randomized Phase III Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib Versus Observation for Patients with Tumors Harboring the Anaplastic Lymphoma Ki-nase (ALK) Fusion Protein." Dr. Li. 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." Activated: 5/6/16.
- CTSU/EAY131, "Molecular Analysis for Therapy Choice (MATCH)." Dr. Villalobos. Activated: 8/12/15.
- CTSU/NRG-CC003, "Randomized Phase II/III Trial of Prophylactic Cranial Irradiation with or without Hip-pocampal Avoidance for Small Cell Lung Cancer." Activated: 12/7/15; Temporarily closed: 10/13/17.

### **Closed Studies**

- 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. Owonikoko and Byers. Activated: 2/7/17; Closed: 7/23/18.
- <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. Gettinger and Bazhenova. Activated: 12/18/15; Closed: 4/23/18.
- S1403, "A Randomized Phase II Trial of Afatinib Plus Cetuximab versus Afatinib Alone in Treatment-Naïve Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer (NSCLC)." Drs. Goldberg, Lilenbaum, and Politi. Activated: 3/25/15; Closed: 4/23/18.
- 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>LungMAP</u>, "A Master Protocol to Evaluate Biomarker-Driven Therapies and Immunotherapies in Previous-ly-Treated Non-Small Cell Lung Cancer (Lung-MAP Screening Study)." Drs. Papadimitrakopoulou, Hirsch, Herbst, et al.

<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. Reckamp and
Dragnev.

<u>S1900A</u>, "A Phase II Study of Rucaparib in Patients with Genomic LOH- or BRCA-Positive Stage IV Non-Small Cell Lung Cancer (Lung-MAP Substudy)." Drs. Riess and Wheatley-Price.

<u>A081702</u>, "A Randomized Phase III Study of Pembrolizumab versus Investigator's Choice Chemotherapy in Patients with Previously-treated Malignant Pleural Mesothelioma." Dr. Garland.

<u>EA5163/S1709</u>, "A Randomized, Phase III Study of Firstline Immunotherapy alone or in Combination with Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non Small Cell Lung Cancer (NSCLC) with Immunobiomarker SIGNature driven Analysis." Dr. Chiang.

### **Concepts in Development**

<u>\$1700,</u> "Strategies to Improve Lymph Node Examination of Non-Small Cell Lung Tumors (SILENT)." Dr. Osarogiagbon.

<u>\$1827.</u> "A Randomized Phase III Trial of MRI Surveillance with or without Prophylactic Cranial Irradiation in Small-Cell Lung Cancer." Dr. Rusthoven.

<u>S1900B</u>, "A Phase II Study of LOXO-292 in Patients with RET Fusion-Positive Stage IV Non-Small Cell Lung Cancer (Lung-Map Sub-Study)". Dr. Papadimitrakopoulou.

<u>S1900C</u>, "Talazoparib plus Avelumab in Non-Small Cell Lung Cancer (Lung-Map Sub-Study)." Dr. Skou-lidis.

S1910, "A Phase III Study of Concurrent Chemoradiation Therapy and Atezolizumab followed by Consoli-dation Atezolizumab versus Chemoradiation Therapy followed by Consolidation Atezolizumab for Patients with Locally Advanced Non-Small Cell Lung Cancer." Dr. Lin



# Since 1956,

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

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

# Thanks, team!



### Cumulative Accrual by Institution and Study

*Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.* 

	51206	51400	51400F	574006	514001	57400K	51403	57507	5161 <sup>9</sup>	A087105	M51216	C140503	C30610	E4512	EA5742	EA5161	NRGCC003	R1306
Arizona MC, U of	3	1	_	_	_	_	_	_	_	_	2	_	_	1	_	_	_	_
Arkansas, U of	_	4	_	_	_	_	_	_	_	_	1	1	2	_	_	_	_	_
Baptist MU-NCORP	_	14	_	_	5	_	2	1	_	_	17	_	2	_	_	_	_	_
Baylor College	_	1	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_
Beaumont NCORP	_	2	_	_	_	_	_	_	_	_	2	_	_	_	_	_	_	_
Boston Medical Ctr	_	4	_	_	2	_	_	_	_	_	2	_	_	_	_	_	_	_
Brooke Army Med Ctr	_	6	_	_	2	_	_	_	_	_	8	_	_	_	_	_	_	_
CORA NCORP	_	14	_	1	3	_	_	_	_	_	2	_	_	_	_	_	_	_
CRC West MI NCORP	_	11	_	_	1	_	2	_	_	_	1	_	_	_	_	_	_	_
Carle CC NCORP	1	4	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_
Cincinnati MC, U of	_	6	_	_	2	_	_	_	_	1	11	_	3	1	1	_	_	_
City of Hope Med Ctr	2	15	_	_	2	_	_	_	_	1	4	_	_	_	_	_	_	_
Cleveland Clinic OH	_	10	_	_	1	_	_	1	_	3	28	_	_	_	9	_	_	_
Colorado, U of	_	2	_	_	1	_	_	_	_	3	23	12	_	1	1	_	_	1
Columbia MU-NCORP	_	2	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Columbus NCORP	_	15	_	_	1	_	3	2	_	_	_	_	1	_	_	_	_	_
Davis, U of CA	10	20	_	3	3	_	4	2	_	2	31	6	13	1	2	_	_	_
Dayton NCORP	1	5	_	_	1	_	2	_	_	_	2	_	_	_	2	_	_	_
Essentia HIth NCORP	_	9	_	1	2	_	_	_	_	_	_	_	_	_	_	_	_	_
Fred Hutchinson CRC	_	20	_	1	4	1	_	_	_	1	9	_	_	_	_	_	_	_
Georgia NCORP	_	22	2	1	5	3	_	1	_	_	_	_	1	_	_	_	_	_
Greenville NCORP	_	16	_	1	6	_	2	_	_	_	_	_	_	_	_	_	_	_
Gulf South MU-NCORP	_	6	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_
H Lee Moffitt CC	_	10	_	_	1	_	_	_	_	3	68	_	_	_	6	_	_	_
Harrington CC	_	8	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Hawaii MU-NCORP	4	7	_	_	1	1	7	1	_	_	_	_	_	_	_	_	_	_
Heartland NCORP	7	53	3	_	8	_	2	7	_	_	_	_	7	_	_	_	_	_
Henry Ford Hospital	2	9	_	_	_	1	_	_	_	1	17	_	_	_	4	_	_	_
Irvine, U of CA	_	9	_	_	2	_	_	1	_	2	6	_	_	_	1	_	_	_
Kaiser Perm NCORP	_	48	_	1	6	_	28	_	_	13	133	_	3	1	9	_	_	_
Kansas City NCORP	_	1	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Kansas, U of	1	39	_	_	12	1	2	_	_	_	22	_	1	_	6	_	_	_
Kentucky, U of	_	8	1	_	4	_	_	_	_	_	_	_	_	_	_	_	_	_
Lahey Hosp & Med Ctr	1	11	_	1	1	_	3	1	_	_	21	_	_	_	2	1	_	2
Loma Linda Univ	_	6	_	1	1	_	_	1	_	1	2	_	_	_	1	_	_	_
Loyola University	4	11	_	_	4	_	_	_	_	_	11	_	_	_	2	1	_	_
MAVERIC	_	16	2	_	9	1	_	_	_	_	1	_	_	_	_	_	_	_

### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51206	51400	51400F	51400G	514001	51400K	51403	51507	5161 <sup>9</sup>	A08710	5 A15727	6 C140503	C30610	E4512	EA5742	EA5767	NRGCC003	R1306
MD Anderson CC	3	23	_	_	1	_	_	_	_	_	2	_	_	_	_	_	_	5
MUSC MU-NCORP	_	1	_	_	_	_	_	2	1	_	_	_	1	_	_	_	_	_
Methodist Hospital	_	5	_	_	_	_	_	_	_	1	4	_	_	_	_	_	_	_
Michigan CRC NCORP	_	36	_	3	4	1	7	4	_	_	_	_	_	_	_	_	_	_
Michigan, U of	_	13	1	_	4	_	3	1	_	_	45	_	1	_	_	_	_	_
Mississippi, Univ of	_	6	_	_	3	_	_	_	_	1	13	_	1	_	1	_	_	_
Montana NCORP	_	15	_	_	2	_	2	1	_	_	_	_	_	_	_	_	_	_
Mt Sinai Med Ctr	_	4	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_	_
Nevada CRF NCORP	_	5	_	_	3	_	_	_	_	_	_	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	7	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Northwest NCORP	_	6	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_	_
Northwestern Univ	_	2	_	_	1	_	_	3	_	_	_	_	_	_	_	_	_	_
Oklahoma, Univ of	_	8	_	1	2	_	4	_	_	_	_	_	_	_	_	_	_	_
Oregon Hlth Sci Univ	_	13	_	3	7	_	_	_	_	_	3	_	_	_	1	_	_	_
Ozarks NCORP	_	16	_	_	2	_	3	1	_	1	1	_	_	_	_	_	_	_
PCRC NCORP	_	17	_	_	_	_	_	_	_	_	4	6	_	_	_	_	_	_
Providence Hosp	_	14	_	_	_	_	_	_	_	_	9	_	2	1	1	_	_	_
Rochester, Univ of	_	21	1	1	1	_	2	1	_	_	_	_	_	_	_	_	4	_
San Antonio, U of TX	_	13	_	_	3	_	5	_	_	_	_	_	3	_	_	_	_	_
San Diego, U of CA	_	12	_	_	1	_	7	_	_	1	3	_	_	_	_	_	_	_
So Calif, U of	_	_	_	_	_	_	-	_	_	1	6	_	_	_	_	_	_	_
Southeast COR NCORP	1	69	2	3	14	2	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	_	_	_	_	_	4	_	_	_	_	_	_	_	_	_	_
VAMC Kansas City	_	6	_	_	1	_	_	_	_	_	_	_	1	_	_	_	_	_
Wayne State Univ	_	12	_	2	_	_	2	1	_	_	1	_	1	_	_	_	_	_
Wichita NCORP	_	22	1	1	3	1	8	_	_	_	_	_	13	_	_	_	_	_
Wisconsin NCORP	_	7	_	_	_	_	1	_	_	_	_	_	_	_	_	_	_	_
Yale University	12	27	_	1	4	_	24	_	_	3	33	_	_	2	8	_	_	_
Alliance	_	374	5	12	39	4	24	9	_	_	_	_	_	_	_	_	_	_
CCTG	_	18	_	1	3	_	_	_	_	_	_	_	_	_	_	_	_	_
ECOG-ACRIN	_	313	4	9	58	1	9	9	_	_	_	_	_	_	_	_	_	_
NRG	1	192	4	2	24	4	13	6	_	_	_	_	_	_	_	_	_	_
Total	53	1,732	26	51	275	22	174	60	1	40	557	27	56	8	59	2	4	8



# Lymphoma Committee

Leaders	hı	10
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Chair:	Jonathan W. Friedberg, M.D.
Vice-Chair:	Sonali M. Smith, M.D.
Executive Officer:	Susan M. O'Brien, M.D.
Statisticians:	Michael LeBlanc, Ph.D.
	Hongli Li, M.S.
Scientific Leadership	
Translational Medicine:	Lisa M. Rimsza, M.D.
Radiation Oncology:	Louis S. Constine, M.D.
Imaging:	Lawrence H. Schwartz, M.D.
Pathology:	Lisa M. Rimsza, M.D.
Early Therapeutics:	Daruka Mahadevan, M.D., Ph.D.
Designates	
Cancer Control:	TBD
Data Coordinators:	Jeri Jardine
	Iris Syquia
Oncology Research Professionals:	
CRA:	Erin M. Cebula, M.P.H.
Nurse:	TBD
Patient Advocate:	Hildy Dillon, M.P.H.
Pharmaceutical Science:	Lara M. Au, Pharm.D.
	Holly Chan, Pharm.D.
Protocol Coordinator	Cara Laubach

### Time/Location

Friday, October 5, 2018 4:00 pm— 7:00 pm

Room: Crystal B (Lobby Level)

### **Agenda**

4:00 pm: Welcome: Drs. Jonathan Friedberg and Sonali Smith

4:10 pm: Presentation by Sandeep Dave, M.D., M.S., Director, Cancer

Genetics and Genomics Program, Duke Cancer Institute: "Biology of DLBCL and a Path Forward for Genomics Analyses

and SWOG Studies."

4:50 pm: Genomics Q&A

5:00 pm: Presentation of SWOG Lymphoma Committee ISHL and ASH

abstracts:

a. S0816: Dr. Ha

Potential impact of consolidation radiation therapy for advanced Hodgkin Lym-phoma: a secondary modeling of SWOG S0816 with receiver operating charac-teristic analysis

b. S0816: Dr. Stephens

Long-term Follow-up of SWOG S0816: Response-Adapted Therapy for Stage III/IV Hodgkin Lymphoma Demonstrates Limitations of PET-adapted Approach

Correlative abstracts: S0016C Dr. Burack

Subclonal Mutations of TP53 are Common in Untreated Follicular Lymphoma and Mutation Status is Predictive of PFS when CHOP is Combined with 131-lodine Tositumomab but not with Rituximab: an Analysis of SWOG S0016

5:40 pm: Updates on Open Studies:

a. S1608: Dr. Barr

b. A051301: Dr. Stiff

c. EA4151: Dr. Till

d. E4412: Dr. Amengual

6:10 pm Studies in Development

a. S1826: Dr. Herrera

b. S1818: Dr. Brem

c. Alliance-DLBCL: Dr. S. Smith

d. ECOG-MCL: Dr. S. Spurgeon

e. Alliance-TCL: Dr. Amengual

6:50 pm Other Business

7:00 pm Adjourn

### **Open Studies**

<u>S1608</u>, "Randomized Phase II Trial in High-Risk Relapsed Refractory Follicular Lymphoma." Dr. Barr. Ac-tivated: 8/10/17.

<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." Dr. Ramsey. Activated: 8/29/13.

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.



# Lymphoma Committee

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.

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

### **Developing Studies**

<u>S1826</u>, "Nivolumab (Opdivo) or Brentuximab Vedotin (Adcetris) Plus AVD in Patients with Newly Diag-nosed Advanced Stage Classical Hodgkin Lymphoma." Drs. Herrera and Friedberg.

<u>S1818</u>, "A Phase II/III Randomized Study of R-miniCHOP With or Without Oral Azacytidine in Very Elderly Patients with Newly Diagnosed Diffuse Large B Cell Lymphoma." Drs. Brem and Smith.

# Lymphoma Committee

### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51608	A051301	C51701	E1472	EAAISI	9177
Arizona MC, U of	_	_	_	1	_	_
Baylor College	_	1	_	_	_	_
Brooke Army Med Ctr	_	_	_	2	_	_
CRC West MI NCORP	1	_	_	_	_	_
Cincinnati MC, U of	_	_	_	3	_	_
City of Hope Med Ctr	_	1	_	_	3	_
Cleveland Clinic OH	_	_	_	_	_	4
Colorado, U of	_	1	_	_	_	_
Columbia MU-NCORP	_	_	_	3	_	_
Davis, U of CA	_	_	1	_	_	_
Fred Hutchinson CRC	_	_	2	_	1	_
Greenville NCORP	_	_	_	_	1	_
Hawaii MU-NCORP	_	_	_	1	_	_
Heartland NCORP	1	_	_	_	_	_
Kaiser Perm NCORP	_	_	_	7	_	_
Kansas City NCORP	_	_	_	1	_	1
Kansas, U of	_	_	2	_	_	_
Kentucky, U of	_	_	_	_	_	4
King Faisal Spec Hos	_	1	_	_	_	_
Montana NCORP	_	_	_	4	_	_
Rochester, Univ of	2	2	3	16	_	9
San Antonio, U of TX	_	_	_	_	3	_
Tennessee, U of	_	_	_	_	_	1
Tulane University	_	_	1	_	_	_
Utah, U of	1	_	_	_	_	_
Wayne State Univ	_	_	_	1	_	_
Alliance	1	_	_	_	_	_
Total	6	6	9	39	8	19

# Melanoma Committee

Designates

### Leadership Chair: ...... Antoni Ribas, M.D., Ph.D. Vice-Chair: ......Kenneth F. Grossmann, M.D., Ph.D. Executive Officer: ...... Christopher W. Ryan, M.D. Statisticians: ..... Michael Wu, Ph.D. ...... Megan Othus, Ph.D. ...... James Moon, M.S. ...... Michaella Latkovic-Taber, M.P.H. **Scientific Leadership** Radiation Oncology: ..... Evan J. Wuthrick, M.D. Surgery: ...... Robert H.I. Andtbacka, M.D. Imaging:......Kenneth F. Grossmann, M.D., Ph.D. ...... Martin Allen-Auerbach, M.D. Medical Oncology: .....Lawrence E. Flaherty, M.D. Pathology: ..... Michael T. Tetzlaff, M.D., Ph.D. Non-Melanoma Skin Cancer: ......Nikhil I. Khushalani, M.D. Early Therapeutics: ......Jeffrey A. Sosman, M.D. SWOG's ECOG Liaisons: ...... Sapna Pradyuman Patel, M.D. ...... Kevin B. Kim, M.D. ......Andrew Poklepovic, M.D.

Digital Engagement:.....Zeynep Eroglu, M.D.

Designates	
Cancer Control Liaison: Sancy L	eachman, M.D., Ph.D.
Thach-Giao Truon	g, M.D. (Survivorship)
Data Coordinator:	Vicky Kim
	Jourdain Hayward
	Joseph Sanchez
	Sean O'Bryan
	Jeri Jardine
La	ura Kingsbury, M.R.T.
Oncology Research Professionals:	
CRA: Kacie L. S	Simpson, B.S., C.C.R.P.
Nurse: Lisa S	. Morgan, R.N., O.C.N.
Patient Advocate:	. Valerie Guild, M.B.A.
Pharmaceutical Science:	Yang, Pharm.D., Ph.D.
Mai	i T. Nguyen, Pharm.D.
Protocol Coordinator:	Danae Campos

### Time/Location

Friday, October 5, 2018 9:30 am— 11:30 am Room: Crystal B (Lobby Level)

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# Melanoma Committee

### **Agenda**

Welcome: Drs. Ribas and Grossmann (5 min)

Immuno-oncology support committee – a new opportunity in progress (10 min, 9:35-9:45): Kenneth Grossmann, M.D., Ph.D.

**Active Studies** (9:45-10:45, each talk capped to 10 min, presenters encouraged to be closer to 5 min)

- **S1320**, "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>\$1512</u>, "A Phase II Study of PD-1 Blockade with Pembrolizumab in Patients with Locally Advanced and Meta-static Desmoplastic Melanoma (DM)." Drs. Kendra and Hu-Lieskovan. Activated: 10/20/16.
- S1616, "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. VanderWalde and 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 Progres-sion 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 Detectable Stage III-IV High Risk Melanoma.
- **S1901**, "Randomized Phase 3 Study of Adjuvant Pembrolizumab in combination with Dabrafenib and Trametinib vs Dabrafenib and Trametinib vs Pembrolizumab Alone in Patients with High-Risk Resected 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 liaisons report (10 min 11:20-11:30) David Lawson/Andrew Poklepovich



### **SWOG/Hope Foundation Impact Award Program**

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March 1, 2019

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# Melanoma Committee

### **Cumulative Accrual by Institution and Study**

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51350	51404	51512	57607	51616	E3672	EA613A	EA6747
Arizona MC, U of	2	11	_	_	_	_	_	_
Arkansas, U of	7	12	_	_	_	_	1	_
Bay Area NCORP	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	2	29	_	_	_	_	1	_
Columbia MU-NCORP	_	3	_	_	_	_	_	_
Columbus NCORP	3	4	_	_	_	_	_	_
Davis, U of CA	_	3	_	_	_	_	_	_
Dayton NCORP	1	7	_	_	_	_	_	_
Essentia HIth NCORP	_	1	_	_	_	_	_	_
Georgia NCORP	_	20	1	_	_	_	_	_
Greenville NCORP	_	_	_	_	_	1	_	_
Gulf South MU-NCORP	_	4	_	_	_	_	_	_
H Lee Moffitt CC	_	52	4	_	_	_	_	_
Hawaii MU-NCORP	1	3	_	_	_	_	_	_
Heartland NCORP	5	27	_	_	_	_	_	_
Irvine, U of CA	_	1	_	_	_	_	_	_
Kaiser Perm NCORP	30	74	_	_	_	4	6	20
Kansas City NCORP	_	1	_	_	_	_	_	1
Kansas, U of	17	25	_	_	_	_	2	_
Lahey Hosp & Med Ctr	1	4	_	_	_	_	_	_
Los Angeles, U of CA	4	23	2	2	2	_	5	_
Loyola University	8	1	_	_	_	_	_	_
MD Anderson CC	_	43	_	_	_	_	_	_

# Melanoma Committee, cont.

### Cumulative Accrual by Institution and Study

Includes accrual through 7/31/2018. Includes studies that are currently open, or that closed since 1/1/2017.

	51320	51404	51512	51607	51616	E3612	EA6134	EA6747
Michigan CRC NCORP	_	8	_	_	_	_	_	_
Michigan, U of	5	12	_	_	_	_	_	_
Mississippi, Univ of	_	1	_	_	_	_	_	_
Montana NCORP	_	4	_	_	_	_	_	_
Mt Sinai Med Ctr	_	10	_	_	_	_	_	_
Nevada CRF NCORP	4	_	_	_	_	_	_	_
New Mexico MU-NCORP	_	9	_	_	2	_	_	_
Northwest NCORP	_	11	_	_	_	_	_	_
Northwestern Univ	_	16	_	_	2	1	_	_
Ohio State Univ	15	33	3	_	2	_	2	_
Oregon Hlth Sci Univ	_	12	_	_	_	_	_	_
Ozarks NCORP	2	4	_	_	_	_	_	_
PCRC NCORP	2	17	_	_	_	_	_	_
Rochester, Univ of	4	6	_	_	_	_	2	_
San Antonio, U of TX	_	7	_	_	_	_	_	1
San Diego, U of CA	_	6	_	_	_	_	_	_
San Francisco, U-CA	8	_	_	_	_	_	_	_
So Calif, U of	_	_	1	_	_		_	_
Southeast COR NCORP	7	10	1	_	_	_	_	_
Sutter Cancer RC	_	5	_	_	_		2	5
Tennessee, U of	_	6	_	_	3	_	_	_
Utah, U of	8	31	_	_	_	_	_	_
VAMC Kansas City	_	1	_	_	_	_	_	_
Wayne State Univ	_	9	_	_	_	_	2	_
Wichita NCORP	4	13	_	_	_	_	_	_
Wisconsin NCORP	1	8	_	_	_		_	_
Yale University	_	6	_	_	_	_	_	6
Alliance	13	144	_	_	3	_	<del>-</del>	_
CCTG	_	122	_	_	_	_	_	_
ECOG-ACRIN	42	302	_	_	_	_	<del>-</del>	_
NRG	18	106	_	_	5	_	_	_
Total	219	1,345	12	2	19	6	26	36

The publications listed below were received by the Group Chair's Office as published, accepted, submitted or reflect change in status since the SWOG Spring 2018 Group Meeting. Conference abstracts are not included.

### ADOLESCENT AND YOUNG ADULT (AYA) COMMITTEE

### **Published/Accepted Manuscripts**

No publication information for this cycle.

### BARLOGIE-SALMON MYELOMA COMMITTEE

### **Published/Accepted Manuscripts**

Multiple Studies\* Disease and outcome disparities in multiple myeloma: exploring the role of race/ethnicity in the Cooperative Group clinical trials. S Ailawadhi, S Jacobus, R Sexton, A Stewart, A Dispenzieri, M Hussein, JA Zonder, J Crowley, A Hoering, B Barlogie, R Orlowski, S Rajkumar. Blood Cancer Journal Jul 6;8(7):67, 2018. [\*E1A00, E1A06, E2A02, E4A03, E5A93, E9486, S0204, S0232, S9321] https://www.ncbi.nlm.nih.gov/pubmed/29980678

### **Submitted Manuscripts**

No publication information for this cycle.

### **BREAST COMMITTEE**

### **Published/Accepted Manuscripts**

So221 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>, Dec 1;109(12), 2017. [see also SXQOLCmte] https://www.ncbi.nlm.nih.gov/pubmed/29546345

SO230 Final analysis of the prevention of early menopause study (POEMS)/ SWOG Intergroup SO230. 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>, accepted. (see also Ca Surv Cmte) 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 Jun;17(6):1324-1331, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29588392

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. <a href="Annals of Oncology">Annals of Oncology</a>, Mar 1;29(3):654-660, 2018. https://www.ncbi.nlm.nih.gov/pubmed/?term=sharma+p+breast+s9313

PACCT-1 Prospective trial of adjuvant chemotherapy guided by a21-gene expression assay in breast cancer. J Sparano, RJ Gray, D Makower, K Pritchard, K Albain, D Hayes, CE Geyer, E Dees, M Goetz, J Olson, JR, J Abrams, T Lively, S Badve, TJ Saphner, L Wagner, T Whelan, M Ellis, L Paik, D Wood WC, P Ravdin, M Keane, H Gomez Moreno, P Reddy, T Goggins, I Mayer, A Brufsky, DToppmeyer, V Kaklamani, J Berenberg, G Sledge. New England Journal of Medicine Jul 12;379(2):111-121, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29860917

### **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)

S0226 A phase III randomized trial of anastrozole and fulvestrant versus anastrozole or sequential anastrozole and fulvestrant as first-line therapy for postmenopausal women with metastatic breast cancer: Final survival outcomes of SWOG S0226. RS Mehta, WE. Barlow, KS Albain, TA Vandenberg, SR Dakhil, NR Tirumali, DL Lew, DF Hayes, JR Gralow, HH Linden, RB Livingston, GN Hortobagyi. New England Journal of Medicine. submitted.



S0500 Circulating Tumor Cell Clusters in Patients with Metastatic Breast Cancer Starting First Line Chemotherapy: A Correlative Study of SWOG Study S0500. C Paoletti, J Miao, E Dolce, E Darga, M Repollet, G Doyle, J Gralow, G Hortobagyi, J Smerage, W Barlow, D Hayes. <u>Journal of Clinical Oncology</u>, submitted 2018.

<u>S0800</u> Immune profiling of pre- and post-treatment breast cancer tissues from the SWOG S0800 neoadjuvant trial. X Li, S Warren, V Pelekanou, V Wali, A Cesano, M Liu, P Danaher, N Elliott, Z Nahleh, D Hayes, G Hortobagyi, W Barlow, C Hatzis, LPusztai. <u>Clinical Cancer Research</u>, submitted.

### **CANCER CARE DELIVERY COMMITTEE**

### **Published/Accepted 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. <a href="Cancer Epidemiology">Cancer Epidemiology</a> Jun 21;55:117-122, 2018. PMID29936140. https://www.ncbi.nlm.nih.gov/pubmed/29936140

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. <a href="Journal of the National Cancer Institute">Journal of the National Cancer Institute</a> Mar 9 [Epub ahead of print], 2018. [see also Prev & Epi Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29534197

<u>S9916</u> Estimating global treatment toxicity burden from adverse-event data. SM Lee, DL Hershman, J Miao, X Zhong, J Unger, Y Cheung.
<u>Cancer</u> Feb 15;124(4):858-864, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29112232

Multiple Studies A New Framework for Patient Engagement in Cancer Clinical Trials Cooperative Group Studies [Commentary]. P Deverka, R Bangs, K Kreizenbeck, D Delaney, D Hershman, CD Blanke, S Ramsey.

Journal of the National Cancer Institute Jun 1;110(6):553-559, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29684151

<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>, Jul 20.

doi: 10.1002/cam4.1657 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/30030904

<u>Multiple Studies</u> Geographic Distribution and Survival Outcomes for Rural Cancer Patients Treated in Clinical Trials. J Unger, A Moseley, B Symington, M Chavez-MacGregor, S Ramsey, D Hershman. <u>JAMA</u> <u>Network Open</u>, accepted, 2018.

Multiple Stuides\* 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>, Mar 27 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih. gov/pubmed/29584550

### **Submitted Manuscripts**

S1204 The prevalence of HIV, Hepatitis B, and Hepatitis C among newly diagnosed cancer patients treated in academic and community oncology practices: SWOG S1204. S Ramsey, J Unger, L Baker, R Little, R Loomba, J Hwang, R Chugh, M Konerman, K Arnold, A Menter, E Thomas, R Michels, C Walker Jorgensen, GV Burton, N Bhadkamkar, D Hershman. JAMA Oncology, submitted 2018.

Multiple Studies\* Osteoporosis in Colorectal Cancer Survivors: Analysis of the Linkage between SWOG Trial Enrollees and Medicare Claims. A Barzi, D Hershman, C Till, W Barlow, S Ramsey, H-J Lenz, H Hochster, J Unger. [\*S9304, S9415, S9420] Osteoporosis International, submitted 2018 [see also GI Cmtel

<u>Multiple Studies</u> Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician/Patient Barriers to Cancer Clinical Trial Participation [Brief Report]. J Unger, R Vaidya, D Hershman, L Minasian, M Fleury. <u>JNCI</u>, submitted 2018.



### **CANCER SURVIVORSHIP COMMITTEE**

### **Published/Accepted Manuscripts**

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. <u>Journal of the National Cancer Institute</u>, accepted. (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). H Greenlee, D Lew, DL Hershman, V Newman, L Hansen, S Hartman, J Korner, Z Shi, C Sardo Molmenti, A Sayegh, L Fehrenbacher, S Lo, J Klemp, K Rinn, JM Robertson, J Unger, J Gralow, K Albain, R Krouse, C Fabian. Obesity, accepted.

C70807 Men's Eating and Living (MEAL) study (CALGB 70807 [Alliance]): recruitment feasibility and baseline demographics of a randomized trial of diet in men on active surveillance for prostate cancer. JK Parsons, JP Pierce, J Mohler, E Paskett, S Jung, M Morris, E Small, O Hahn, P Humphrey, JR Marshall. British Journal of Urology International Apr;121(4):534-539, 2018. PMID28437029; PMC5654696. https://www.ncbi.nlm.nih.gov/pubmed/28437029

C89803 Dietary fat intake after colon cancer diagnosis in relation to cancer recurrence and survival. E Van Blarigan, C Fuchs, F-S Ou, D Niedzwiecki, S Zhang, L Saltz, R Mayer, A Hantel, A Venook, S Ogino, M Song, E Giovannucci, J Meyerhardt. Cancer Epidemiol Biomarkers

Prev. Jul 23 Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/30038051

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 Mesino, H Kindler, A Venook, S Ogino, Y Li; X Zhang, K Ng, WC Willett, E Giovannucci, CS Fuchs, J Meyerhardt. JNCI Cancer Spectrum, Feb;2(2);pky017. PMID29877501; PMC5977856. [see also GI Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29877501

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. <u>Journal of the National Cancer Institute</u>, accepted. [see also GI Cmte]

Multiple Studies\* Gonadotropin-releasing hormone analogs during chemotherapy for preservation of ovarian function and fertility in premenopausal early breast cancer patients: a systemic review and meta-analysis of individual patient-level data. M Lambertini, H Moore, R Leonard, S Loibl, P Munster, M Bruzzone, L Boni, J Unger, R Anderson, K Metha, S Minton, F Poggio, K Albain, D Adamson, B Gerber, A Cripps, G Bertelli, S Seiler, M Ceppi, A Partridge, L Del Mastro. Journal of Clinical Oncology May 2 [Epub ahead of print], 2018. [\*S0230, other] https://www.ncbi.nlm.nih.gov/pubmed/29718793

<u>Pilot.</u> Rationale, Development, and Design of the Altering Intake, Managing Symptoms (AIMS) Dietary Intervention for Bowel Dysfunction in Rectal Cancer Survivors. V Sun, T Crane, S Slack, A Yung, S Wright, S Sentovich, K Melstrom, M Fakih, R Krouse. <u>Contemporary Clinical Trials</u> May;68:61-66, 2018. [see also SXQOL Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29567283

### **Submitted Manuscripts**

S1316 Intellectual Equipoise and Challenges Accruing Patients with Advanced Cancer to a Trial Randomizing to Surgical or Non-Surgical Management (SWOG S1316). G Deutsch, J Deneve, M Al-Kasspooles, V Nfonsam, C Gunderson, A Alvarez Secord, P Rodgers, S Hendren, E Silberfein, M Grant, J Sloan, V Sun, K Arnold, G Anderson, R Krouse. Journal of Pain & Symptom Management, submitted 2018.

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, under review [see also GI Cmte]

### PREVENTION AND EPIDEMIOLOGY COMMITTEE

### **Published/Accepted Manuscripts**

S9217 Chemoprevention in Prostate Cancer: Current Perspective and Future Directions [Opinion]. J Ricardo Rivero, IM Thompson, M Liss, D Kaushik. Cold Spring Harbor Perspectives in Medicine 2018 Jan 8. pii: a030494. doi:10.1101/cshperspect.a030494. [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/29311128



<u>S9217</u> Reduced Risk of Prostate Cancer with 5a-Reductase Inhibitors.
[Editorial]. IM Thompson, P Goodman, C Tangen. <u>Journal of the National Cancer Institute</u> Mar 14. doi: 10.1093/jnci/djy038. [Epub ahead of print],
2018. https://www.ncbi.nlm.nih.gov/pubmed/?term=thompson+i+Reduced+Risk+of+Prostate+Cancer+with+5a-Reductase+Inhibitors

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. <u>Journal of the National Cancer Institute</u>, Mar 9 [Epub ahead of print], 2018. [see also CCD Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29534197

Multiple Studies\* 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 Benlloch, M Ahmed, E Saunders, Tangen, P Goodman, IM Thompson, D Albanes, C Haiman, R Eles. [\*S9217, other]

Nature Genetics Jun 11;9(1):2256, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29892016

Multiple Studies\* Agnostic pathway/gene set analysis of genome-wide association data identifies novel associations for pancreatic cancer. N Walsh, H Zhang, P Hyland, Q Yang, E Mocci, M Zhang, E Childs, I Collins, Z Wang, A Arslan, L Beane-Freeman, P Bracci, F Canzian, E Duell, S Gallinger, G Giles, G Goodman, P Goodman, D Albanes, C Fuchs, M Gaziano, C Haiman, EA Klein, R Stolzenberg-Solomon. [\*S0000, S9217, multiple other] Journal of the National Cancer Institute, accepted, 2018.

Multiple Studies\* Fine-mapping of prostate cancer susceptibility loci in a large meta-analysis identifies candidate causal variants. T Dadaev, E Sanders, P Newcombe, C Tangen, P Goodman, IM Thompson, D Albanes, C Haiman R Eles, D Conti, Z Kote-Jarai. [\*S0000, S9217] Nature Communications Jun 11;9(1):2256, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29892050

Multiple Studies\* Low free testosterone and prostate cancer risk: a collaborative analysis of 20 prospective studies. E Watts, P Appleby, A Perez-Cornago, H Bas Bueno-de-Mesquita, J Chan, C Chen, B Cohn, M Cook, L Flicker, N Freedman, G Giles, E Giovannucci, R Gislefoss, G Hankey, R Kaaks, P Knekt, Kolonel, T Kubo, L Le Marchand, R Luben, T Luostarinen, S Männistö, E Metter, K Mikami, R Milne, K Ozasa, E Platz,



J Quirós, H Rissanen, N Sawada, M Stampfer, F Stanczyk31, P Stattin, A Tamakoshi, C Tangen, I Thompson, K Tsilidis, S Tsugane, G Ursin, L Vatten, N Weiss, B Yeap, N Allen, T Key, RC Travis. [\*S9217, OTHER]

<u>European Urology</u>, Aug 1 [Epub ahead of print], 2018 https://www.ncbi.nlm.nih.gov/pubmed/30077399

### **Submitted Manuscripts**

- S0000 Discovery of common and rare risk loci for colorectal cancer. J Huyghe, S Bien, T Harrison, H Kang, S Chen, S Schmit, D Albanes, P Goodman, E Platz, C Tangen, L Hsu, U Peters. <u>Nature Genetics</u>, submitted (provisionally accepted) 2018.
- Solate Randomized Double-Blind Placebo-Controlled Biomarker Modulation Study of Vitamin D in Premenopausal Women at High Risk for Breast Cancer (SWOG Solate). K Crew, G Anderson, D Hershman, M Terry, P Tehranifar, D Lew, M Yee, E Brown, S Kairouz, N Kuwajerwala, T Bevers, J Doster, C Zarwan, L Kruper, L Minasian, L Ford, B Arun, M Neuhouser, G Goodman, P Brown. Journal of Clinical Oncology, submitted.
- <u>S9217</u> Case-only Methods Identified Genetic Loci Predicting a Subgroup of Men with Reduced Risk of High-grade Prostate Cancer by Finasteride. J Dai, M Leblanc, P Goodman, M Lucia, I Thompson, C Tangen. <u>Cancer Prevention Research</u>, submitted 2018.
- S9217 Long-term impact of finasteride on prostate cancer mortality: Results from the Prostate Cancer Prevention Trial (SWOG S9217). P Goodman, C Tangen, M Lucia, L Ford, L Minasian, H Parnes, I Thompson. JAMA, submitted 2018.
- Multiple Studies\* Prediagnostic circulating markers of inflammation and risk of esophageal adenocarcinoma: a study within the National Cancer Institute Cohort Consortium. M Cook, M Barnett, C Bock, A Cross, P Goodman, G Goodman, C Haiman, K Khaw, M McCullough, C Newton, M Boutron-Ruault, E Lund, M Rutegard, M Thornquist, M Spriggs, C Giffen, N Freedman, T Kemp, C Kroenke, L Le Marchand, J Young Park, M Simon, L Wilkens, L Pinto, A Hildesheim, P Campbell. [\*S9217, other] Gut, under review 2018.
- Multiple Studies\* A functional variation in PSA that confers lower risk is also associated with more aggressive disease and lower survival in men with prostate cancer. S Srinivasan, T Kryza, N Bock, C Stephens, Y Dong, J Panchadsaram, L Moya, J Rohl, J Perry-Keene, K Buzacott, M Gago, J Schleutker, C Maier, K Muir, C Tangen, H Gronberg, N Pashayan, D Albanes, A Wolk, R Eles, J Clements, J Batra. [\*S0000, S9217] Nature Genetics, submitted 2018.

### 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 Dec 1;109(12), 2017. [see also Breast Cmte] Https://www.ncbi.nlm.nih. gov/pubmed/29546345
- S0927 Omega-3 fatty acid use for obese breast cancer patients with aromatase inhibitor-related arthralgia (SWOG S0927). S Shen, J Unger, K Crew, C Till, H Greenlee, J Gralow, S Dakhil, L Minasian, J Wade, M Fisch, NL Henry, D Hershman. <u>Breast Cancer Research and Treatment</u>, accepted.
- <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 (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> Jul 10;320(2):167-176, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29998338
- 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, Apr 10;36(11):1088-1095, 2018. [see also GU Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29522326
- <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> Mar 20 [Epub ahead of print], 2018. [\*S9916, S1804, other] [see also GU Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29572075
- Pilot Rationale, Development, and Design of the Altering Intake,
  Managing Symptoms (AIMS) Dietary Intervention for Bowel Dysfunction
  in Rectal Cancer Survivors. V Sun, T Crane, S Slack, A Yung, S Wright, S
  Sentovich, K Melstrom, M Fakih, R Krouse. Contemporary Clinical Trials
  May;68:61-66, 2018. [see also Ca Surv Cmte] https://www.ncbi.nlm.nih.
  gov/pubmed/29567283



### **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, J Unger, H Moore, J Stewart, C Isaacs, T Hobday, M Salim, G Hortobagyi, J Gralow, G Budd, K Albain, C Ambrosone, S McCann. Breast Cancer Research, 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 Jun 13;2:27, 2018. [see also GU Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29951640
- 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 (No147 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, under review. [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, in press. http://ascopubs.org/doi/full/10.1200/CCI.17.00122

### **EARLY THERAPEUTICS AND RARE CANCERS COMMITTEE**

No publication information for this cycle.

### **EXECUTIVE COMMITTEE**

<u>Multiple</u> Proceedings of the 2017 Meeting of the Coalition of Cancer Cooperative Groups. M Bertagnolli, S Blaney, C Blanke, W Curran, J Dancey, R Mannel, P O'Dwyer, M Schnall, Wolmark N. <u>Journal of the</u> <u>National Cancer Institute</u>, under review 2018.

### **GASTROINTESTINAL COMMITTEE**

### Published/Accepted Manuscripts

- 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. New England Journal of Medicine Mar 29;378(13):1177-1188, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29590544
- C80405 Identification of a Genomic Region between SLC29A1 and HSP90AB1 Associated with Risk of Bevacizumab-Induced Hypertension: CALGB 80405 (Alliance). M Li, F Mulkey, C Jiang, B O'Neil, B Schneider, F Shen, P Friedman, Y Momozawa, M Kubo, D Niedzwiecki, H Hochster, H-J Lenz, JN Atkins, H Rugo, S Halabi, W Kelly, H McLeod, F Innocenti, M Ratain, A Venook, K Owzar, DKroetz. Clinical Cancer Research 2018 Jun 5 [Epub ahead of print]. https://www.ncbi.nlm.nih.gov/pubmed/29871907
- 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 Feb;2(2);pky017. PMID29877501; PMC5977856. https://www.ncbi.nlm.nih.gov/pubmed/29877501 (see also Ca Surv 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, accepted. [see also Ca Surv Cmte]
- E2204 An intergroup randomized phase II study of bevacizumab or cetuximab in combination with gemcitabine and in combination with chemoradiation (capecitabine and radiation) in patients with resected pancreatic carcinoma: a trial of the ECOG-ACRIN Cancer Research Group (E2204). JD Berlin, Y Feng, P Catalano, JL Abbruzzese, PA Philip, RR McWilliams, AM Lowy, AB Benson, AW Blackstock. Oncology 94(1):39-46, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29040974



### **Submitted Manuscripts**

- S1313 A Phase IB/II Randomized Study of FOLFIRINOX + Pegylated Recombinant Human Hyaluronidase versus FOLFIRINOX alone in Patients with Metastatic Pancreatic Adenocarcinoma (SWOG S1313). R Ramanathan, S McDonough, P Philip, S Hingorani, J Lacy, J Kortmansky, J Thumar, E Chiorean, AF Shields, D Behl, P Mehan, R Gaur, T Seery, K Guthrie, H Hochster. Journal of Clinical Oncology, submitted 2018.
- C80405 Circulating 25-Hydroxyvitamin D levels and Survival in Patients with Advanced or Metastatic Colorectal Cancer: Findings From CALGB/SWOG 80405 (Alliance). C Yuan, K Sato, B Hollis, S Zhang, D Niedzwiecki, F-S Ou, I-W Chang, BH O'Neil, F Innocenti, H-J Lenz, C Blanke, A Venook, R Mayer, C Fuchs, J Meyerhardt, K Ng. <u>Journal of Clinical Oncology</u>, submitted 2018.
- 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, under review. [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, under review. [see also SXCQOL Cmte]
- <u>Multiple Studies\*</u> Osteoporosis in Colorectal Cancer Survivors: Analysis of the Linkage between SWOG Trial Enrollees and Medicare Claims. A Barzi, D Hershman, C Till, W Barlow, S Ramsey, H-J Lenz, H Hochster, J Unger. [\*S9304, S9415, S9420] <u>Osteoporosis International</u>, submitted 2018 [see also CCD Cmte]

### **GENITOURINARY COMMITTEE**

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

### **Published/Accepted Manuscripts**

<u>S0337</u> 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. <u>JAMA</u> May 8;319(18):1880-1888, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29801011
- 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. Cancer Treatment and Research Communications 16 (2018):18:23, 2018. [posting on PubMed pending]; https://ac.els-cdn.com/S2468294218300327/1-s2.0-S2468294218300327-main.pdf?\_tid=1b132f41-dc30-4c63-a9c3-712d18f69af9&acdnat=1535146400\_84be1 ea81e98ab603e99b7d12c97ddfe
- 50421 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. Journal of Patient-Reported Outcomes Jun 13;2:27, 2018. [see also SXCQOL Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29951640
- 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.
- <u>S1314</u> From the other side: The patient perspective on cancer clinical trials. Bangs R, Crispino A. <u>Urologic Oncology: Seminars and Original Investigations</u> Feb 7 [Epub ahead of print], 2018. https://www.ncbi.nlm. nih.gov/pubmed/29428573
- <u>S1602</u> Background and update for S1602 "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". RS Svatek, C Tangen, S Delacroix, W Lowrance, SP Lerner. <u>European Urology Focus</u>, in press, 2018.
- 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,



- Multiple Studies\* Mechanisms and Funding Opportunities in Genitourinary Cancer Clinical Research. C Ryan. <u>Urologic Oncology: Seminars and Original Investigations</u> Jul 31 [Epub ahead of print], 2018. [\*S8507, S8949, S9217] https://www.ncbi.nlm.nih.gov/pubmed/30072304 F-S Ou, I-W Chang, BH O'Neil, F Innocenti, H-J Lenz, C Blanke, A Venook, R Mayer, C Fuchs, J Meyerhardt, K Ng. <u>Journal of Clinical Oncology</u>, submitted 2018.
- 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, under review. [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, under review. [see also SXCQOL Cmte]
- Multiple Studies\* Osteoporosis in Colorectal Cancer Survivors: Analysis of the Linkage between SWOG Trial Enrollees and Medicare Claims. A Barzi, D Hershman, C Till, W Barlow, S Ramsey, H-J Lenz, H Hochster, J Unger. [\*S9304, S9415, S9420] Osteoporosis International, submitted 2018 [see also CCD Cmtel

### **GENITOURINARY COMMITTEE**

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

### **Published/Accepted Manuscripts**

S0337 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 May 8;319(18):1880-1888, 2018. https://www.ncbi.nlm.nih.gov/ pubmed/29801011

- 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. Cancer Treatment and Research Communications 16 (2018):18:23, 2018. [posting on PubMed pending]; https://ac.els-cdn.com/S2468294218300327/1-s2.0-S2468294218300327-main.pdf?\_tid=1b132f41-dc30-4c63-a9c3-712d18f69af9&acdnat=1535146400\_84be1 ea81e98ab603e99b7d12c97ddfe
- <u>S0421</u> 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> Jun 13;2:27, 2018. [see also SXCQOL Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29951640
- 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.
- <u>S1314</u> From the other side: The patient perspective on cancer clinical trials. Bangs R, Crispino A. <u>Urologic Oncology: Seminars and Original Investigations</u> Feb 7 [Epub ahead of print], 2018. https://www.ncbi.nlm. nih.gov/pubmed/29428573
- <u>S1602</u> Background and update for S1602 "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". RS Svatek, C Tangen, S Delacroix, W Lowrance, SP Lerner. <u>European Urology Focus</u>, in press, 2018.
- 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 of Clinical Oncology</u>, May 20;36(15):1498-1504, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29624463



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, Apr 10;36(11):1088-1095, 2018. [see also SXCQOL Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29522362

Multiple Studies\* Mechanisms and Funding Opportunities in Genitourinary Cancer Clinical Research. C Ryan. <u>Urologic Oncology: Seminars and Original Investigations</u> Jul 31 [Epub ahead of print], 2018. [\*S8507, S8949, S9217] https://www.ncbi.nlm.nih.gov/pubmed/30072304

<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> Mar 20 [Epub ahead of print], 2018. [\*S9916, S1804, other] [see also SXCQOL Cmte] https://www.ncbi.nlm.nih.gov/pubmed/29572075

### **Submitted Manuscripts**

No publication information for this cycle.

### **LEUKEMIA COMMITTEE**

### **Published/Accepted Manuscripts**

S0106 Phase 1/2 Trial of GCLAM with Dose-Escalated Mitoxantrone for Newly Diagnosed AML or Other High-Grade Myeloid Neoplasms. A Halpern, M Othus, E Huebner, BL Scott, P Becker, M Percival, P Hendrie, KM Gardner, TL Chen S Buckley, KL Orlowski, A Anwar, F Appelbaum, H Erba, E Estey, R Walter. <u>Leukemia</u> Apr 17 [Epub ahead of print], 2018. https://www.ncbi.nlm.nih.gov/pubmed/?term=halpern+a+gclam

C10404 Lenalidomide consolidation benefits patients with CLL receiving chemoimmunotherapy: results for CALGB 10404 (Alliance). JC Byrd, AS Ruppert, NA Heerema, AE Halvorson, M Boyd, E Hoke, MR Smith, JE Godwin, S Couban, TA Fehniger, M Thirman, MS Tallman, FR Appelbaum, RM Stone, S Robinson, JE Chang, SJ Mandrekar, RA Larson. Blood

<u>Advances</u>, Jul 24;2(14):1705-1718, 2018. https://www.ncbi.nlm.nih.gov/pubmed/30030269

Multiple Studies\* 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]. Blood Jun 21;131(25):2782-2788, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29618479

Multiple Studies\* 2nd Cycle Remission Achievement with 7+3 is
Associated with Shorter Survival in Adults with Newly Diagnosed Acute
Myeloid Leukemia: Analysis of Recent SWOG Trials. M Othus, E Estey,
G Garcia-Manero, B Wood, D Stirewalt, J Godwin, J Weick, J Anderson,
F Appelbaum, H Erba, R Walter. [\*S8600, S9031, S9333, S0106, S1203]
Leukemia [Brief Communication], accepted 2018.

<u>Multiple Studies\*</u> Relative survival following response to 7+3 versus azacytidine is similar in acute myeloid leukemia and high-risk myelodysplastic syndromes: An analysis of four SWOG studies. M Othus, M Sekeres, S Nand, G Garcia-Manero, F Appelbaum, H Erba, Eli Estey. [\*S0106, S1203, S1117, S0703] <u>Leukemia</u>, accepted.

### **Submitted Manuscripts**

S1203 Rapid Donor Identification Improves Survival in High Risk First Remission AML Patients. J Pagel, M Othus, G Garcia-Manero, M Fang, J Radich, D Rizzieri,G Marcucci, S Strickland, M Litzow, M Savoie, S Spellman, D Confer, J Chell, M Brown, B Medeiros, T Lin, G Uy, B Powell, R Bayer, RA Larson, RM Stone, D Claxton, J Essell, S Luger, S Mohan, A Moseley, H Erba, F Appelbaum. <u>Journal of Clinical Oncology</u>, submitted 2018.

C10403 Adults with Acute Lymphoblastic Leukemia: Results of US Intergroup Trial C10403. W Stock, S Luger, A Advani, Y Jun, R Harvey, C Mullighan, C Willman, N Fulton, K Laumann, G Malnassy, E Paietta, E Parker, S Geyer, K Mrózek, B Sanford, G Marcucci, M Liedtke, D Claxton, M Foster, F Appelbaum, H Erba, M Litzow, M Tallman, R Stone, R Larson. New England Journal of Medicine, submitted.



### **LUNG COMMITTEE**

### Published/Accepted Manuscripts

<u>S1400\*</u> In Search of an Oncogene Driver for Squamous Lung Cancer. [Invited Commentary]. D Gandara, J Riess, P Lara Jr. [\*1400B, C and D]
<u>JAMA Oncology</u> Jun 14 [Epub ahead of print], 2018. https://www.ncbi. nlm.nih.gov/pubmed/29902311

### **Submitted Manuscripts**

No publication information for this cycle.

### LYMPHOMA COMMITTEE

### **Published/Accepted Manuscripts**

C50604 CALGB 50604: risk-adapted treatment of nonbulky early-stage Hodgkin lymphoma based on interim PET. 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. Blood Jul 26 [Epub ahead of print]. https://www.ncbi.nlm.nih.gov/pubmed/30049811

### **Submitted Manuscripts**

S0016 Genomic Alterations Important for the Prognosis in Patients with Follicular Lymphoma Treated on SWOG Study S0016. X Qu, H Li, R Braziel, V Passerini, L Rimsza, E Hsi, J Leonard, S Smith, O Weigert, M Leblanc, JW Friedberg, M Fang. <u>Blood</u>, submitted 2018.

S9704 Autologous Transplantation as Consolidation for High Risk Aggressive T-Cell Non-Hodgkin's Lymphoma: A SWOG 9704 Intergroup Trial Subgroup Analysis. Z Al-Mansour, H Li, JR Cook, LS Constine, S Couban, DA Stewart, TC Shea, P Porcu, JN Winter, BS Kahl, S Smith, DC Marcellus, KP Barton, GM Mills, M LeBlanc, L Rimsza, SJ Forman, JP Leonard, RI Fisher, JW Friedberg, P Stiff. Leukemia & Lymphoma, submitted 2018.

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. Lancet Oncology, under review.

### **MELANOMA COMMITTEE**

No publication information for this cycle.

### PHARMACEUTICAL SCIENCES COMMITTEE

### **Published/Accepted Manuscripts**

Multiple Studies Drug interaction screening in SWOG Clinical Trials. DL Hertz, R Siden, J Modlin, LL Gabel, S-F Wong. American Journal of Health-System Pharmacy, May 15; 75(10):607-612, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29748299

### **RADIATION ONCOLOGY COMMITTEE**

### **Published/Accepted 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 Aug 1;24(15):3500-3509, 2018. https://www.ncbi.nlm.nih.gov/pubmed/29661779



# Let's Make More Time

